TOSSD - TRACKING GLOBAL HEALTH EXPENDITURE IN SUPPORT OF THE SDGs

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Abstract

The COVID-19 pandemic has underscored the need for better tracking and monitoring domestic and international investments in health, including on pandemic preparedness. The total official support for sustainable development (TOSSD) framework can help, as it captures both cross-border flows to developing countries, such as international assistance, and domestic contributions to global public goods, such as pandemic preparedness. This pilot study tests the current TOSSD methodology for tracking the global financing for health, and explores how TOSSD can be shaped to best respond to the emerging information needs of the international community.

Foreword

TOSSD is a statistical framework that aims to track the global financing of the SDGs. It is composed of two pillars: (i) cross-border resource flows to developing countries and (ii) global and regional expenditures on international public goods (IPGs), development enablers, and global challenges. The development of TOSSD is overseen by the International TOSSD Task Force.

This working paper is part of a series of TOSSD pilot studies exploring different options for measuring TOSSD. They are meant to inform the TOSSD Task Force as well as the international community working on, or interested in, the financing of the SDGs. The general objective of this pilot is to test the current TOSSD methodology for tracking the global financing for health, and explore how it can be shaped to best respond to the international community's emerging information needs, including those of developing countries. The need for this work emerged in the context of the COVID-19 crisis and the increasing demand for measuring the financing of IPGs, in particular on health. Because of the multiple challenges impeding the achievement of global health objectives, however, the scope of the study goes beyond COVID-19 or global pandemics, thereby covering global health financing more broadly.

This study is based on a comprehensive literature review as well as interviews with recognised experts from national administrations, international organisations, academia, and private foundations. After briefly showing how TOSSD Pillar I improves the measurement of the international public financing of health in developing countries, it focuses on measuring the public financing of health-related international public goods (IPGs) in TOSSD Pillar II. We test the current TOSSD reporting instructions and propose options for further refining the methodology, based on the broader objectives selected by the TOSSD Task Force. To illustrate the order of magnitude of TOSSD under each of the options, we provide estimates of public funding that would be captured for selected providers.

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Abbreviations and acronyms

ACT-A	Access to COVID-19 Tools Accelerator
AFD	French Development Agency (Agence Française de Développement)
AMC	Advance Market Commitment
AMR	Anti-microbial Resistance
BMGF	Bill and Melinda Gates Foundations
CEPI	Coalition for Epidemic Preparedness Innovations
CGD	Centre for Global Development
CGH	Common Goods for Health
CRS	Creditor Reporting System
DAC	Development Assistance Committee (OECD)
DNDi	Drugs for Neglected Diseases Initiative
EDCTP	European & Developing Countries Clinical Trials Partnership
EU	European Union
FDA	Food and Drug Administration
Gavi	Global Alliance for Vaccine Initiative
GPMB	Global Preparedness Monitoring Board
GPG	Global public good
GBARD	Government Budget Allocations for Research and Development
GERD	Gross domestic expenditure on R&D
IP	Intellectual property
IAVI	International AIDS Vaccine Initiative
IGI	International Genomics Institute

IHR	International Health Regulations
IPGs	International Public Goods
IFFIm	International Finance Facility for Immunisation
JEE	Joint External Evaluations
LAC	Latin American country
LDCs	Least developed countries
LMICs	Low- and middle-income countries
MVI	Malaria Vaccine Initiative
NIH	National Institutes of Health
ND	Neglected disease
NCD	Non-communicable disease
OECD	Organisation for Economic Co-operation and Development
ODA	Official development assistance
PDP	Product development partnership
RPG	Regional public good
R&D	Research and development
SHA	System of health accounts
SSC	South-South Co-operation
SDGs	Sustainable Development Goals
TPP	Target product profiles
TOSSD	Total Official Support for Sustainable Development
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UKRI	UK Research and Innovation
UN	United Nations
UNICEF	United Nations Children's Fund
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNU-IIGH	United Nations University – International Institute for Global Health
WHO	World Health Organization

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Executive summary

The COVID-19 pandemic has underscored the need for increased and more targeted global (domestic and international) investments in health, including through international assistance for developing countries and support for global public goods (GPGs) such as pandemic preparedness. Understanding the full array of public financing for health is essential to guiding these policy decisions and investments. TOSSD is well positioned to play this role with its two-pillar approach: Pillar I on cross-border flows to developing countries, and Pillar II on contributions to global public goods and challenges. After briefly showing how Pillar I improves greatly the measurement of the international public financing of health in developing countries, this pilot study focusses on measuring the financing of health-related GPGs in Pillar II.

Main findings:

1. **The objective of, and narrative around, measuring the financing of global public goods need to be clarified**. The experts interviewed confirmed that TOSSD can play an important role in monitoring the financing of global public goods. However, they emphasised that while this agenda is appropriate for promoting *global* sustainable development, it is fundamentally and conceptually different from an agenda that specifically promotes *sustainable development in developing countries*, which is the current overarching TOSSD definition. TOSSD needs to distinguish more clearly between these two objectives. Such a clarification is necessary to determine the scope of activities covered in Pillar II.
2. **The current TOSSD eligibility criteria for counting research and development (R&D) funding as a contribution to GPGs need to be reviewed, both for conceptual reasons** – the scope of activities currently covered is too broad to be presented as "promoting sustainable development in developing countries" and too restrictive to capture funding that promotes global sustainable development – **and for the practical challenges involved in operationalising some of the criteria at this stage**. In particular:
    - In the case of academic and knowledge-oriented research, which represents the bulk of public R&D funding, the current R&D eligibility rules have almost no restriction since almost all health R&D meets the criteria of (i) being potentially applicable to developing countries or related to basic research; and (ii) being conditional to open access to scientific publications and research data. While these rules are appropriate with a measurement approach focussed on global sustainable development, they may be too broad for a measure that focusses on the benefits and sustainable development of developing countries.
    - In the case of funding for product development, the current R&D eligibility rules have strict conditions on access to health technologies, which aim to reflect the benefit to developing countries. This pilot shows that screening R&D against funders' access policies is relevant and needed, as demonstrated by the COVID-19 crisis, but that making it a strict eligibility condition may be too restrictive and difficult to operationalise at this stage. It may be too restrictive for several reasons: while important and applied in some cases, conditions on access are not relevant for all types of funding and are in general outside the mandate of R&D funding agencies; even patented innovations generally provide substantial transboundary benefits, including in developing countries; TOSSD should keep the incentives for developing the technologies crucially needed to address global health challenges. Moreover, R&D funders do not currently track access policies in their systems, which makes the reporting difficult to operationalise at this stage.

- Therefore, policies on access to health technologies could be tracked as policy flags (through keywords), on a voluntary and progressive basis, rather than strict eligibility conditions. Regarding the scope of R&D funding captured in Pillar II, we propose different options depending on the clarification of the overall objective, i.e. promoting "global sustainable development" or promoting "sustainable development in developing countries". While in the former almost all health R&D could be included, in the latter the scope should be limited to R&D focussed on the needs of developing countries. By way of illustration, based on 2019 data, we estimate that, for the European Union (EU) institutions and the United States combined, these options would result in the inclusion in Pillar II of USD 38 billion and USD 2 billion of public funding respectively, with only USD 68 million captured in official development assistance (ODA). While the options proposed would make the reporting more practical (e.g. it could build upon other existing data collection processes), national mandates would need to ensure that reporters can compile activity-level data. To ensure alignment with the internationally agreed statistical standards for R&D, reporting should be done in co-operation with the institutions in charge of these statistics**.**

3. **If the objective and narrative around Pillar II are linked to global sustainable development, other domestic and international health-related activities could be included as contributions to GPGs** given the broad recognition by the international community of their large positive global spill-overs:
   - There was a very broad agreement among the experts consulted that international co-operation for health should be captured and encouraged very broadly in TOSSD Pillar II.
   - Most of the experts advocated for including in Pillar II domestic expenditures on health security given the clear and large positive global spill-overs. The experts recommended referring to the Joint External Evaluation (JEE) indicators that lay out the core health security capacities that countries should have, and relying, in terms of data, on the current efforts of the OECD and the World Health Organisation (WHO) to map the System of Health Accounts (SHA) to the JEE indicators. An estimation of SHA public expenditure currently linked to health security for 21 countries that report to the OECD shows that they amounted to approximately USD 13.3 billion in 2019.
4. Finally, there is a high demand for tracking **private philanthropy** under a satellite indicator in TOSSD, given its essential contribution to global health, the SDGs and global public goods.

Main recommendations to the International TOSSD Task Force:

1. Discuss the pros and cons of linking TOSSD Pillar II to global sustainable development as opposed to "sustainable development in developing countries" and the implications this would have for the scope of Pillar II and the overarching TOSSD definition.
2. Regarding the measurement of R&D funding in Pillar II:
   - Consider tracking funders' policies on access to health technologies through a policy flag (keyword) rather than a strict eligibility condition.
   - Consider revising the scope of R&D captured according to the clarification on the Pillar II objective, preferably towards a global sustainable development approach.
3. If Pillar II aims to promote global sustainable development, consider including (i) all expenditure on international health co-operation; and (ii) domestic expenditure on health security.
4. Consider capturing philanthropic financing for the SDGs in a satellite indicator.

Part I. Overview, context and objectives of the health pilot study

1 Overview and key recommendations

The COVID-19 pandemic has underscored the need to understand the full array of public financing for global health, which is essential to guiding global (i.e. domestic and international) health policy decisions and investments. How much does international public financing support health in developing countries? How much does domestic public financing support health-related international public goods, including health security, research and development (R&D), etc.? Are public investments in health R&D sufficiently aligned with global public health needs? Do they address the need to provide equitable and global access to health technologies? How much public funding goes to neglected topics such as poverty-related diseases, rare diseases, anti-microbial resistance, etc.? These are key public policy questions that require an integrated, coherent and global response.

TOSSD can provide a comprehensive framework for the global community to monitor these issues and measure progress towards the achievement of global health objectives. The TOSSD framework is composed of two Pillars: (i) cross-border resource flows to developing countries; and (ii) expenditures on international public goods (IPGs), development enablers and global challenges. In TOSSD, IPGs include global public goods (GPGs), regional public goods (RPGs) and other IPGs that do not have fully global benefits.[1]

The general objective of this pilot is to test the current TOSSD methodology for tracking the global financing for health and explore how it can be shaped to best respond to the international community's emerging information needs, including those of developing countries, and to encourage efforts to progress towards global health objectives as defined in the SDGs. While this study investigates financing issues related to pandemic preparedness, because of the multiple challenges that must be overcome to achieve global health objectives, the scope of the pilot goes beyond the case of COVID-19 or global pandemics, thereby covering global health financing more broadly.

In order to investigate these issues, we have reviewed a large body of literature and interviewed a group of recognised experts from:

- Global organisations with expertise in health financing (WHO, the OECD, the UN Institute for Global health and the Centre for Global Development),
- National biomedical R&D funding institutions (the US National Institutes of Health),
- Biomedical research institutions (the International Genomics Institute),
- Experts in health development co-operation (Christophe Paquet and Agnès Soucat from the French development agency and Olivier Weil, professor in global health),
- Specialists in R&D policy and biomedical innovation (Ohid Yaqub),
- Experts in the measurement of R&D and health expenditure (the OECD, Policy Cures Research and Marco Schäferhoff), and
- Philanthropic foundations specialised in health (the Wellcome Trust).

[1] The TOSSD Task Force decided to use the more comprehensive concept of "international public goods", which includes global public goods (e.g. climate mitigation) and regional public goods (e.g. peace and security or transboundary water management) which were considered as very important to track and encourage.

Chapter 6 presents the perspective of all the experts interviewed on TOSSD and the tracking of global health financing.

1.1. Tracking the cross-border financing of health in developing countries, including for international public goods – TOSSD Pillar I

In Chapter 3 we show how TOSSD improves the information available to recipient countries on external financing for health.

Developing countries need international financing to address their multiple health challenges. While the existing international statistical system captures a large part of this financing, important gaps remain. **TOSSD will fill these data gaps and improve transparency on external resources for health in developing countries.** In particular, it will provide a better picture of **South-South Co-operation (SSC)**, which is particularly important in the health sector. Some SSC providers are already reporting on TOSSD (e.g. Chile, Costa Rica, Indonesia, Nigeria) and others, who are represented in the International TOSSD Task Force, could start reporting in the future (e.g. Brazil, Colombia). However, more needs to be done to capture some SSC providers that do not yet participate in the TOSSD framework but whose support is very important in the health sector. For example, recent estimates show that Chinese health-related development finance amounted to USD 652 million in 2017 and the experts interviewed emphasised that Malaysia is also an important player in this sector. More recently, the COVID-19 crisis has shown the importance of international assistance from these providers, including to developed countries. For example, People's Republic of China (hereafter "China") and India have donated around 75 million and 11 million COVID-19 vaccine doses, respectively. The experts interviewed highlighted that **TOSSD could allow the reporting of South-North flows** to take account of all international assistance efforts, and thereby go beyond the traditional North/South divide.[2]

In addition to highlighting SSC flows to health, the first TOSSD data collection shed light on cross-border support to developing countries not captured so far, for example in medical research. TOSSD enables the tracking of how innovative financing instruments are used in the health sector, including the mobilisation of private finance by official actors (for example, official guarantees are used in the health sector). The experts emphasised that it would be important to provide a comprehensive picture of the official financing for international public goods. Currently, IPGs are only tracked in the second Pillar of TOSSD, which captures resources provided at the domestic and international (supra-national) level. All cross-border flows to developing countries are classified in Pillar I and there is currently no mechanism to track those that contribute to IPGs. **TOSSD should have a method for tracking IPGs in Pillar I, for example through a combination of sectors and keywords**.

[2] This issue has been raised previously in the TOSSD consultation with Latin American and Caribbean providers as well as by some Arab providers in the context of their reporting on development finance.

Recommendations

In view of the above findings on the tracking of cross-border resource flows in Pillar I, the International TOSSD Task Force could:

- Seek to increase the coverage of SSC providers by increasing the number of TOSSD Task Force members who report and bringing in other SSC providers that currently do not participate in the TOSSD discussions (e.g. Argentina, India, Malaysia and Uruguay).
- Consider allowing the reporting in TOSSD of South-North flows.
- Develop a mechanism in Pillar I to track the cross-border financing of international public goods in developing countries.

1.2. Tracking the public financing of international public goods for health at the domestic and supra-national level – TOSSD Pillar II

The primary focus of this pilot is on tracking the financing of health-related IPGs in TOSSD Pillar II. Chapter 4 investigates the extent to which the TOSSD framework is fit for tracking the global financing of health-related IPGs, and how it can be shaped to better respond to the international community's emerging information needs.

1.2.1. The general definition and narrative around TOSSD Pillar II

The consultation with experts highlighted that **TOSSD can play a key role in monitoring financial flows to global public goods for health**, including pandemic preparedness and response, health R&D, international norms. By filling current data gaps and providing comprehensive and comparable data on IPG/GPG-financing, TOSSD could make an important contribution to international health policy discussions.

In order to better fit this agenda, the general definition and narrative around TOSSD Pillar II may need to be reviewed. In particular, many experts emphasised that measuring support to global public goods, health-related or not, is fundamentally and conceptually different from measuring support "to promote sustainable development in developing countries". They emphasised the need to distinguish more clearly between these two objectives in TOSSD, and recommended framing Pillar II around global sustainable development and the benefits to all countries. The overarching TOSSD definition should also reflect this global nature. While Pillar I should be focussed on the sustainable development of recipient countries and providing transparency on external flows to them, Pillar II should be focussed on global sustainable development and transparency provided to the global community. This would also address the concerns that TOSSD will inflate the financing that providers claim as a support to developing countries. **Some interviewees also noted that in a global context marked by the COVID-19 pandemic, focusing Pillar II on GPGs rather than IPGs would clarify the Pillar II narrative.** The concept of IPGs in TOSSD covers GPGs, regional public goods and international public goods the benefits of which are not necessarily fully global.

Recommendations

In view of the above findings on the general definition and narrative around TOSSD Pillar II, the International TOSSD Task Force could:

- Discuss the pros and cons of linking Pillar II to global sustainable development and the implications this would have for the scope of Pillar II and for the overarching TOSSD definition.
- Explore the relevance of refocussing the narrative of Pillar II on global public goods rather than international public goods.

1.2.2. Tracking R&D funding as a contribution to international public goods for health

R&D funding is analysed extensively in Section 4.3 of this pilot given the existing reporting instructions that needed to be tested, the complexity of the topic and its particular importance in achieving global public health objectives. We seek to confirm, in light of the broad consultation with experts, the COVID-19 crisis and the first TOSSD data collection, that the TOSSD eligibility criteria for counting R&D funding in Pillar II (see Box 4.2) are conceptually relevant, i.e. that they reflect the reality of R&D funding and provide the right incentives for achieving global public health objectives. We also test whether they are sufficiently operational, i.e. is reporting and data collection feasible.

> *The current broad coverage of health R&D topics in TOSSD Pillar II is appropriate with a measurement approach focussed on global sustainable development and the benefits to all countries*

In terms of research topics, TOSSD Pillar II covers all those related to the SDGs and potentially applicable to at least one developing country in addition to basic research. **The consultations carried out in this pilot show that almost all health R&D meets this criterion**. Although often not explicitly linked to the 2030 Agenda, health R&D can generally be considered as contributing to the SDGs, which deal with all the factors that contribute to human health and well-being. However, the experts interviewed mentioned **some cases where the application of the TOSSD sustainability criteria**, which require contributing to at least one SDG target while anticipating "no substantial detrimental effect" on any other target, **would be subjective and dependent on culture** (e.g. many people in the deaf community have opposed the use of innovative genome-editing techniques to prevent and treat deafness, which they do not see as a disease but rather as a fundamental part of their identity). Health R&D can also generally be considered applicable to other populations, including in developing countries.

While the current broad coverage of health R&D topics is appropriate for measuring public funding that promotes international public goods and global sustainable development, it may be too broad as part of a measure that focusses on "sustainable development in developing countries". Most of the experts interviewed supported the current broad coverage of R&D topics in Pillar II, which includes almost all diseases in addition to basic health and biological research. Some interviewees emphasised, however, that not all basic research translates into tangible human benefits. Others stressed on the contrary that fundamental knowledge is a key enabler of human health improvements and that it would be practically challenging to classify basic research according to its potential benefits. The experts also emphasised that while this broad coverage may be relevant for encouraging investments in international public goods, the financing captured should not be presented as promoting the sustainable development of developing countries in particular. Clarifying a global sustainable development objective in the TOSSD definition and narrative could therefore provide a rationale for such a broad coverage. **If the primary objective of Pillar II is to measure official support to promote "sustainable development in developing countries", which is the current overarching TOSSD definition, then the scope should be limited to R&D topics that are focussed on their needs**, for example neglected poverty-related diseases (see Table 1.1 below for an examination of what such an eligibility option would entail).

The COVID-19 crisis provides a strong justification for the current broad coverage of health R&D topics in TOSSD. Today, most of the public investments in COVID-19 R&D are not captured in official development assistance (ODA) and development finance statistics because they are not primarily aimed at supporting developing countries. If the scope of Pillar II was on diseases that affect disproportionately developing countries (e.g. malaria or tuberculosis) – which is currently not the case – it would capture more funding than ODA but would still exclude COVID-19 R&D. However, given that the development of COVID-19 technologies is clearly a pre-requisite for sustainable development everywhere, including in developing countries, there is a strong case for including and encouraging investment in COVID-19 R&D as part of a broader measure of the financing of the SDGs. For example, we estimate that for Canada, the European Commission, the United Kingdom and the United States, the current TOSSD R&D rules, which are not limited to diseases that affect primarily developing countries, but are conditional to scientific publications and health technologies being accessible in these countries (see below), capture nearly USD 35 billion of COVID-19 R&D funding that would otherwise not be captured in any statistics on the financing of the SDGs.

Conditioning public funding for research to the "open access" principle is relevant for promoting international public goods, but not sufficient to conclude that there is a benefit to developing countries

The experts interviewed broadly supported making the eligibility of research funding conditional to the principle of open access, which will make the knowledge effectively an international public good. Open access is already required by many R&D funders and given that almost all health R&D topics are covered in the TOSSD R&D reporting instructions as explained above, this means that almost all academic and knowledge-oriented health research, which represents a major part of public R&D funding, is currently eligible under Pillar II. However, the experts also emphasised that while open access is important for promoting global access to knowledge, it is not sufficient to assert the benefit to developing countries, where the primary issue is not access to knowledge but the capacity to perform research.

The TOSSD screening of R&D funding against access to health technologies is relevant and needed, but making it an eligibility condition may be too restrictive and difficult to operationalise at this stage

In the case of funding for product development, the current R&D eligibility rules have strict conditions on access to health technologies, which aim to reflect the benefit to developing countries.

Screening R&D funding counted in TOSSD Pillar II against the principle of access to health technologies is needed and would fill a key information gap in current global health policy. Unaffordable access to health technologies is an important barrier to health sustainability in both developing and advanced countries. Affordability is a particular focus for Southern R&D funders (e.g. India, Malaysia). In addition, the COVID-19 crisis introduced a new push to the debate on access to medicines and placed it high on the global policy agenda. By providing information on policies that encourage global access to medicines, TOSSD would respond to a key information need of the international community.

The current TOSSD R&D criteria are generally relevant for describing R&D policies that promote the affordability of health technologies. Pricing-based schemes (e.g. differential pricing), mechanisms to promote competitive manufacturing (e.g. non-exclusive licensing of patents) and the free sharing of technologies in the public domain were all found effective in promoting the affordability of health technologies, either globally or directly in developing countries, and were used to a certain extent by R&D funders. **Much of the public investment in COVID-19 R&D should be eligible under the current TOSSD eligibility rules,** which promote affordable access to health innovations in developing countries but do not require "equal access" (see Table 4.3). However, although essential, affordability is only one dimension of access to health technologies, particularly in developing countries: **appropriateness** – whether the technologies are suitable for developing countries' markets – and **availability** –

whether they are registered in developing countries and available for use – are also important policy dimensions that should be tracked.

While screening R&D projects against funders' policies on access to health technologies is important, making it a strict eligibility condition for counting the funding in Pillar II may be too restrictive and difficult to operationalise at this stage. It may be too restrictive for several reasons: while applied in some cases, conditions on the accessibility or affordability of health technologies are generally not required by domestic R&D funding institutions either because this is not always relevant and feasible, or because they do not have the mandate to do so; broad and affordable access to health technologies can be achieved or promoted through other means than funders' R&D policy; even if not immediately available for everyone, health technologies will still be accessible to many and eventually become international public goods; while encouraging broad access to health technologies, it is important that TOSSD keeps incentives for more investments to develop the technologies that are crucially needed to address global health challenges and achieve the SDGs. In addition, a number of experts highlighted the practical challenges in operationalising the reporting on access policies at this stage, given that this information is currently not tracked in R&D funders' systems.

National mandates and more operational reporting guidelines are needed to ensure that providers have the capacity to report activity-level data on health R&D funding, in co-operation with the institutions responsible for international R&D statistics

Total public funding for health R&D is well measured, in particular through government budget allocations for R&D (GBARD) and gross domestic expenditure on R&D (GERD) statistics produced by the OECD and the United Nations Educational, Scientific and Cultural Organization (UNESCO) Institute for Statistics, **but not with the level of granularity sought in TOSSD.** This aggregate measurement would not allow, for example, the screening of R&D projects against the principle of access to health technologies, or tracking important sub-categories in health R&D (e.g. R&D on specific diseases). Therefore, while these data could potentially be used provisionally, depending on the eligibility choices of the International TOSSD Task Force (see the options proposed below)**, activity-level reporting, where possible and in co-operation with the relevant institutions in charge of international R&D statistics, should ultimately be the goal in order for TOSSD data to be useful**. For many R&D funders, in particular in health, project-level data on R&D funding are available with information on most of the TOSSD key fields.

The most important challenge is the mandate for collecting and reporting TOSSD data. Recent developments, in particular through discussions in the G20 and other global fora, underscore how TOSSD can help serve as a tool for monitoring and measuring financing for global public goods, including pandemic preparedness. Such discussions can facilitate domestic engagement and the cross-governmental mainstreaming of TOSSD. A whole-of-government reporting mandate is all the more important as R&D funding data may sit under different government administrations and the screening of R&D projects against the principle of access to health technologies can only be made by funders themselves, as relevant screening information can often be confidential. **In addition, in order to be applicable to R&D funders the TOSSD R&D reporting instructions will need to be more practical and the scope of reporting clearer**.

Options for tracking and measuring R&D funding in Pillar II

The promotion by R&D funders of access to health technologies could be tracked as a policy flag, on a voluntary and progressive basis, rather than a strict eligibility condition. Access to health innovations is a key enabler of "ensuring healthy lives for all" and an essential element of today's global public health policy. At the same time, it should not be made a strict eligibility criterion for the conceptual and practical reasons mentioned above. Therefore, access policies could rather be tracked as a voluntary (at least in the short term) policy flag, for example in the "key words" field. Based on the recommendations provided by the experts interviewed, we propose a definition of a flag on "access to health technologies", including more detailed guidance, in Table 4.4. Screening R&D projects against access is resource-intensive and implementation would need to be progressive.

In terms of eligibility, The TOSSD Task Force should clarify the objective of TOSSD Pillar II and revise the scope of R&D captured in Pillar II accordingly, preferably towards a global public goods and global sustainable development approach. Table 1.1 presents a summary of some options that the Task Force could consider for adjusting the scope of R&D funding captured in Pillar II, with an illustration of the order of magnitude of public funding potentially captured in each of these options, using the United States and European Union (EU) as examples.

Recommendations

In view of the above findings on the tracking of R&D funding in Pillar II, the International TOSSD Task Force could:

- Consider tracking the principle of access to health technologies through a policy flag rather than presenting it as a strict eligibility condition.
- Clarify the objective of Pillar II and revise the scope of R&D captured accordingly (see Table 1.1), preferably towards a global public goods and global sustainable development approach.

Table 1.1. Summary of the options for counting R&D funding in TOSSD Pillar II

	In line with the current general objective and definition of TOSSD	If the TOSSD definition and objective is expanded to cover support for global sustainable development	
Options proposed depending on the objective and definition of Pillar II [1]	Option 1: Measuring R&D funding "provided to promote the sustainable development of developing countries".	Option 2: Measuring R&D funding provided to promote global sustainable development, with a focus on application-specific R&D (excluding "pure" basic research).	Option 3: Measuring R&D provided to promote global sustainable development.
What is eligible?	R&D focussed on the needs of developing countries: • R&D funding for neglected diseases that affect primarily developing countries (malaria, tuberculosis, etc.) beyond what is captured in ODA.[1] • Contributions to international product development partnerships (PDPs) that are in co-operation with developing countries and are primarily focussed on equitable access in developing countries (e.g. ACT-A). • Any other R&D investment where access in developing countries is a clear and important objective.	Product development for all health technologies. All applied health research. Purpose-oriented basic health and biological research.	Almost all health R&D is eligible. Reporters would still have the possibility to exclude activities they would consider as purely domestic.

Difficulty in operationalising the criteria	Easy: R&D funding for neglected diseases is already tracked in the G-FINDER survey, and data on contributions to international PDPs are easy to collect.	Difficult: "Product development" and "Purpose-oriented basic research" are not categories that are readily available in current R&D funding data. The application of the eligibility criteria would need to be very practical, and operational guidelines could be developed with the support of a consultative group of health experts.	Easy: In terms of eligibility the data collection would be easy given that it would cover almost all health R&D.
Estimation of R&D funding covered using the US and EU as an example (2019)	USD 2 billion	USD 20 billion	USD 38 billion

Note: [1] A more detailed elaboration on these options is provided in Section 4.3.6. None of the options proposed corresponds to the current scope of R&D captured. For reference, only USD 63 million R&D funding for neglected diseases in option 1 is already captured in ODA.

1.2.3. Tracking other global and domestic health expenditures as contributions to international public goods

In defining the scope of health-related activities in TOSSD Pillar II, the TOSSD Task Force has so far discussed mainly the treatment of health R&D. What other domestic and global expenditures provide positive transboundary spill-overs that are sufficiently valuable to the international community to be considered as contributions to IPGs and included in TOSSD Pillar II?

Tracking the financing of international health co-operation and coordination

There was a very broad agreement among the experts consulted in this pilot that international co-operation for health should be captured very broadly in TOSSD Pillar II. The COVID-19 crisis illustrates more than ever that international co-operation is essential to ensure global health security. It also shows that national egoism, illustrated in vaccine nationalism, can be an important barrier to global health security. Therefore, activities that help ensure health security at the international level should be captured and encouraged in TOSSD. Beyond health security, international health co-operation is also needed to address a number of other global health challenges, for example the increasing burden of non-communicable diseases, which represent nearly three-quarters of global deaths. The experts interviewed from WHO highlighted that they consider the entirety of the organisation's work, which covers all aspects related to health, as contributing to the 2030 Agenda. Therefore, all the activities that provide a framework for countries to co-operate on health matters should be encouraged and tracked in TOSSD. The current TOSSD reporting instructions do allow for such a broad coverage. However, in the same way as outlined above, it was also emphasised that these activities should be seen from their global nature and not as focussing on developing countries' benefits.

Tracking domestic financing for global health security

The COVID-19 pandemic illustrates again that global public goods such as health are only provided if every country contributes. Just before the crisis hit the world, the Global Health Security Index had shown that "most countries have not allocated funding from national budgets to fill identified preparedness gaps". In 2018, domestic public spending on health – not counting health R&D – reached USD 4.9 trillion. How much of this spending generates benefits that extend to other countries i.e. contributes to IPGs?

Most of the experts interviewed advocated for including domestic expenditures on pandemic preparedness and health security in general in TOSSD Pillar II. National surveillance, diagnostic capacities and immunisation were viewed as essential by many. The role of pharmaceutical regulation agencies was also emphasised as very important, as the validity of their drug approvals can extend to many other countries, including

developing countries. The experts also mentioned the fight against anti-microbial resistance as essential for global health security. Finally, the pandemic has demonstrated again the importance of the "One Health" approach, integrating animal and human health, in better preventing pandemics. While the experts emphasised potential definitional issues in some of the above concepts, they recommended referring to the international frameworks in place for addressing health security. **The core health security capacities are best defined in the Joint External Evaluations (JEE) indicators**, which are used to assess progress made by countries in implementing the International Health Regulations (IHR).

Where possible, TOSSD should use already existing data and current efforts to better track health security expenditures. The primary framework for measuring national health expenditure is the System of Health Accounts (SHA). Efforts are being undertaken currently by the OECD and WHO to map the JEE and SHA categories, and use SHA data as proxy for health security expenditures. Some of the SHA categories can be fully, or almost fully, linked to the JEE health security indicators; others are only partially mapped. Some JEE indicators, for example on animal health, go beyond the SHA, which is focussed only on human health. To further decide how to distribute the SHA expenditure categories to JEE, and how to measure the health security expenditure beyond human health, the OECD and WHO are planning some pilots with a few countries.

Pillar II could start with including the SHA public expenditures that are fully or almost fully mapped to the JEE health security indicators, and that are already tracked for many countries. Across 21 countries that already report to the OECD at the health care sub-function level, this expenditure is estimated at approximately USD 13.3 billion. Further improvements in the tracking of health security through the SHA could also be reflected in TOSSD. In addition, TOSSD could allow countries that already have the capacity to report health security expenditures currently not (well) reflected in the SHA to do so. A medium-term objective could also be to work with SHA providers to seek more granular data where possible. The added value of TOSSD is that it will present SHA expenditures on health security complemented by other health expenditures contributing to global public goods for health, in particular R&D, international health co-operation and cross-border flows to developing countries. It will also present these expenditures alongside other contributions to global public goods, e.g. climate mitigation.

Recommendations

In the same way as outlined above, the scope of global and domestic health expenditure that could be included in Pillar II will depend on the overall objective of TOSSD and Pillar II:

- If the overall objective of TOSSD Pillar II is to measure financing that promotes the sustainable development of developing countries, we recommend not including any of the above expenditures.
- If the overall objective of TOSSD Pillar II is to track expenditures that promote global sustainable development and IPGs, we recommend including (i) all expenditures that promote international health co-operation; and (ii) domestic expenditures that contribute to health security, using the JEE indicators as a reference and the OECD and WHO SHA as a data source, while allowing countries to report additional activities on health security currently not (well) tracked in the SHA.

1.3. Tracking the contributions of philanthropic organisations to global health

TOSSD is designed to mainly capture public, or "official", financing for the implementation of the SDGs. However, the role of private finance, particularly from philanthropic organisations, in implementing the SDGs is also recognised in the 2030 Agenda. Private philanthropic foundations are particularly active in the area of health. Chapter 5 investigates the relevance of including a satellite indicator of philanthropic financing in the TOSSD framework, using health as a case study.

1.3.1. Philanthropic organisations contribute considerably to improving global health and well-being

The philanthropic financing of global health is considerable. For example, in 2019 the total grants provided by the Bill & Melinda Gates Foundation (BMGF) amounted to nearly USD 3.5 billion, out of which USD 2.1 billion (60%) was provided to support health objectives. Moreover, next to its core contributions to Gavi, the Vaccine Alliance and the Global Fund, which totalled to USD 509 million, the BMGF was the third largest donor to WHO in 2018-19, with contributions totalling USD 455 million. In the fiscal year 2019-20, the Wellcome Trust provided grants of nearly USD 1.5 billion, almost all of which focussed on health research. **Philanthropic foundations' contribution to health development co-operation in particular is essential**. For some recipient countries, such as India, support from philanthropic foundations in the health sector is larger than support from bilateral providers.

The COVID-19 crisis has further highlighted the critical role of private foundations in funding global health. A survey carried out in 2020 by the OECD Development Assistance Committee indicated that private foundations committed approximately USD 1.6 billion as an immediate response[3] to the COVID-19 crisis, including both support to developing countries and to global public goods (e.g. COVID-19 R&D). Overall, since the beginning of the COVID-19 crisis, the BMGF has committed USD 1 billion in grants and mobilised USD 750 million in guarantees, forgivable loans and other financing from their Strategic Investment Fund. **Beyond their financial contribution, philanthropic foundations play an important role in shaping international co-operation for health.** Private philanthropies have initiated many international partnerships aimed at addressing global health challenges, including for example the Access to COVID-19 Tools (ACT)-Accelerator.

Philanthropic foundations typically aim to contribute to global public goods. They are strongly focussed on "open science" and global access to health technologies. They also often seek to address market failures, by supporting R&D for health technologies characterised by high social demand but insufficient commercial incentives (e.g. the development of an Ebola vaccine anti-microbial innovation).

1.3.2. TOSSD could track, in a satellite indicator, the philanthropic financing of the SDGs, which is currently only partially captured in international statistics

While philanthropic financing for global health is essential, it is currently only partially tracked in international statistics on financing for sustainable development. Private philanthropy for development is relatively well tracked in the Creditor Reporting System (CRS), but the coverage could be further improved in TOSSD by including contributions primarily supporting global objectives such as climate action or medical research (e.g. cancer, genomics). For example, while the Wellcome Trust granted around USD 1 billion of funding in 2019, only USD 324 million (32%) was captured in the CRS.

There is a high demand for tracking private philanthropy in TOSSD. Previous TOSSD pilots have already shown the high demand in recipient countries for having a better picture of philanthropic financing in their countries. The experts interviewed in this pilot also confirmed the need to track more globally the contributions of philanthropic actors to advancing global health objectives. The need for tracking private grants was also emphasised by the UN Working Group on Measurement of Development Support established by the Inter-Agency and Expert Group on the Sustainable Development Goal Indicators.

Recommendations

In view of the above findings, the International TOSSD Task Force could envisage capturing philanthropic financing for the achievement of the SDGs, particularly health, in a satellite indicator.

[3] The survey covered only expenditures from January to April 2020.

2 Context and objectives of the health pilot study

2.1. The concept of TOSSD

In recent decades, developing countries have had access to a growing array of financing sources, both domestically and internationally, with the emergence of new actors (e.g. emerging providers in Asia and Latin America) and a growing resource base of concessional and non-concessional resources from official providers and private actors. In addition, one of the core features of the 2030 Agenda is its universality. It sets global Sustainable Development Goals (SDGs) that benefit all countries and to which all nations should contribute, for example ensuring healthy lives or combating climate change.

With this increasing number of actors and instruments available, and the broader global public goods agenda enshrined in the SDGs, a transparent and inclusive measurement framework is needed to reflect the totality of public finance provided to promote sustainable development in developing countries and at the global level. Since the Addis Ababa Conference, which called for a holistic approach that enhances synergies among all these actors and types of resources, the international community with the support of the OECD has been working to develop a new measurement framework for the SDG era: the "total official support for sustainable development (TOSSD)". The TOSSD framework aims to provide a comprehensive picture of external official support for sustainable development in developing countries and of global public support to the SDGs through international public goods.

TOSSD encompasses all financing provided by official bilateral and multilateral institutions, regardless of the level of concessionality involved or instrument used. It includes both concessional and non-concessional financing provided through various instruments, such as grants, loans, equity and mezzanine finance. It aims to cover activities that contribute to and enable sustainable development, including contributions to international public goods that are relevant for sustainable development.

The TOSSD measurement framework[4] is composed of two pillars that track officially supported (i) cross-border flows to developing countries; and (ii) finance for promoting development enablers and international public goods and to address global challenges at regional and global levels.

In the first semester of 2017, an international task force[5] was established to carry out the technical work required to operationalise TOSSD and ensure that it conforms to international statistical standards. Since then, the Task Force has developed a full statistical methodology and collected a first comprehensive set of TOSSD data on 2019 activities (International TOSSD Task Force, 2020[1]).

[4] For further information on TOSSD, see: *What is total official support for sustainable development (TOSSD)?* (OECD, n.d.[64]).

[5] For further information see: International Task Force (OECD, n.d.[65]).

2.2. Why a TOSSD pilot on global health financing?

The COVID-19 crisis reminds us that global health remains a critical challenge for sustainable development in all countries…

With more than 4 million deaths to date across almost all countries of the world,[6] the COVID-19 pandemic has reminded us of the global nature of infectious diseases. In addition, the resulting socio-economic costs, with dramatic increases in poverty and inequalities, demonstrate the interlinkages between the Sustainable Development Goals and the central role that SDG 3 – "ensure healthy lives and promote well-being for all at all ages" – will play for the achievement of the 2030 Agenda. While no country is immune to the devastating damage of the COVID-19 pandemic, developing countries are more exposed given their relatively higher health and socio-economic vulnerabilities.

In terms of health financing, the pandemic has demonstrated the need for a global approach, supporting developing countries in addressing their specific vulnerabilities, and at the same time investing in international public goods for health at all levels, including at the domestic and international levels. This is a matter of policy coherence for sustainable development.

… and that significant gaps remain to achieve global health objectives

COVID-19 has shown that almost all countries were unprepared for a global public health emergency, most notably due to underinvestment in preparedness (G20 High-Level Independent Panel, 2021[2]) . Just before the crisis hit the world, the Global Health Security Index noted that "most countries have not allocated funding from national budgets to fill identified preparedness gaps"[7]. The G20 high-level independent panel on the financing of global commons for pandemic preparedness and response (PPR) estimates the funding gap in international financing for "global public goods that are at the core of effective pandemic prevention and preparedness" to be a minimum of USD 75 billion for the next five years, or USD 15 billion per year. This estimate covers only the financing needed to support global-level functions and for developing countries to invest in the country-level global public goods needed for pandemic PPR; it does not take into account the need to scale up domestic preparedness expenditures.

Although representing a major challenge today, COVID-19 and global pandemics are only one of the barriers to achieving SDG 3 and ensuring healthy lives for all. Other international public goods for health remain underfunded. For example, effective vaccines and/or treatments are still missing for a number of neglected diseases that particularly affect poor countries, such as tuberculosis or the Zika fever, partly because market mechanisms fail to provide for such R&D given the low expected returns (Chalkidou et al., 2020[3]). Persistent gaps in health technologies also exist in other areas, such as antimicrobials, non-vascular dementia, and some rare diseases (OECD, 2018[4]). In addition, addressing the high and increasing burden of non-communicable diseases (NCDs) is a major challenge globally (Foreman et al., 2018[5]). With 41 million deaths each year, representing 71% of all deaths globally, NCDs are by far the leading cause of death worldwide. Low- and middle-income countries are again particularly exposed here, as they represent 77% of all NCD deaths,[8] partly due to missing or inaccessible treatments.

Even when health technologies exist, an additional and important barrier to global health is the issue of access to these technologies. The global health crisis has revitalised the discussions on access to medicines for all and intellectual property rights (IPRs) (Acharya, 2020[6]; Gurry, 2020[7]; OECD, 2020[8]; Chakrabarti, 2020[9]). Although particularly under the spotlight during the COVID-19 pandemic given the

[6] Data extracted from the John Hopkins University Dashboard as of August 2021.

[7] See https://www.ghsindex.org/wp-content/uploads/2019/10/2019-Global-Health-Security-Index.pdf.

[8] See https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases.

need to quickly intervene across borders, the issue of global access is also relevant for many other health technologies that are not sufficiently accessible to those most in need.

Tracking all public financing that contributes to global health is essential to measure progress towards filling the current gaps and to achieve global health objectives

Because of the multiple challenges that must be overcome to achieve global health objectives as defined in the SDGs, the scope of this pilot goes beyond the case of COVID-19 or global pandemics, and focusses on global health financing more broadly. How much does international public financing support health sustainability in developing countries? How much does domestic public financing support health-related international public goods, including through health security, R&D, etc.? Are public investments in health R&D sufficiently aligned with global public health needs? Do they address the need to provide equitable and global access to health technologies? How much public funding goes to neglected topics such as poverty-related diseases, rare diseases, anti-microbial resistance, etc.? These are key public policy questions that require an integrated, coherent and global response. Understanding the full array of public financing for global health is essential to guiding these policy decisions.

However, today there is no comprehensive measure of public financing that allows us to answer all these questions. This is due to a number of reasons, including significant data gaps and a fragmented measurement landscape with different sources using different methodologies and approaches – owing to the fact that the financing landscape is itself fragmented. Therefore, in order to accurately identify all health financing gaps, and measure progress towards filling these gaps, a comprehensive measure of global health financing is needed.

TOSSD, which aims to capture the global financing of sustainable development, is designed to play this role. In addition, some of the above questions emerging as key policy areas in the context of the COVID-19 pandemic, in particular on health R&D, have already been discussed by the international TOSSD Task Force. For example, the Task Force reflected on the issue of access to health technologies long before the new coronavirus appeared (International TOSSD Task Force, 2021, p. Annex E[10]).

The general objective of this pilot is to test the current TOSSD methodology for tracking global financing for health, explore how it can be shaped to best respond to the international community's emerging information needs in this area and encourage efforts to progress towards global health objectives as defined in the SDGs.

2.3. Pilot study objectives and methodology

The pilot study had four specific objectives:

1. Explore the potential of TOSSD to fill data gaps on external resource flows to developing countries in the health sector.
2. Test specific technical or statistical parameters and methodological features of the TOSSD measure, in particular the relevance of the current TOSSD methodology for capturing global public health financing in support of the SDGs.
3. Investigate the public financing of health-related international public goods and explore how the TOSSD methodology can be shaped to best respond to the international community's emerging information needs, including those of developing countries.
4. Assess the capacity of TOSSD reporters to collect data on investments in health-related IPGs and on additional resource transfers to developing countries.

The pilot study methodology consisted of three phases:

- **Phase 1 – Desk review:** For the health pilot, the TOSSD Secretariat analysed a large body of literature on health financing, health R&D policies, access to medicines, intellectual property protection, the financing of the COVID-19 response, relevant documentation from multilateral organisations, the first TOSSD data collection, documentation and data from major providers to the health sector, including official providers and philanthropic providers, etc. (see the references at the end of the report).
- **Phase 2 – Consultations, interviews and analysis:** In addition to the desk review, the pilot was based on consultations and interviews with a large group of recognised experts from:
    - Global organisations with expertise in health financing (WHO, the OECD, the UN Institute for Global health and the Centre for Global Development),
    - National biomedical R&D funding institutions (the US National Institutes of Health),
    - Biomedical research institutions (the International Genomics Institute),
    - Experts in health development co-operation (Christophe Paquet and Agnès Soucat from the French development agency and Olivier Weil, professor in global health),
    - Specialists in R&D policy and biomedical innovation (Ohid Yaqub),
    - Experts in the measurement of R&D and health expenditure (the OECD, Policy Cures Research and Marco Schäferhoff), and
    - Philanthropic foundations specialised in health (the Wellcome Trust).

Chapter 6 presents the perspective of all these actors on TOSSD and the tracking of the global financing of health. These consultations were the primary basis of the findings presented in this pilot.

- **Phase 3 – Final report:** this is the present document, which provides summary conclusions and recommendations based on the desk review, the interviews carried out with the organisations and experts, and the subsequent analysis.

The remainder of this paper is organised as follows:

- Chapter 3 briefly explores the potential of TOSSD Pillar I – cross-border flows to developing countries – to fill data gaps on external resource flows for health in developing countries.
- The primary focus of this pilot is the financing of international public goods for health, in particular how to best track this financing in TOSSD Pillar II. We investigate this issue in Chapter 4 We first test the relevance of the current TOSSD methodology, in particular the general definitions and the R&D reporting instructions, for capturing the financing of international public goods for health. Given its complexity and particular importance in achieving global public health objectives, R&D funding is analysed extensively. We also explore other global and domestic health expenditures that could be counted in Pillar II as contributions to international public goods.
- Chapter 5 goes beyond public financing and investigates the relevance of tracking the funding provided by philanthropic organisations, given their particularly important contribution in the health sector.
- Finally, Chapter 6 presents the perspectives of all the experts interviewed on TOSSD and the tracking of the global financing of health.

Part II Tracking the global financing for health in TOSSD

3 Tracking the cross-border financing of health in developing countries, including for international public goods – Pillar I

3.1. What is the issue?

Cross-border resource flows in health are today mainly captured through official development assistance (ODA). However, ODA is primarily a measure of international aid designed to measure donor effort, in particular from OECD-DAC countries. In this section, we investigate how TOSSD can/will fill important data gaps on external official health financing in developing countries.

3.2. Developing countries need international financing to address their multiple health challenges

Ensuring healthy lives for all is a particularly difficult challenge in developing countries. The COVID-19 crisis has shown that many are unprepared for public health emergencies. Gaps in pandemic preparedness in developing countries were already identified before the COVID-19 crisis, and international funding has been largely insufficient to address these gaps (OECD, 2020[11]).

Strong and well-functioning health systems are a pre-requisite for effective pandemic preparedness. The COVID-19 pandemic has illustrated the need to improve the resilience of health systems in all countries. Health systems in developing countries are particularly fragile. For instance, there are only 2 doctors per 1 000 citizens on average in the Latin American and the Caribbean (LAC) region – with the exception of Cuba and Argentina – compared to the OECD average of 3.5 (OECD/The World Bank, 2020, p. 116[12]). In Asia and Pacific, the number of doctors is on average also lower than the OECD average, with only 1 doctor per 1 000 citizens on average in the region's lower-middle and low-income countries (OECD/WHO, 2018, p. 84[13]).

Given their limited domestic resources, developing countries need international financing to improve health conditions for their populations and contribute to global health security. Improving the tracking of this financing will help identify the financing gaps and monitor progress in responding to developing countries' financing needs. Higher transparency on the full spectrum of external resources will also support better budgeting and allocation of resources in developing countries. While the existing international statistical system captures a large part of the international financing for developing countries, in particular through the OECD's Creditor Reporting System and more specifically the ODA measure, important gaps remain. TOSSD will help fill these data gaps.

3.3. TOSSD can fill important data gaps on external resources to developing countries in the health sector

3.3.1. TOSSD can provide a better picture of South-South Co-operation, which is particularly important in the health sector, and could envisage the tracking of South-North flows

The experts interviewed highlighted that SSC is particularly important in the health sector, but not well tracked today (see the interviews with experts from WHO, the United Nations University – International Institute for Global Health [UNU-IIGH] and the French Development Agency [AFD] in Chapter 6). TOSSD would make a particularly important contribution if it tracked these flows in a comprehensive and comparable manner.

The first TOSSD data collection has proven that TOSSD can shed light on health SSC not shown so far in international development finance statistics. For example, TOSSD data for 2019 show that SSC in the health sector by Chile supported many countries in the LAC region but also in Africa; that SSC in health by Indonesia covered in particular activities in health education and family planning; and that Nigeria supported five African countries – Gambia, Niger, Rwanda, Sierra Leone and Uganda – through SSC in health in areas such as basic health care, health education, health policy and medical services.

However, more needs to be done to better cover SSC, given its particular importance in the health sector. For example Latin American countries dedicated 17% of their bilateral SSC projects to health sectors in 2016. Moreover, one-fifth of their projects contributed to SDG 3 on "good health and well-being" in the same year (Ibero-American General Secretariat, 2018, p. 18[14]). Brazil, which is a member of the TOSSD Task Force, is particularly contributing to health and SDG 3 (Ibero-American General Secretariat, 2018, p. 174[14]), for example by supporting Mozambique to develop local pharmaceutical manufacturing capacities (Russo et al., 2014[15]). Other Latin American members of the TOSSD Task Force, such as Colombia and Costa Rica, also strongly focus on the health sector in their SSC interventions (Ibero-American General Secretariat, 2018, pp. 172 - 193[14]). Of these three countries, only Costa Rica is currently reporting on TOSSD, but Brazil is planning to start reporting in 2021 and Colombia is currently exploring its reporting capacity. Efforts should be made to integrate other important Latin American SSC providers in TOSSD, in particular Argentina and Uruguay.

SSC in health is also very important in Asia. The experts interviewed noted that Malaysia is a particularly important actor in the health sector. For example, a public-private partnership including the Malaysian Ministry of Health and Egyptian firms has recently developed a new hepatitis C drug that will provide affordable treatment for millions of patients still awaiting access to these treatments in developing countries.[9] The experts also emphasised the role of the People's Republic of China in health development co-operation. It is among the major SSC providers in Asia and has for example greatly contributed to the health sector in Africa over the past 60 years. This has included "(i) dispatching medical teams; (ii) constructing health care facilities; (iii) providing medicines and medical equipment; and (iv) donating to health funds" (Wang and Sun, 2014, p. 2[16]). Recent estimates show that health development assistance provided by China has increased, in real prices, from USD 323 million in 2007 to USD 652 million in 2017 (Micah et al., 2019[17]). China has also donated more than 78 million vaccine doses to support other countries facing the COVID-19 pandemic.[10] Under the Indian Vaccine Maitri Initiative, India, another major SSC player, has donated around 11 million COVID-19 vaccine doses to many countries around the world.[11] Efforts should be made to integrate the main Asian health SSC providers such as China, India and Malaysia into TOSSD.

[9] See https://dndi.org/press-releases/2021/first-hepatitis-c-treatment-developed-through-south-south-cooperation-registered-in-malaysia/.

[10] See https://launchandscalefaster.org/covid-19/vaccinedonations.

[11] See https://www.mea.gov.in/vaccine-supply.htm and https://launchandscalefaster.org/covid-19/vaccinedonations

South-South health co-operation is also important in Africa. For example, through the regional disease surveillance systems enhancement (REDISSE) project, the West African Health Organisation (WAHO),[12] which does not report on TOSSD, supports many West African countries in improving their disease surveillance and response capacities. Many other African SSC providers are also contributing to health (UNDP and NEPAD/AUC, 2019[18]).

The coverage of SSC in TOSSD is expected to improve over the next few years. This can be achieved by increasing the number of TOSSD Task Force members who report but also bringing in other SSC providers that currently do not participate in TOSSD discussions. The TOSSD Task Force may wish to adopt a regional approach to engage with the providers currently not represented in TOSSD, with the support of providers who are already members of the Task Force.

The TOSSD Task Force could explore the possibility of allowing the reporting of South-North flows. The experts emphasised that TOSSD Pillar I should not be limited to flows to developing countries (see for example the interview with experts from the UNU-IIGH in section 6.5). It would also be important to track cross-border South-North flows to show the full spectrum of the global cross-border financing of health. This issue was also previously raised in the TOSSD consultation with Latin America providers[13] and by some Arab providers in the context of their reporting on development finance. TOSSD aims to be a global measure for all providers, therefore it should valorise all international assistance efforts equally and go beyond the traditional division of North providers/South recipients. The experts highlighted the example of the Chinese aid provided to some European countries in response to the COVID-19 crisis.[14] They also mentioned the example of Cuban doctors sent to Northern countries to manage the crisis.

3.3.2. TOSSD sheds light on cross-border support to developing countries not captured so far, for example on medical research

TOSSD can provide transparency on external resources for research in developing countries not captured so far. For example, in the first TOSSD data collection, the EU reported USD 20 million of financing for research institutions in developing countries. This financing is not captured in ODA because the primary objective is not the development of the recipient country but rather the participation of researchers from that country in a broader research project that takes place mainly within the provider country and that is not focussed on developing countries. Another example is the US National Institutes for Health (NIH). Although the NIH mission is mainly focussed on domestic funding, it also has a substantial cross-border programme, which provides support to many developing countries. In 2020 the NIH granted approximately 300 awards directly to institutions located in developing countries, for a total amount of USD 124 million (see section 6.2). This funding is also not captured in ODA, for the same reasons for the EU, but is reportable in TOSSD.

3.3.3. TOSSD will capture innovative financing instruments and private finance that is mobilised to support developing countries' health sectors

The mobilisation of private finance through official interventions can be very important in the health sector. For example, the European Commission announced in 2020 a EUR 600 million guarantee to support the purchasing

[12] The West African Health Organisation is a specialised Institution of the Economic Community of West African States (ECOWAS). See https://www.wahooas.org/web-ooas/en/who-we-are

[13] See https://www.oecd.org/dac/financing-sustainable-development/development-finance-standards/LAC_Main_Messages_WEB.pdf

[14] See https://ec.europa.eu/commission/presscorner/detail/en/ip_20_600

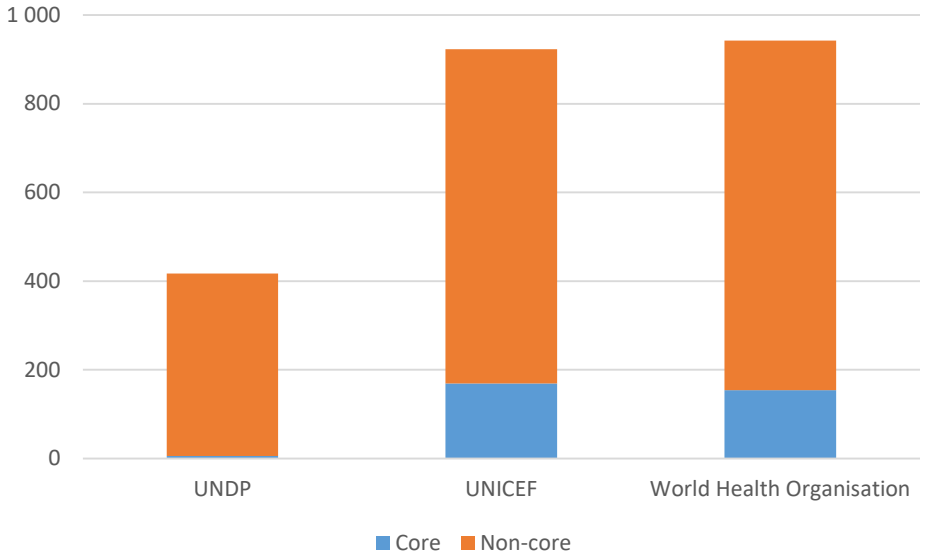
of vaccines for low and middle income countries.[15] The Gavi's International Finance Facility for Immunisation (IFFIm) mobilises private finance through the issuance of vaccine bonds. Bondholders are repaid with the official contributions of IFFIm donors, who include a number of advanced and developing countries.[16] Several experts also emphasised the innovative financing instruments that have been used to finance the HIV/AIDS response in developing countries, including debt conversion instruments or social and development impact bonds (Atun et al., 2016[19]).

3.3.4. TOSSD can better reflect the resources actually spent in developing countries for health

Experts emphasised that it would be important to reflect the amount of financing actually received in the field (see interview with experts from WHO in section 6.1). Current donor reporting reflects the funding they put in the system, but not the resources actually received by developing countries. For example, health services providers (e.g. non-governmental organisations [NGOs]) retain a significant part of the funding as administration costs, and only a share of the total funding goes to the actual project. The experts noted that it would be interesting to unpack even further the USD 20 billion collected in TOSSD Pillar I for 2019.

TOSSD provides a much better picture of health financing channelled through multilateral institutions. In TOSSD, multilateral institutions report on both their core and non-core resources, while in the CRS they report only the former, the latter being reported by donor countries. This allows for collecting more granular information on non-core resources and related projects. The first TOSSD data collections showed that these earmarked resources constitute the bulk of the activities of multilateral institutions, including in health (see Figure 3.1).

Figure 3.1. Multilateral health financing in 2019: New TOSSD data and additional details on non-core resources from UN entities, USD million



Note: UNDP = United Nations Development Program; UNICEF = United Nations Children's Fund.
Source: International TOSSD Task Force (2020[1]), *TOSSD online database*, https://tossd.online

[15] See the Access to COVID-19 tools funding commitment tracker: https://www.who.int/publications/m/item/access-to-covid-19-tools-tracker.

[16] See https://www.gavi.org/investing-gavi/innovative-financing/iffim

3.3.5. TOSSD should include mechanisms to track international public goods in Pillar I

The experts interviewed emphasised the importance of TOSSD providing a full picture of the financing of global public goods, including through cross-border flows to developing countries. It is important to know how much of global public funding supports health-related international public goods, and the current Pillar II would provide only a partial picture of this as it does not cover international financing to support developing countries' investments in global public goods at the country level, which is included in Pillar I. In addition, TOSSD offers the opportunity to view certain types of support to developing countries from their GPG rather than aid nature and this should be promoted. The TOSSD Task Force should develop a mechanism to track support to GPGs in Pillar I, for example through sector codes or a new keyword, or both.

It will be important to improve the tracking of the financing for pandemic preparedness given the need to quickly scale up investments in this area. A cross-sectoral keyword may be a good option given that pandemic preparedness is not limited to activities under "infectious disease control" (OECD, 2020[11]). For example, the COVID-19 pandemic has shown again the importance of the "One Health" approach, which integrates animal and human health, to better address global health threats. As the Rome declaration underlines, "sustained investments in global health, towards achieving Universal Health Coverage with primary healthcare at its centre, One Health, and preparedness and resilience, are broad social and macro-economic investments in global public goods".[17] The TOSSD Force could take as a reference the scope of pandemic preparedness and/or health security proposed in the frameworks of the Global Preparedness Monitoring Board (GPMB) and the Joint External Evaluations (JEE) (see section 4.4.3).

Recommendations

In view of the above findings on the tracking of cross-border resource flows in Pillar I, the International TOSSD Task Force could:

- Seek to increase the coverage of South-South Co-operation (SSC) providers, by increasing the number of TOSSD Task Force members who report, and by bringing in other SSC providers that currently do not participate in the TOSSD discussions (e.g. Argentina, India, Malaysia and Uruguay). The Task Force may wish to adopt a regional approach to engage with providers currently not represented in TOSSD, with the support of providers that are already members of the Task Force.
- Consider allowing the reporting of South-North flows.
- Develop a mechanism in Pillar I to track the cross-border financing of international public goods in developing countries.

[17] See https://global-health-summit.europa.eu/rome-declaration_en

4 Tracking the financing of international public goods for health at the domestic and supra-national level – Pillar II

This chapter is the main focus of the report. We investigate the extent to which TOSSD Pillar II is fit for tracking the global financing of health-related international public goods and how it can be shaped to best respond to the international community's emerging information needs. A key finding is that the general definition and narrative around TOSSD Pillar II may need to be reviewed to better fit the global public goods for health agenda, which needs to be distinguished from support to developing countries. The scope of health R&D funding captured in Pillar II should be revised following the overall clarification on the Pillar II objective, and policies for access to health technologies could be tracked as policy flags rather than a strict eligibility condition. If the objective of Pillar II is to promote global sustainable development, then international health co-operation should also be measured very broadly and domestic spending on health security could also be captured in Pillar II, building on current efforts to link the system of health accounts (SHA) to the Joint External Evaluations (JEE) indicators.

4.1. What is the issue?

TOSSD is the first measurement framework that aims to provide a comprehensive picture of the financing of international public goods (IPGs), both regional and global. The general definition and statistical parameters of TOSSD Pillar II have been discussed and agreed by the international TOSSD Task Force in 2018 and 2019 (see Box 4.1).[18] Specific eligibility criteria for specific items related to the financing of health-related IPGs have also already been agreed, in particular on R&D funding (see Box 4.2). However, these definitions and criteria need to be reviewed, and the scope of health financing captured in Pillar II further examined, for a number of reasons:

- The Pillar II criteria, in particular the general definitions and those that apply to R&D funding, can now be reviewed in light of the first TOSSD data collection that took place in 2020 (on 2019 resources).
- While specific eligibility criteria have been developed for R&D funding, the treatment of health financing in general has not yet been discussed by the Task Force. What other types of health expenditure should be included in TOSSD as contributions to IPGs?
- Finally, and perhaps more importantly, the COVID-19 pandemic introduced a new push for the need to measure the financing of global public goods (GPGs). How can the TOSSD methodology be shaped to best respond to the international community's information needs in this area?

In this chapter we investigate the extent to which the TOSSD framework is fit for tracking the global financing of health-related IPGs and respond to the international community's emerging information needs. While the analysis relates to health financing in general, specific focus is also placed on the COVID-19 crisis and related financing issues.

The remainder of this chapter is organised as follows:

- In section 4.2 we explore the relevance of the general definition and narrative around TOSSD Pillar II.
- In section 4.3 we test the relevance of the eligibility criteria that apply to R&D funding to be counted as a contribution to IPGs.
- In section 4.4 we investigate other global and domestic health expenditures and the extent to which they could be included in TOSSD Pillar II as contributions to IPGs.

[18] See https://www.tossd.org/task-force/.

Box 4.1. TOSSD Pillar II - contributions to international public goods: definitions and parameters

The TOSSD statistical measure includes all officially supported resources to promote sustainable development in developing countries. It includes two pillars: Pillar I tracks official cross-border flows to developing countries, and Pillar II aims to measure the global public financing that supports IPGs and address global challenges. TOSSD is a global measure where all countries can be providers.

Definitions

In TOSSD the concept of **sustainability is linked to the Sustainable Development Goals (SDGs)**. An activity is deemed to support sustainable development if it directly contributes to at least one of the SDG targets as and if no substantial detrimental effect is anticipated on one or more of the other targets.

International public goods (IPGs) are goods that provide benefits that are non-exclusive and available for all to consume at least in two countries.[1] The term "good" refers to resources, products, services, institutions, policies and conditions. **Global challenges** are issues or concerns that bring disutility on a global scale and that need to be addressed globally.

International public goods include in particular global public goods (GPGs), whose benefits are nearly universal (e.g. stable climate), and regional public goods, whose benefits extend to countries that belong to the same region (e.g. transboundary water management). The "regional" dimension can also apply to "challenges" (e.g. acid rain can be considered a regional challenge) and "development enablers" (e.g. regional peacekeeping activities).

Development enablers are the means that help provide IPGs and/or address global challenges. They often have the characteristics of IPGs. They can be seen as "intermediate" IPGs as opposed to final IPGs.

Eligibility criteria for Pillar II and link with developing countries

A Pillar II activity, as with any other TOSSD activity, is deemed to support sustainable development if it meets the criteria outlined above. In addition, an activity can be included in TOSSD Pillar II if it:

- Provides substantial benefits to TOSSD-eligible countries or their populations, and/or
- Is implemented in direct co-operation with TOSSD-eligible countries, or private or public institutions from these countries, as a means of ensuring the benefit to TOSSD-eligible countries or their populations

The first criterion is meant to exclude public investments that exclusively or overwhelmingly benefit provider countries' own populations (e.g. primary education, climate adaptation). The second criterion recognises the importance of international co-operation, in particular the involvement of developing countries in global issues, as put forward by the 2030 Agenda. In the case of multilateral organisations, "direct co-operation with TOSSD-eligible countries" is presumed when some TOSSD-eligible countries are members of the organisation.

Additional guidance on the eligibility of activities in Pillar II is provided in Annex E of the TOSSD reporting instructions.

What is the delineation between the two pillars of TOSSD?

Pillar I includes all cross-border flows to developing countries, even those that support IPGs or address global challenges (e.g. communicable disease control). Pillar II includes resources provided either at the domestic level or at the level of multilateral institutions.

Note: [1] Not all countries have adopted the concept of international public goods.
Source: International TOSSD Task Force (2021[10]), *TOSSD Reporting Instructions*, https://www.tossd.org/docs/reporting-instructions.pdf

4.2. The general definition and narrative around TOSSD Pillar II

4.2.1. TOSSD can play a key role in monitoring the highly prioritised global public goods for health agenda

The COVID-19 crisis has shown again that while global public goods for health are essential to sustainable development, they remain largely underfunded (see section 2.2). The G20 High-Level Independent Panel on the Financing of Global Commons for Pandemic Preparedness and Response calls on countries to substantially increase investments in global public goods, both at the domestic and international level (G20 High-Level Independent Panel, 2021[2]). In order to track progress and build accountability in the financing of GPGs, a measurement framework is needed. In the outcome document of the 2021 Financing for Development Forum,[19] UN member states commit themselves to undertake "further deliberations on financing of global public goods in order to accelerate the achievement of the 2030 Agenda for Sustainable Development, the Addis Ababa Action Agenda, the Paris Agreement and the Sendai Framework for Disaster Risk Reduction."

The experts interviewed in this pilot confirmed the key role that TOSSD can play in monitoring the highly prioritised global public goods investment agenda (see the interviews in Chapter 6). The interviewees from the Centre for Global Development (CGD), who supported the work of the G20 High-Level Independent Panel, emphasised that TOSSD would make a key contribution to international health policy discussions, in particular at the monitoring level, if it was able to provide comprehensive and comparable data on public funding of IPGs for health. They highlighted that currently the data are either missing or highly disparate and fragmented, with different sources using different methodologies and approaches. In addition, recent developments, in particular through discussions in the G20 and other global fora, underscore how TOSSD can help serve as a tool for monitoring and measuring financing for global public goods, including pandemic preparedness.

4.2.2. The general definition and narrative around TOSSD Pillar II may need to be reviewed to better fit the global public goods agenda

This section examines the general definition and narrative around Pillar II. According to the TOSSD reporting instructions, the general objective and definition of TOSSD Pillar II are as follows:

> *The Total Official Support for Sustainable Development (TOSSD) statistical framework aims to provide a comprehensive picture of global, official and officially-supported resource flows provided to promote sustainable development in developing countries.*
>
> *The Total Official Support for Sustainable Development (TOSSD) statistical measure includes all officially-supported resources to promote sustainable development in developing countries. This includes i) cross-border flows to developing countries and ii) resources to support development enablers and/or address global challenges at regional or global levels. (International TOSSD Task Force, 2021[10])*

Many experts emphasised that measuring the financing of international or global public goods, health-related or not, is fundamentally and conceptually different from measuring support "to promote sustainable development in developing countries", which is the current overarching TOSSD definition (see the interviews with experts from WHO, the UNU-IIGH, the AFD and the CGD in Chapter 6). The paper presented to the TOSSD Task Force on the specific treatment of health R&D in TOSSD (Rogerson and Blampied, 2018[20]) already emphasised that "delivering global public goods, or combatting global bads, is ethically different to promoting R&D as an agenda specifically benefitting

19 https://www.un.org/development/desa/financing/sites/www.un.org.development.desa.financing/files/2021-04/E-FFDF-2021-L1_0.pdf

developing countries, however that is defined". More recently, the G20 High-Level Independent Panel on the Financing of Global Commons for Pandemic Preparedness and Response (2021[2]) stressed that the prevention of pandemics or climate change requires a clear recognition of "the benefits that all nations share", and that support to these areas "is fundamentally not about aid, but about investment in global public goods from which all nations benefit".

The two approaches – measuring support to promote global sustainable development and global public goods as opposed to measuring support to promote sustainable development in developing countries - have different implications in terms of activities covered. Most experts advocated for the second Pillar to be framed around global sustainable development and the benefits to all countries, not just the developing ones. **The overarching TOSSD definition should also reflect this global nature. While Pillar I should be focussed on the sustainable development of developing countries and providing transparency on external flows to them, Pillar II should be focussed on global sustainable development and transparency provided to the global community.** This would also address concerns that TOSSD will inflate the financing that providers claim as a support to developing countries.

In a global context marked by the COVID-19 pandemic, some experts have emphasised that focusing Pillar II on GPGs would clarify the Pillar II narrative. Indeed, the TOSSD Secretariat has often been asked why TOSSD uses the term IPGs rather than GPGs. The reason for this choice has been to cover, in addition to GPGs, regional and other IPGs. The Task Force could explore in more detail what would be the consequence of refocussing the narrative on GPGs. Most of what is included in Pillar II now can be considered as contributing to GPGs (e.g. climate mitigation, support to refugees, R&D) and many regional public goods also contribute to GPGs (e.g. regional pandemic surveillance, regional peace operations).

Several concepts and definitions are proposed at the international level to capture the GPG nature of health. The TOSSD definitions of IPGs and global challenges are broader than all these definitions (see Table 4.1). Health security focusses on the transboundary nature of public health, excluding for example non-communicable diseases (NCDs). Global public goods for pandemic preparedness and response are defined as a narrowest version of health security, focussing on the functions that are fully dedicated to pandemic control, as opposed to other functions that also benefit countries in normal times. The definition of common goods for health (CGH) focusses on market failures and things that cannot be funded through market mechanisms, including for example neglected diseases that particularly affect poor populations, but not other infectious diseases or NCDs for which market incentives exist given their large impact in rich countries.

Table 4.1. International definitions used in relation to global public goods for health

International public goods and global challenges as defined in TOSSD	Global public health security as defined by WHO	Global public goods for pandemic preparedness and response (PPR) as defined by the G20 High-Level Independent Panel	Common goods for health as defined by WHO
IPGs are goods which provide benefits that are non-exclusive and available for all to consume in at least two countries. IPGs include in particular **global public goods** and **regional public goods**. **Global challenges** are issues or concerns that bring disutility on a global scale and that need to be addressed globally.	The activities required, both proactive and reactive, to minimise the danger and impact of acute public health events that endanger people's health across geographical regions and international boundaries.	The panel distinguishes between two levels of global public goods for PPR: • Pure global public goods such as surveillance and R&D. • Other investments that have a clearer benefit for individual countries or regions, such as strengthened national capacities to stop the spread of infectious diseases, but which nonetheless have positive externalities for the global community.	Population-based functions or interventions that require collective financing, either from the government or donors based on the following conditions: • Contribute to health and economic progress; • There is a clear economic rationale for interventions based on market failures, with focus on (i) public goods (non-rival, non-exclusionary) or (ii) large social externalities. CGH must generate large societal health benefits that cannot be financed through market forces.

Source: The definitions of global public health security and common goods for health are taken from WHO: https://www.who.int/health-topics/health-security#tab=tab_1, https://www.who.int/health-topics/common-goods-for-health#tab=tab_3; and the scope of activities included in global public goods for pandemic preparedness and response is taken from: G20 High-Level Independent Panel (2021[2]), *Report of the G20 High-Level Independent Panel on the Financing of Global Commons for Pandemic Preparedness and Response, a Global Deal for Our Pandemic Age*, https://pandemic-financing.org/report/foreword/.

Recommendations

In view of the above comments, the International TOSSD Task Force could:

- Discuss the pros and cons of linking Pillar II to global sustainable development and the implications this would have for the scope of Pillar II and for the overarching TOSSD definition.
- Explore the relevance of refocussing the narrative of Pillar II on global public goods rather than international public goods.

4.3. Tracking R&D funding as a contribution to international public goods for health

4.3.1. What is the issue?

R&D funding is analysed extensively in this pilot, given the existing reporting instructions that needed to be tested, the complexity of the topic and its particular importance in achieving global public health objectives. Funding for health R&D can contribute to global public goods and the achievement of the SDGs through the generation of new knowledge or the invention of life-saving technologies, and as such may be counted in TOSSD. However, to what extent should spending on health R&D counted in TOSSD Pillar II focus on the health of populations of developing countries? The International TOSSD Task Force has addressed this issue through two main points:

- Consistent with a GPG approach, the TOSSD Task Force agreed that R&D funding counted in TOSSD Pillar II should not be limited to diseases primarily affecting developing countries but rather have a broader coverage and include also diseases incident both in advanced and developing countries (Rogerson and Blampied, 2018[20])[20]. This broad coverage has been translated into (i) the general Pillar II eligibility principle requiring "substantial" rather than "exclusive" or "disproportionate" benefits to developing countries; and (ii) in criterion "a)" of the R&D eligibility rules, which includes all research topics that are "potentially applicable" to developing countries (see Box 4.2).
- Access to medical knowledge and technologies can be restricted, particularly in developing countries, through intellectual property and unaffordable prices. To what extent should the outcome of R&D be sufficiently shared and accessible at the global level, in particular in developing countries, so that it can be considered as contributing to IPGs or addressing global challenges? The TOSSD Task Force has decided that the benefits to developing countries would be defined through the requirement that health-related discoveries and innovations are broadly accessible to researchers and populations from developing countries (see Box 4.2). This is consistent with the SDGs which emphasise the importance of affordable health technologies.[21]

In this section we seek to confirm whether the TOSSD eligibility criteria for counting R&D funding in Pillar II are conceptually relevant, i.e. do they reflect well the reality of R&D funding and provide the right incentives for achieving global public health objectives? And are they sufficiently operational, i.e. is reporting and data collection feasible? On the basis of our findings we formulate recommendations to the TOSSD Task Force on possible options for adjusting the TOSSD framework.

[20] See also the action points of the sixth and seventh meetings of the TOSSD Task Force: https://www.tossd.org/docs/TOSSD-Action-Points-Sweden-WEB.pdf, https://www.tossd.org/docs/Action%20Points%20-%207th%20Meeting%20of%20the%20TOSSD%20TF.pdf.

[21] SDG target 3.8 mentions the importance of "access to safe, effective, quality and affordable essential medicines and vaccines for all" to achieve universal health coverage (UHC), and SDG target 3.b emphasises the need to "provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health".

Box 4.2. TOSSD criteria for counting R&D funding as a contribution to IPGs

R&D[1] is defined as research and experimental development comprising creative and systematic work undertaken in order to increase the stock of knowledge – including knowledge of humankind, culture and society – and to devise new applications of available knowledge. TOSSD includes financing by the official sector of R&D into issues directly related to the Sustainable Development Goals. In addition, it includes basic research, which is defined as experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts without any particular application or use in view. Although not explicitly mentioned in the 2030 Agenda, basic research is a principal requirement for innovation for sustainable development.

Officially-supported cross-border flows for R&D activities in TOSSD-eligible countries are included in Pillar I. R&D activities carried out in the provider country, in a non-TOSSD-eligible country or at the level of a multilateral institution are eligible for reporting under TOSSD Pillar II provided that:

a) The research subject is SDG-related and potentially applicable to more than one country, including at least one TOSSD-eligible country, or the research subject is related to basic research. The first criterion is meant to exclude R&D that is relevant to the SDGs but for which the applicability is largely domestic.

b) In the case of scientific publications and research data, the funder institution's public access policy is based on the principle of open access. This will ensure that results of the research are put in the public domain and therefore available for populations and scientists worldwide, including in TOSSD-eligible countries.

c) In the case of official support for experimental development,[2] the activity is eligible provided that it meets one of the following conditions:

- The results of the R&D activity are expected to be put in the public domain, for example through applied public research.
- Research contracts are associated with conditions that aim at promoting competitive manufacturing, for example through non-exclusive licensing[3].
- The support consists of schemes such as advance market commitments (AMC) which aim at developing a product at low prices.

In addition, in cases where R&D is followed by an activity that promotes access to a product in developing countries, both the promotion activity and the original R&D activity are eligible.

The criteria aim to ensure that R&D activities with potential transnational applicability provide benefits to populations and scientists in TOSSD-eligible countries, by requiring that the results of the R&D activity are available to them and/or by promoting access to innovation and technologies in these countries.

Notes:
[1] Definitions in this section are taken from the Frascati Manual available at: http://www.oecd.org/sti/frascati-manual-2015- 9789264239012-en.htm
[2] Experimental development is systematic work, drawing on knowledge gained from research and practical experience and producing additional knowledge, which is directed to producing new products or processes or to improving existing products or processes.
[3] Non-exclusive licence grants to the licensee the right to use the intellectual property rights (IPRs), but on a non-exclusive basis. That means that the licensor can still exploit the same IPRs and he/she can also allow other licensees to exploit the same intellectual property.
Source: International TOSSD Task Force (2021[10]), *TOSSD Reporting Instructions* https://www.tossd.org/docs/reporting-instructions.pdf

4.3.2. The current broad coverage of health R&D topics in TOSSD is appropriate with a measurement approach focussed on global sustainable development and the benefits to all countries

This section examines the scope of R&D potentially covered in TOSSD, which is defined as follows:

> *R&D activities … are eligible for reporting under TOSSD Pillar II provided that: a) The research subject is SDG-related and potentially applicable to more than one country, including at least one TOSSD-eligible country, or the research subject is related to basic research. The first criterion is meant to exclude R&D that is relevant to the SDGs, but for which the applicability is largely domestic" (International TOSSD Task Force, 2021, pp. 35-36[10]).*

Although often not explicitly linked to the SDGs, health R&D can generally be considered as contributing to sustainable development and potentially applicable to developing countries.

Most applied and translational health R&D can be considered as contributing to sustainable development, although in general is not explicitly linked to the SDGs. While some R&D projects or calls may be explicitly targeted to the SDGs,[22] most often this is not the case. Nonetheless, most health research can still be considered as contributing to the SDGs, which deal with all factors that contribute to populations' health and well-being (see the interview with WHO experts). Some experts emphasised, however, that there can be cases where the "sustainability" of biomedical research – which in TOSSD requires that the activity contributes to one SDG target and that "no substantial detrimental effect is anticipated on one or more of the other targets" – would be rather subjective and dependent on culture, values and interpretation (see the interview with the International Genomics Institute [IGI]). For example, while human genetic editing would be considered an important advancement for those suffering from debilitating neurodegenerative diseases, many voices in the deaf community have opposed the use of this technology to prevent and treat deafness as they do not see it as a disease, but rather as a fundamental part of their identity and culture.

Almost all applied and translational health R&D could be considered "potentially applicable to developing countries". In the area of health research, there are few topics that would not be applicable to at least one developing country. Even certain types of implementation or health systems research that may aim at answering domestic questions (e.g. how to scale interventions or reach particular groups) can inform other countries with similar contexts if publicly available (see the interview with WHO experts). In addition, the cost of screening all R&D projects to identify and exclude those not applicable to developing countries would be too high compared to the little financing that would be excluded. For example, in the 2020 TOSSD data collection, out of EUR 1 billion of funding for health research reported by the EU in Pillar II, only EUR 17 million was flagged as possibly not applicable to developing countries. **Therefore, in order to facilitate providers' reporting, applied and translational health R&D may be considered by default as contributing to the SDGs and "potentially applicable" to developing countries, leaving, however, the possibility for reporters to exclude projects if easily identifiable.**

While not all basic research leads to immediate and tangible benefits for human health, including only part of it would be challenging, and the case can be made that overall basic science is a key enabler of progress in how we prevent and treat diseases. The experts interviewed were more divided on the inclusion of basic research. For some, a broad coverage of basic science would include certain types of research that are not applicable and too disconnected from sustainable development.[23] They highlighted that the current TOSSD criteria result in *de facto* including much more basic research

[22] See for example the H2020 topic https://cordis.europa.eu/programme/id/H2020_SC1-BHC-18-2018.

[23] See the interviews with the IGI, Christophe Paquet and Marco Schäferhoff in Chapter 6

than product development, which may have more impact on saving people's lives. Other experts[24] considered that basic research is essential for sustainable development because:

- It generates new fundamental knowledge that is directly applicable and necessary for developing solutions to health challenges. For example understanding the determinants of cancer or dementia is essential for developing effective prevention or treatment interventions, and early basic transversal research on unknown pathogens helps prepare for future pandemics.[25] A recent study has demonstrated that all 210 new drugs approved by the US Food and Drug Administration between 2010 and 2016 were associated with published research funded by the NIH and that more than 90% of this research was represented by "basic research related to the biological targets for drug action rather than the drugs themselves" (Galkina Cleary et al., 2018[21]).
- Even "pure" basic research enables scientific and technological breakthroughs that can be used in the development of new health technologies – for example the revolutionary CRISPR-Cas gene editing[26] and mRNA vaccines[27] technologies, which come from decades of "pure" fundamental research in biology and biochemistry. In addition, health and biological fundamental knowledge relates to human and natural phenomena (e.g. cells, cognition), which, in general, are not limited to a specific country and can be relevant to populations globally.

While it may be true that not all basic research would have the same, or even any, impact on human health, it would be difficult to include only part of it. First, while in theory a distinction can be made between "pure" basic research that is not application-specific, and purpose-oriented basic research that is more focussed on sustainable development problems (Rogerson and Blampied, 2018[20]), in practice, as noted in interviews with the NIH and Policy Cures Research, classifying R&D projects in these two categories would be complicated and resource intensive. Very detailed and practical classification guidelines would need to be developed with the support of health R&D experts.[28] Second, as emphasised above, research is inherently uncertain, and even pure basic research can lead to unexpected scientific breakthroughs that will translate into large human health benefits – for example the discovery of CRISPR-Cas originated from the study of microbes' defence mechanisms (Ishino, Krupovic and Forterre, 2018[22]).

The experts interviewed suggested that an easier solution would be to include or exclude basic research in full. Excluding basic research entirely "would be to discourage investment in one of the great underlying motors of global development" where public intervention is particularly justified given the "large potential spill-overs beyond the individual investor" (Rogerson and Blampied, 2018[20]). It would also exclude a very large part of public R&D funding. For example, around 52% of NIH funding is allocated to basic research (see section 6.2). **Reinforcing the global public good approach of Pillar II, as opposed to an approach focussed on particular benefits to developing countries, can provide a rationale for the full integration of basic health and biological research**.

[24] See the interviews with experts from WHO, UNU-IIGH, Wellcome Trust or the NIH.

[25] For example the Disease X in WHO's R&D Blueprint is based on the enabling of this early enabling research. See https://www.who.int/activities/prioritizing-diseases-for-research-and-development-in-emergency-contexts

[26] The CRISPR gene editing tool can be used to change DNA sequence and correcting gene errors that cause diseases.

[27] See the infographic of the Canadian Institutes of health Research on "On the long road to mRNA vaccines", https://cihr-irsc.gc.ca/e/52424.html#tl.

[28] See the interview with Policy Cures Research.

If the objective of Pillar II is to measure resources that promote global public goods and global sustainable development, then the broad coverage of health research areas is appropriate.

In line with the universality of the SDG agenda and the need for encouraging investment in GPGs, most experts interviewed supported a broad coverage of R&D topics captured in Pillar II. As explained above, the current TOSSD R&D criteria cover all research topics "applicable" to developing countries, which in terms of disease areas means all diseases that affect developing countries, including those incident in both developing and advanced countries. Most experts interviewed supported this broad coverage as this would be in line with the GPG approach currently needed (see for example the interviews with experts from WHO, Wellcome Trust and CGD in Chapter 6). However, as noted in section 4.2.2, the experts also stressed that this GPG approach would need to be distinguished from support to developing countries. A strengthened GPG approach, not necessarily constrained by the necessity to have tangible benefits to developing countries, would also fully capture basic health and biological research without having to go through the difficult task of distinguishing between "applicable" and "non-applicable" basic research.

The COVID-19 crisis provides a strong justification for this broad coverage. All countries are affected by the dramatic health and socio-economic damages caused by the pandemic and technologies to detect, prevent and treat the disease are in critical need everywhere. While public investments to develop these technologies will generate global benefits, they are not provided primarily to support/promote developing countries' welfare. Therefore, the vast majority of these investments are (rightfully) not captured in official development assistance (ODA). If the scope of Pillar II was on diseases that affect disproportionately developing countries (e.g. malaria or tuberculosis) – which is currently not the case – they would also not be captured in TOSSD. In section 4.3.4, we show that a very large part of public funding for COVID-19 R&D would be eligible under the current TOSSD eligibility rules, which promote access to health innovations in developing countries but do not require equal access, i.e. equal distribution of the technologies across the world. Table 4.2 **illustrates how TOSSD sheds light on key activities that contribute to global sustainable development but that would otherwise not be tracked in international statistics on the financing of the SDGs**. It shows that for the selected providers for which data could be gathered – namely Canada, the EU, the United Kingdom and the United States – TOSSD captures nearly USD 35 billion of COVID-19 R&D funding not captured in ODA.

Table 4.2. Estimation of COVID-19 R&D funding captured in ODA and in the current scope of TOSSD Pillar II, USD million

Provider	International commitments for R&D under ACT-A eligible to ODA (CEPI, 53%; FIND, 100% and Therapeutics Accelerator, 100%)	All international commitments for R&D under ACT-A captured in the current TOSSD Pillar II rules	Additional direct country funding of R&D captured in the current TOSSD Pillar II rules
Canada	52	84	186
EU	61	115	872
United Kingdom	247	396	1 140
United States	..	..	31 897
Total	360	595	34 095

Note: In order to estimate the share of R&D commitments to ACT-A that are counted in ODA, we have applied the ODA coefficients agreed at by the DAC at the time of writing, in August 2021.
Source: Authors' estimation based on WHO (2021[23]), *Access to COVID-19 tools funding commitment tracker*, https://www.who.int/publications/m/item/access-to-covid-19-tools-tracker; NIH (n.d.[24]), *NIH RePORTER database*, https://reporter.nih.gov/advanced-search; BARDA (n.d.[25]), *COVID-19 Medical Countermeasure Portfolio*, https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx; and the UKRI (n.d.[26]), *Database on R&D funding for COVID-19*, https://www.ukri.org/find-covid-19-research-and-innovation-supported-by-ukri/; Canada provided us directly with data on its country funding.

If the objective of Pillar II is to promote "the sustainable development of developing countries", then the scope should be limited to R&D that is focussed on their needs

Some experts told us that if on the contrary the focus of TOSSD is specifically on "promoting sustainable development in developing countries", then the scope of R&D topics is too broad and should be narrowed so that the measure can be meaningful. Marco Schäferhoff (see section 6.10) recommended focusing on product development for neglected diseases (NDs) that predominantly affect poor countries and for which there is insufficient commercial incentive to attract private R&D investments. In one of his papers (Schäferhoff et al., 2019[27]) he proposed a measurement of the financing for global common goods for health (CGH), including what he refers to as "ODA+": ODA for CGH – extracted from the OECD CRS system – plus funding for ND-related product development – extracted from the G-FINDER survey (see Box 4.3). Although focussing on diseases that disproportionately affect developing countries (e.g. tuberculosis), a large part of the R&D funding captured in the G-Finder ND survey is not captured in ODA because it is not primarily aimed at supporting the economic development and welfare of developing countries.

Box 4.3. The G-Finder survey of global funding for global health R&D

The G-FINDER project, conducted by Policy Cures Research with funding from the Bill & Melinda Gates Foundation, tracks global R&D investments on new health technologies for global health issues. Its scope includes basic research, as well as the full spectrum of product-related R&D.

The Neglected Disease (ND) survey

The flagship G-FINDER survey is the Neglected Disease (ND) survey, which tracks annual investments in R&D for new technologies designed to address the persistent global health challenges that disproportionately affect the world's most disadvantaged people. It is widely acknowledged at the global level and is used for example by the WHO Global Observatory on Health Research and Development to monitor R&D funding for neglected diseases.

The ND survey scope is defined by an expert international advisory committee and based on three criteria: (i) the disease disproportionately affects people in low- and middle-income countries; (ii) there is a need for new products; (iii) there is market failure (i.e. there is insufficient commercial market to attract R&D by private industry).

Diseases where commercial incentives for R&D already exist (including diseases prevalent in both high-income and low- and middle-income countries, where appropriate product R&D already occurs in response to high-income country markets) are excluded from the G-FINDER ND survey. Diseases with a mixed picture, such as HIV/AIDS or bacterial pneumonia and meningitis (where commercially-driven R&D does occur in response to high-income country markets, but it does not fully meet the needs of low- and middle-income countries) are included on a restricted basis.

The Emerging Infectious Diseases (EID) and the Sexual & Reproductive Health (SRH) surveys

The scope of the EID survey is based on WHO's R&D Blueprint for Action to Prevent Epidemics (R&D Blueprint). It includes all R&D Blueprint priority diseases, grouped by pathogen family for data collection purposes. The survey also includes diseases not included in the priority list but recognised by the R&D Blueprint as posing major public health risks. The 2021 EID survey (on 2020 data) will include data on COVID-19 R&D. Compared to the ND survey, the EID survey has very few scope restrictions: R&D for almost all product development categories (drugs, vaccines, biologics, and diagnostics) is considered in scope for all priority EID pathogens, as is basic research; R&D for vector control products is included where relevant. Broadly-relevant R&D (e.g. development of platform technologies) is included provided it is specific to, or primarily targeted at, EIDs. Funding not related to the development of new health technologies is excluded from the survey scope.

As with neglected diseases, the definition of sexual and reproductive health aims to capture R&D that is relevant to the needs of people in low- and middle-income countries according to the following overarching criteria: (i) the area is a significant health issue affecting people in low- and middle-income countries; (ii) there is a need for new products (i.e. there is no existing product, or improved or additional products are needed to meet the needs of people in low- and middle-income countries); and (iii) investments in products are suitable for people in low- and middle-income countries.

Research activities NOT included in the scope of G-FINDER

The purpose of G-FINDER is to track and analyse global investment in the research and development of new health technologies for global health issues. It does not capture investment in the entire spectrum of global health research. Many research activities that are extremely important for global health are excluded because they are not related to the development of new tools for the diseases included in the G-FINDER scope. For example, the survey excludes health systems and operations, as well as

sociological, behavioural and epidemiological research not related to the development of new health technologies.

The G-FINDER scope excludes the majority of public health R&D funding. For example, out of the USD 36 billion R&D budget of the US NIH in 2019, only USD 2.1 billion is included in the scope of three G-FINDER surveys. The difference is mainly explained by the exclusion of certain diseases such as non-communicable diseases (or other infectious diseases that don't meet the G-FINDER scope), but also of basic research not oriented towards specific diseases. Basic research in general represents a very important part of public R&D funding (e.g. around 52% of the total NIH budget and 34% of its in-scope 2019 funding for neglected diseases).

Data collection methodology

In terms of participants the G-FINDER survey aims to cover all key public, private and philanthropic organisations involved in global health R&D. The data collection covers both advanced countries and emerging economies, including Argentina, Brazil, Chile, China, Colombia, India, Malaysia, Mexico, Nigeria, Russia, Saudi Arabia, South Africa and Thailand. Reporting to the survey is at the organisation (rather than national) level, meaning that not all countries from whom data are reported will be equally comprehensively represented.

Survey participants are asked to enter details of every global health investment they disbursed or received, including: a specific disease or health issue; a product type (e.g. drugs, vaccines, microbicides); an R&D stage within the product type (e.g. discovery and pre-clinical, clinical development, Phase IV/pharmacovigilance studies of new products); the name of the funder or recipient of the grant; a brief description of the grant and an internal grant identification number; and the grant amount.

The actual data collection is based on reporting by participants, through an online survey platform and an offline grant-based reporting tool, but also the extraction by the G-FINDER team itself of publicly available databases, in particular for some organisations with very large datasets, such as the US Biomedical Advanced Research and Development Authority (BARDA), Department of Defense, and National Institutes of Health (NIH); the European Commission; and Innovate UK.

Note: This box has been drafted with the contribution of Policy Cures Research

4.3.3. Conditioning public funding for research to the "open access" principle is relevant for promoting global public goods but not sufficient to conclude there is a benefit to developing countries

This section examines the following eligibility criterion for counting R&D funding in Pillar II:

> *TOSSD reporting instructions: "b) In the case of scientific publications and research data, the funder institution's public access policy is based on the principle of open access. This will ensure that results of the research are put in the public domain and therefore available for populations and scientists worldwide, including in TOSSD-eligible countries." (International TOSSD Task Force, 2021, pp. 35-36[10]).*

Experts interviewed broadly supported making the eligibility of research funding conditional to the principle of open access, which will make the knowledge effectively a global public good. In 2016, the UN Secretary's General High-Level Panel on Access to Medicines (2016[28]), which was created to advance health-related SDGs, recommended that strong and enforceable policies on data sharing and data access should be a condition for public grants. More recently, the Independent Panel for Pandemic

Preparedness and Response[29] (2021[29]) noted that sharing openly the genome sequence of the novel coronavirus "led to the most rapid creation of diagnostic tests in history", and that openly accessible clinical trials have provided the world with reliable answers on the effectiveness of some treatments for COVID-19.[30] The Independent Panel calls for a renewed commitment to open data principles as the foundation of more effective surveillance and alert systems. Policies on open access to scientific publications and data are generally applied by most major public funders, for example the NIH (see section 6.2), UK Research and Innovation (UKRI),[31] CEPI and ACT-A.[32] Given that almost all health R&D topics are covered in the TOSSD R&D reporting instructions, as explained in section 4.3.2, this means that almost all academic and knowledge-oriented health research, which represents a major part of public R&D funding, is currently eligible under Pillar II (see for example our indicative assessment of the eligibility of NIH funding in section 6.2).

However, the experts interviewed also emphasised that while open access is relevant for promoting global public goods, it is not sufficient to assert the benefit to developing countries (see the interviews with Ohid Yaqub and Olivier Weil in Chapter 6). They stressed that even if the knowledge is in the public domain, local capabilities and infrastructure are needed to extract value from research and appreciate its possible applications. A major rationale for undertaking R&D is not only to increase the stock of knowledge but also to maintain it and develop an ability to absorb new R&D undertaken elsewhere. The primary issue in many developing countries is not open access, but the capacity to perform research.

4.3.4. The TOSSD screening of R&D against funders' policies on access to health technologies is relevant and needed, but making it an eligibility condition may be too restrictive and difficult to operationalise

This section examines the relevance of the following TOSSD eligibility criteria for counting R&D funding in Pillar II:

> *TOSSD reporting instructions: "c) In the case of official support for experimental development, the activity is eligible provided that it meets one of the following conditions:*
>
> - *The results of the R&D activity are expected to be put in the public domain, for example through applied public research.*
> - *Research contracts are associated with conditions that aim at promoting competitive manufacturing, for example through non-exclusive licensing.*
> - *The support consists of schemes such as Advanced Market Commitments (AMC) which aim at developing a product at low prices.*

[29] The Independent Panel was established by WHO Director-General in 2020 with the mission to "provide an evidence-based path for the future, grounded in lessons of the present and the past to ensure countries and global institutions, including specifically WHO, effectively address health threats." See https://theindependentpanel.org/about-the-independent-panel/.

[30] Examples of these openly accessible clinical trials include WHO's "Solidarity" clinical trial (https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/solidarity-clinical-trial-for-covid-19-treatments), the UK's Recovery trial (https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf) and the French-European Discovery (https://presse.inserm.fr/en/published-now-in-the-new-england-journal-of-medicine-the-initial-results-of-the-solidarity-discovery-clinical-trial/41642/).

[31] See https://www.ukri.org/apply-for-funding/before-you-apply/your-responsibilities-if-you-get-funding/making-research-open/#contents-list

[32] https://cepi.net/wp-content/uploads/2020/12/Enabling-equitable-access-to-COVID19-vaccines-v4-18Mar2021.pdf

> *In addition, in cases where R&D is followed by an activity that promotes access to a product in developing countries, both the promotion activity and the original R&D activity are eligible".*
>
> *(International TOSSD Task Force, 2021, pp. 35-36[10])*

Screening the R&D funding counted in TOSSD Pillar II against the principle of access to health technologies would fill a key information gap in current global health policy

The affordability of medicines is an important barrier for health sustainability in both developing and advanced countries. The issue of global access to medicines is a key dimension of SDG 3[33]. It is also a key element of policy coherence for sustainable development (High-Level Panel on Access to Medicines, 2016[28]). The affordability of medicines remains a major obstacle that prevents millions of people in developing countries accessing essential treatments for illnesses such as hepatitis C or cancer. Furthermore, as emphasised in the interview with the International Genomics Institute (see section 6.4), affordability is also a growing concern in many high-income countries (Wirtz et al., 2017[30]; US Government Accountability Office, 2020[31]). Affordability is a greater challenge for chronic conditions and NCDs that need to be treated continuously, and a particular concern for biological medicines such as gene therapies that are costly to develop.

The COVID-19 pandemic introduced a new push to the debate on access to medicines and placed it high on the global policy agenda. At the international level, the United Nations General Assembly[34] and the G20 leaders[35] made commitments towards more equitable and affordable access to health technologies. The proposal currently discussed at the World Trade Organisation (WTO) regarding a possible COVID-19 intellectual property (IP) waiver may also be signalling a big shift in international IP policies towards a better consideration of equitable access and global health needs (Zarocostas, 2021[32]). The proposal was presented by South Africa and India – where access to COVID-19 vaccines is a major issue despite significant local pharmaceutical manufacturing capacities – and is now supported by some of the largest R&D funders in the world, for example the United States and France. The OECD advocates for including provisions for IP sharing and technology transfers in publicly funded contracts for the development of products addressing health emergencies (OECD, 2021[33]). Some vaccine developers have also voluntarily committed to policies encouraging global access to COVID-19 vaccines.

By providing information on policies that promote global access to medicines, TOSSD would respond to a key information need of the international community. Most of the experts interviewed emphasised that it is crucial today to track and progress towards more equitable access (see the interviews with experts from WHO, OECD, CGD and Wellcome Trust in Chapter 6). The provision of data by TOSSD to inform this important policy issue would be a great contribution to the international health policy discussions. In addition, the experts emphasised that **it would be important for TOSSD to introduce a mechanism to hold providers accountable regarding the equitable access policies they announce**. They noted that even when governments do include conditions on affordability and access in their

[33] Sustainable Development Goal 3.8 specifically mentions the importance of "access to safe, effective, quality and affordable essential medicines and vaccines for all" and Sustainable Development Goal 3.b emphasises the need to develop medicines to address persistent treatment gaps.

[34] The United Nations General Assembly issued a "Political Declaration on Equitable Global Access to COVID-19 Vaccines", which included a pledge to treat "COVID-19 vaccination a global public good by ensuring affordable, equitable and fair access to vaccines for all." See https://www.unmultimedia.org/avlibrary/asset/2609/2609855/.

[35] At the Global Health Summit held in May 2021, the G20 leaders committed to "enable equitable, affordable, timely, global access to high-quality, safe and effective prevention, detection and response tools…". See https://global-health-summit.europa.eu/rome-declaration_en.

R&D funding, they often have difficulties in following up and ensuring that these conditions are complied with.

The current TOSSD R&D criteria are generally relevant for describing R&D policies that promote affordability; however, this is only one dimension of access to health technologies

The current TOSSD R&D criteria are generally relevant for describing R&D funders' policies that promote affordability

The conditions included in criteria "c)" of the TOSSD R&D eligibility rules (see Box 4.2) are aimed at promoting global access to health innovations, in particular in developing countries? This section explores the extent of their relevance:

> *TOSSD reporting instructions: "c) In the case of official support for experimental development, the activity is eligible provided that it meets one of the following conditions:*
>
> - *The support consists of schemes such as Advance Market Commitments (AMC) which aim at developing a product at low prices…" (International TOSSD Task Force, 2021, pp. 35-36[10]).*

Schemes and policies that **promote affordability directly through pricing** are (to a certain extent) used and can be effective in providing affordable access to health innovations in developing countries. The experts interviewed emphasised two main types of pricing-based interventions:

- **Differential or tiered pricing** schemes[36] were emphasised as one of the most effective ways for encouraging R&D while ensuring that populations in developing countries can access innovative treatments (OECD, 2018[34]). Such schemes are not uncommon in the pharmaceutical industry (UNITAID, 2016[35]). Some experts noted however that they may not well reflect disparities within countries and across income groups.
- **Schemes aimed at delinking the price of health technologies from the R&D cost, also referred to as pull mechanisms**, are also promoted as effective solutions for equitable access by many experts (OECD, 2020[8]; WHO, 2016[36]; High-Level Panel on Access to Medicines, 2016[28]). The delinking of price from R&D cost is based on the removal of the inherent uncertainty of research and the reward of successful completion of R&D. Examples of pull mechanisms include **advance market commitments (AMC)**, where funders, or buyers, commit in advance to purchasing a specified volume of a health technology still in development if it meets specified criteria and at a guaranteed price; **innovation prizes** – where funders disburse a pre-specified sum upon achievement of a specified milestone related to the development of a health technology; or **grants covering the entire R&D process from discovery to late-stage clinical trials and approval** (OECD, 2020[8]). These mechanisms can be effective in promoting more equitable access or addressing market failures, i.e. low investments in product development in certain areas due to the expectation of insufficient demand and/or low profits. AMC have been used for example in the context of the COVAX initiative.[37]

[36] Differential pricing, also known as tiered pricing, means that different classes of buyers are charged different prices for the same product. In other words, low-income countries are charged less than higher income countries for the same product. See https://www.who.int/immunization/programmes_systems/financing/analyses/en/briefcase_pricingtiers.pdf

[37] See https://www.gavi.org/vaccineswork/gavi-covax-amc-explained

The first TOSSD data collection also showed that **R&D funders can issue specific funding calls or schemes aimed at affordability**. For example the EU funds a research topic on "New anti-infective agents for prevention and/or treatment of neglected infectious diseases (NID)",[38] which aims to develop affordable treatments and vaccines. Affordability is of course a key focus of Southern R&D funders. Under the National Biopharma Mission,[39] the Indian Ministry of Science and Technology (Department of Biotechnology) funds the Innovate in India (I3) initiative, which is explicitly targeted at developing affordable health solutions and products.[40] A South-South public-private partnership between the Malaysian Ministry of Health, Malaysian and Egyptian firms, and not-for-profit institutions has recently achieved its objective to develop a new and affordable hepatitis C drug.[41] International research partnerships that involve developing countries, such as CEPI or FIND, also often target affordability. For example when funding R&D, CEPI defines target product profiles that incorporate affordable target price range and access terms, and takes into account the "proportionately higher ability to pay in upper middle income and high income countries".[42]

> *TOSSD reporting instructions: "c) In the case of official support for experimental development, the activity is eligible provided that it meets one of the following conditions:*
>
> - *Research contracts that are associated with conditions that aim at promoting competitive manufacturing, for example through non-exclusive licensing…" (International TOSSD Task Force, 2021, pp. 35-36[10])*

R&D policies aimed at promoting competitive manufacturing are effective in promoting affordability, although indirectly, and are to a certain extent applied by official R&D funders. The experts interviewed agreed that increased competition can be an effective, although indirect, way to promote the affordability of health innovations. A study by the US Government Accountability Office (2017[37]) showed that less competition is associated with higher drug prices. The use of non-exclusive licences in particular is considered by many experts as relevant for promoting competition and for maximising public health benefits (see the interviews with experts from the CGD, WHO and Welcome Trust) (High-Level Panel on Access to Medicines, 2016, p. 8[28]). **We found evidence of public R&D funders using non-exclusive licensing and other mechanisms that promote competition, in particular on publicly performed research.** Non-exclusive licensing, for example, is the primary option used by the US NIH (see the interview with experts from the NIH in section 6.2) when licensing its own patents resulting from its intramural research programme; or CEPI when it funds programmes dedicated to its own mission.[43] The European Union has issued an amendment to its state aid rules which allows EU member states to support companies' COVID-19 R&D if the beneficiaries commit to grant non-exclusive licences.[44] Other policy tools that promote competition include the granting of

[38] See https://cordis.europa.eu/programme/id/H2020_SC1-BHC-15-2018.

[39] The Indian National Biopharma Mission is an industry-academia collaborative missions for accelerating discovery research to early development for biopharmaceuticals. See https://birac.nic.in/nationalbiopharmamission.php.

[40] See https://birac.nic.in/webcontent/National_Biopharma_Mission_Document.pdf.

[41] See https://dndi.org/press-releases/2021/first-hepatitis-c-treatment-developed-through-south-south-cooperation-registered-in-malaysia/.

[42] See CEPI Policy Documentation, 2017. See https://msfaccess.org/sites/default/files/2018-09/CEPIoriginalPolicy_2017.pdf.

[43] "In cases where CEPI provides funding of a dedicated programme, as described under the shared benefits/shared risks policy, CEPI will seek a non-exclusive, sub-licensable, worldwide license on necessary background IP and foreground IP related to priority pathogens", CEPI Policy Documentation, 2017 https://msfaccess.org/sites/default/files/2018-09/CEPIoriginalPolicy_2017.pdf.

[44] See https://ec.europa.eu/commission/presscorner/detail/en/IP_20_570.

licences for specific purposes or fields of use as opposed to a general right for all fields and uses (see the interview with the NIH). However, it is important to note that while promoting competition may have a positive impact on affordability at the domestic level, and by extension at the global level, this may not coincide with the affordability standards of some developing countries.

> *TOSSD reporting instructions: "c) In the case of official support for experimental development, the activity is eligible provided that it meets one of the following conditions:*
>
> - *The results of the R&D activity are expected to be put in the public domain, for example through applied public research…"* (International TOSSD Task Force, 2021, pp. 35-36[10])

The placement of medical inventions in the public domain can be another way to promote the affordability of health technologies. In general, newly invented health technologies are likely to get patented regardless of whether they are developed by the public or private sectors (OECD, 2020[8]) (see the interview with experts from the NIH). However, the current discussions at the WTO for COVID-19 intellectual property waiver may indicate a shift in international IP policies, particularly regarding health technologies that address global public emergencies.[45] In addition, the current international IP regime allows countries to apply certain IP exclusions and exceptions. For example, while medical devices and products are generally patentable, medical treatment procedures and methods (e.g. surgery, therapy or diagnostic methods) are often not patentable.[46] This means that applied and implementation research on medical methods will generally be placed in the public domain and accessible worldwide.

In addition to the above mechanisms, the experts emphasised that technology transfers to developing countries and voluntary market mechanisms for intellectual property sharing are effective for promoting global and affordable access to medical innovations.

- **Transfers of government-owned technology to developing countries can be very effective in supporting local access to health products.** For example, NIH experts told us that they have developed strategies to license and transfer NIH technologies to institutions in developing countries to meet local and regional needs and support developing countries' access to these technologies (Salicrup, Harris and Rohrbaugh, 2005[38]). Although this is not done in a systematic manner, there are numerous examples of NIH technology transfers to developing countries, including Argentina, Brazil, Chile, China, Egypt, India, Indonesia, Korea, Mexico, South Africa and other Sub-Saharan African countries, for diseases such as HIV/AIDS, tuberculosis, malaria or dengue.
- **Private voluntary mechanisms such as voluntary licences or open innovation models can also promote access to health innovations in developing countries.** Access policies can be applied by the R&D performer rather than the R&D funder. Voluntary licences have proven to be effective in reducing the cost of many treatments (High-Level Panel on Access to Medicines, 2016[28]), as illustrated by HIV drugs, which have become much more accessible in developing countries in the 2000s thanks to technology transfers to Indian manufacturers, which significantly reduced the cost of the treatments.[47] More recently, several of the principal COVID-19 vaccine developers have set up voluntary licensing agreements with other manufacturers and competitors (OECD, 2021[33]), both in advanced countries (e.g. Johnson & Johnson to Merck, or Pfizer/BioNTech to Sanofi and Novartis) and developing countries (e.g. AstraZeneca to the Serum Institute of India). Seeking multiple manufacturers located in

[45] See https://www.sciencedirect.com/science/article/pii/S014067362101151X?via%3Dihub.

[46] This is the case for example in the European Patent Convention. See https://www.epo.org/law-practice/legal-texts/html/epc/2020/e/ar53.html.

[47] See https://foreignpolicy.com/2021/05/07/stopping-drug-patents-pandemics-coronavirus-hiv-aids/.

different regions is also one of the approaches followed by CEPI to promote equitable access[48]. In addition to voluntary licensing, some companies, such as AstraZeneca, have declared that they will sell their vaccine at cost during the pandemic period, and Moderna pledged to not enforce its COVID-19 related patents against "those making vaccines intended to combat the pandemic."[49] Philanthropic patent pools, such as the Medicine Patent Pool (MPP), have also been effective in promoting affordable access through the facilitation of licence agreements between patent holders and generic manufacturers.

The COVID-19 R&D illustrate well the relevance of the TOSSD criteria on access to health technologies. Our indicative assessment of the considerable public funding provided to support COVID-19 R&D indicates that **most of this funding should be eligible under current TOSSD eligibility rules as** (i) most R&D funders requested open access to COVID-19 related scientific publications and data; and (ii) there are many cases where R&D funding was associated or followed by conditions or actions that aim to promote access to COVID-19 technologies in developing countries (see Table 4.3). It is important to note that current TOSSD R&D instructions promote access to health innovations in developing countries but do not require equal access, i.e. equal distribution of the technologies across the world.

Table 4.3. Examination of the eligibility of COVID-19 R&D against the current TOSSD criteria

TOSSD R&D criteria	COVID-19 R&D compliance
a) The research is "SDG-related" and "potentially applicable" to at least one developing country.	Yes – COVID-19 R&D contributes to the SDGs, for example 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." It is also applicable to developing countries.
b) In the case of scientific publications and research data, the funder institution's public access policy is based on the principle of open access.	Yes – Most R&D funders have requested open access to COVID-19 scientific publications and data. Examples include the UK's Recovery trial[1] and the French-European Discovery.[2]
c) In the case of official support for experimental development, the results of the R&D are expected to be put in the public domain or the affordability of the resulting technology is promoted, for example through pricing-based schemes or the promotion of competition (e.g. through non-exclusive licences).	Yes – This criterion has been met in the following cases: • Providers that have contributed to the COVID-19 Tools (ACT) Accelerator, which is aimed at providing global and equitable access to COVID-19 technologies, may consider all their investments in the technologies (diagnostics, therapeutics and vaccines) in which ACT-A has invested as eligible. For example, the vaccine portfolio of CEPI, through which the ACT-A vaccine pillar is operated, includes 14 vaccine development initiatives.[3] • EU countries may consider their COVID-19 product development investments as eligible given that the European Union has issued an amendment to its state aid rules which allows EU member states to support companies' COVID-19 R&D if the beneficiaries commit to grant non-exclusive licences. • Several vaccine developers (e.g. Oxford-AstraZeneca) have pledged to sell COVID-19 vaccines at "no-profit, no-loss" pricing to promote access in developing countries.[4] • Other companies (e.g. Moderna)[5] have declared that they will not enforce any IP infringement on COVID-19 related patents. In addition, the proposal currently discussed at the WTO on a possible waiver of COVID-19 IP may result in the placement of COVID-19 technologies in the global public domain.

48 See https://cepi.net/wp-content/uploads/2020/12/Enabling-equitable-access-to-COVID19-vaccines-v4-18Mar2021.pdf.

49 https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19.

In addition, cases where R&D is followed by an activity that promotes access to a product in developing countries, both the promotion activity and the original R&D activity are eligible.	Yes – This criterion has been met in the following cases:[6] • Countries that have contributed to the COVID-19 Tools (ACT) Accelerator, which is aimed at providing access to developing countries, can in principle report all their funding for the development of COVID-19 diagnostics, therapeutics and vaccines. • Countries that have donated or subsidised the purchase of vaccines for developing countries can in principle report all their funding for the development of COVID-19 vaccines. E.g. G7 countries just committed 1 billon vaccine doses to be delivered in 2021 and 2022.

Note: [1]https://www.recoverytrial.net/; [2]https://presse.inserm.fr/en/published-now-in-the-new-england-journal-of-medicine-the-initial-results-of-the-solidarity-discovery-clinical-trial/41642/; [3]See https://cepi.net/research_dev/our-portfolio/; [4]See https://cepi.net/wp-content/uploads/2020/12/Enabling-equitable-access-to-COVID19-vaccines-v4-18Mar2021.pdf; [5]See https://investors.modernatx.com/news-releases/news-release-details/statement-moderna-intellectual-property-matters-during-covid-19; [6] Should the current initiative discussed at the WTO on a COVID-19 IP waiver go through, this would be another example of a situation where "R&D is followed by an activity that promotes access to a product in developing countries".
Source: Authors' assessment.

While affordability is important, it is only one dimension of access to health technologies

Affordability is only one dimension of access to health technologies in developing countries; appropriateness and availability are also essential and should be tracked (see the interview with experts from the Wellcome Trust and WHO). Before being affordable, health technologies need to be made available in developing countries and appropriate for these markets. To be available, health products need to be registered in developing countries' markets. To be appropriate, they need to have characteristics, or target product profiles (TPP),[50] that are suitable to developing countries' markets (e.g. storage conditions, route of administration). For example, when CEPI provides funding for product development, it defines TPPs that are suitable for developing countries' markets in collaboration with WHO.[51]

R&D co-operation with developing countries is not uncommon, for example through the implementation of clinical trials, and can help ensure that the health technology is appropriate. Although not part of the R&D specific criteria, co-operation with developing countries is part of the general TOSSD Pillar II eligibility criteria.[52] The 2020 TOSSD data collection demonstrated that this criterion would be relatively easy to meet. For example, out of a total of EUR 1 billion reported by the EU in health research, the TOSSD Secretariat could identify at least EUR 262 million corresponding to projects where there is a partner from developing countries. Partnering with developing countries in the development of health products can help ensure that these are suitable. For example a malaria vaccine candidate, developed by a research team from the United Kingdom, Burkina Faso and the United States, is currently being tested in Burkina Faso with funding from the European & Developing Countries Clinical Trials Partnership (EDCTP) (Datoo et al., 2021[39]). This will ensure that the vaccine is suitable for patients in Burkina Faso and other similar countries.

[50] According to WHO's definition, a target product profile (TPP) outlines the desired "profile" or characteristics of a target product that is aimed at a particular disease or diseases. TPPs state intended use, target populations and other desired attributes of products, including safety and efficacy-related characteristics. In the context of public health, TPPs set R&D targets for funders and developers. See https://www.who.int/observatories/global-observatory-on-health-research-and-development/analyses-and-syntheses/target-product-profile/who-target-product-profiles.

[51] See https://msfaccess.org/sites/default/files/2018-09/CEPIoriginalPolicy_2017.pdf

[52] The general TOSSD Pillar II criteria require that eligible activities provide "substantial benefits" to developing countries or be implemented "in co-operation with TOSSD-eligible countries" (See Box 4.1. TOSSD Pillar II - contributions to international public goods: definitions and parameters).

However, conditioning the R&D funding counted in Pillar II to funders' policies on access to health technologies may be too restrictive

Most of the experts interviewed considered that conditioning the eligibility of R&D counted in Pillar II to funders' policies on access to health technologies would be too restrictive for several reasons: in general, domestic R&D funding institutions do not condition their support to the accessibility or affordability of health technologies either because this is not always relevant and feasible, or because they do not have the mandate to do so; broad and affordable access to health technologies can be achieved or promoted through other means than funders' R&D policies; even if not immediately available for everyone, health technologies will still be accessible to many and will eventually become global public goods; while encouraging broad access to medicines and health innovations, it is important that TOSSD keeps incentives for more investments to develop the technologies crucially needed to address global health challenges and achieve the SDGs.

> **In general, domestic R&D funding institutions do not condition their support to the accessibility or affordability of health technologies either because this is not always relevant and feasible, or because they do not have the mandate to do so.**

Tying public funding for R&D to conditions on accessibility and affordability is not always relevant or feasible because of the nature of the current R&D funding model and the uncertainty inherent in research (see the interviews with experts from the NIH, the IGI and Ohid Yaqub in Chapter 6). In the current R&D funding model, public funding is in general more focussed on early-stage basic and applied research, while the translation of laboratory inventions to approved medicines that people can use is more funded by private enterprises. Early stage research cannot be linked to access and affordability yet because the outcome is still unknown, and even when inventions are made, much of the risk and cost in translating these inventions into health products is borne by the private sector developer. For example, the average duration of product development for medicines that reach marketing approval is 10 to 15 years and the probability for a drug in phase I of clinical trials to be approved ranges from 7% to 45% (OECD, 2018[4]). Requesting conditions on access makes more sense when funding is provided for the later stage product development. In order to be able to impose conditions on access and affordability, governments should be more open to funding the translation and product development part of R&D (see the interview with IGI) (OECD, 2020[8]).

Nevertheless, a significant part of R&D public funding goes to translational research and product development. While examples of such funding aimed at promoting access to health innovations in developing countries exist, these are exceptions as domestic R&D funders generally do not have the mandate to promote affordability or accessibility (see the interviews with the NIH and IGI). R&D funding for products primarily focused on developing countries is, in principle, captured in ODA. The first TOSSD data collection also showed that beyond ODA, examples of R&D not primarily focussed on developing countries, but still promoting access and affordability for their populations, also exist. For example, the EU-funded ELEVATE project aims to develop low-cost portable and point-of-care human papillomavirus (HPV) testing that is accessible to populations in Europe and Latin America[53]. However, these examples are exceptions and, in general domestic R&D agencies are not focussed on affordability, or only indirectly through competition as explained above. This is because they don't have the mandate to promote affordability (see the interview with the NIH), with R&D policies and incentives rather focussed on the need to commercialise inventions through partnerships with the private sector. It should also be noted that a large part of R&D funding is unsolicited, meaning that the researcher has submitted the research proposal themselves with no specific targets established by the funder (see the interview with the NIH).

[53] See https://cordis.europa.eu/project/id/825747.

However, as noted above there may be indications of a better consideration of global access in future R&D and IP policies.

R&D funding initiatives clearly focussed on affordability and access in developing countries are mainly undertaken at the international level through international product development partnerships (see Box 4.4). One expert interviewed, Olivier Weil, suggested that if equitable access is a strict eligibility criterion, then it could be linked to these initiatives.

Therefore, strict eligibility rules on affordability and accessibility of health technologies would capture a relatively small share of global R&D funding, which is primarily provided at the domestic level.

Box 4.4. International research partnerships

A number of international health partnerships have been established to address global health challenges.

Philanthropic product development partnerships (PDPs) have been created to support product development for a number of diseases, often neglected and poverty-related diseases that cannot be addressed through market mechanisms. PDPs generally have a very clear focus on making the products available at affordable cost in countries most in need. Examples of these arrangements include the Global Alliance for Vaccine Initiative (Gavi), whose mission is to provide "equitable and sustainable" access to vaccines in developing countries; the Coalition for Epidemic Preparedness Innovations (CEPI), which aims to support the "development of vaccines against emerging infectious diseases and enable equitable access to these vaccines for people during outbreaks"; the Malaria Vaccine Initiative (MVI) developed by PATH, an international non-profit organisation that works "to accelerate health equity"; the International AIDS Vaccine Initiative (IAVI), whose mission is to "translate scientific discoveries into affordable, globally accessible public health solutions"; FIND, a global alliance for diagnostics that seeks to "ensure equitable access to reliable diagnosis around the world"; and the European & Developing Countries Clinical Trials Partnership (EDCTP), a public-public partnership between countries in Europe and sub-Saharan Africa aimed at accelerating "the clinical development of new or improved medicinal products for the identification, treatment and prevention of poverty-related infectious diseases, including (re-)emerging diseases."

Networks of research funding agencies are another type of international R&D partnership. They include the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R) or the Global Alliance for Chronic Diseases (GACD), one of the few partnerships focussed on non-communicable diseases.

International collaboration initiatives also exist in basic science, for example the Human Frontier Science Program (HFSP), which promotes "international collaboration in basic research focused on the elucidation of the sophisticated and complex mechanisms of living organisms".

Broad and affordable access to health technologies can be achieved or promoted through means other than funders' R&D policies

The experts interviewed emphasised that there is no one-size-fits-all in how governments look at the issue of access to health technologies, and that regulations and policies can differ noticeably across the board (see the interviews with experts from the WHO and Ohid Yaqub). Making the eligibility of R&D funding in Pillar II conditional on funders' access policies would be too restrictive as the affordability and accessibility of health technologies can be supported or achieved through other means, such as:

- **Production factors and market dynamics** – including production process innovation, productivity gains, economies of scale and the removal of uncertainty around returns to investment[54] – are key drivers of cost reduction for health technologies. For example, some medicines, such as those based on chemical synthesis, are known to be relatively cheap to produce even if there are no conditions on affordability and access, compared to biopharmaceuticals such as vaccines. In addition, DNA vaccines are cheaper to manufacture than mRNA vaccines (OECD, 2020[40]).
- International trade and the use of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities:
    - As shown by the COVID-19 crisis, **export restrictions** by drug producing countries can constitute important barriers to accessing health technologies in developing countries, regardless of affordability.
    - In order to promote affordable access to health technologies for their populations, all WTO countries can use the **"flexibilities" included in the TRIPS agreement**, including the use of compulsory licencing, parallel import, government use licensing, the application of strict patentability criteria, and for least-developed countries (LDCs) the possibility of not granting patents.[55] The use of these flexibilities has been key, for example, in the supply of lower-priced generic HIV treatments, particularly in developing countries ('t Hoen et al., 2018[41]; Delalande et al., 2020[42]). Compulsory licences can be issued either to supply the domestic market or to export medicines to countries with insufficient pharmaceutical manufacturing capacities. To our knowledge, the latter approach has been used only once, in 2007 by Canada to export antiretroviral drugs to Rwanda (Ooms and Hanefeld, 2019[43]). However, it is very important to note that while in principle the TRIPS flexibilities can be used by countries, in practice their widespread application is often threatened by pressures exerted by patent-holding countries and the so-called "TRIPS-plus obligations" included in many trade agreements that make it very difficult for developing countries to use these flexibilities[56] (Wirtz et al., 2017[30]; High-Level Panel on Access to Medicines, 2016[28])
- **Domestic regulation of pharmaceutical prices** either directly or indirectly through the determination of treatments covered by the insurance system. For example, most OECD countries, including Turkey which is a developing country, regulate pharmaceutical prices (OECD, 2018[34]). In 1997, India established the National Pharmaceutical Pricing Authority (NPPA) with the mission "to ensure availability and accessibility of medicines at affordable prices."[57]
- **Procurement interventions**, for example through the use of pooled procurements and competitive bidding (Wirtz et al., 2017[30]).[58]

[54] See for example an explanation from Gavi on the Economics of Vaccine Production https://www.who.int/immunization/programmes_systems/financing/analyses/en/briefcase_vacproduction.pdf?ua=1

[55] The TRIPS agreement exempts least-developed countries (LDCs) from implementing patent protection for pharmaceutical products and from protecting clinical trial data.

[56] The "TRIPS plus" provisions often include IP protection rules that exceed the minimum standards required by the TRIPS Agreements, allowing, for example, a patent duration that exceeds the standard 20 years.

[57] See https://www.nppaindia.nic.in/en/about-us/about-national-pharmaceutical-pricing-authority/.

[58] See for example Panel 4 "A comprehensive suite of essential medicines policies to reduce prices" from the Lancet Commissions' study on "Essential medicines for universal health coverage" (Wirtz et al., 2017[30]).

Even if not immediately available for everyone, health technologies will still be accessible to many, and will eventually become global public goods

Strict conditions on intellectual property or affordability will exclude many technologies that still contribute to global health and the achievement of the SDGs. Even if the health technology is patented and may not be immediately affordable for the entirety of the world population, it still benefits many patients in developing countries through trade. In addition, IP protection is limited in time and all inventions will eventually be placed in the public domain and become available (see interview with experts from WHO). For example, many of the medicines considered essential by the WHO are in the global public domain.[59] In addition, as emphasised above, during the lifetime of the patent, the current TRIPS regime includes flexibilities that allow countries to bypass the obligation to grant IP protection, including through compulsory licences or exemption from the obligation to provide patents for LDCs, which can in principle produce the patented drug without the consent of the patent holder. For example, Bangladesh has recently benefited from this exemption and allowed local manufacturers to produce a generic version of remdesivir to treat COVID-19, which is still patented by Gilead Sciences in many other countries (WTO, 2020[44]). However, very few LDCs have drug manufacturing capacity and those that have can only produce certain drugs. In addition, as noted above the TRIPS flexibilities are often undermined by the so-called "TRIPS-plus provisions" included in trade agreements.

While encouraging broad access to health technologies, TOSSD should encourage more investments to develop the technologies crucially needed to address global health challenges and achieve the SDGs

- As noted above, strict eligibility rules on the accessibility of health technologies would capture a very small share of global R&D funding. **The experts interviewed emphasised that TOSSD should encourage more R&D spending on multiple health challenges rather than introduce a restrictive counting approach** (see the interviews with experts from WHO, the CGD and Ohid Yaqub). They emphasised that TOSSD should provide the right incentives to develop the technologies needed to achieve the SDGs. TOSSD should encourage more R&D spending on "neglected topics, on those with uncertainty surrounding paybacks but potential game-changers or 'disruptors', on expansion of knowledge with broad ramifications beyond a single health (in our case) challenge, and more generally the patient and sustained application of science, information and technological ingenuity toward solving large development challenges" (Rogerson and Blampied, 2018[20]).

Tracking R&D funders' policies on access to health technologies may also be difficult to operationalise at this stage

A number of experts highlighted the practical challenges involved in operationalising the principle of access to health technologies:

- Some of the categories included in the TOSSD R&D instructions ("product-oriented", "non-exclusive licences", etc.) are not tracked in funders' internal systems.
- Publicly-available information and data on research grants exist, including basic project information (research organisation, project description, etc.) and the funding schemes and calls where funders specify certain policy objectives or targets. However, these data may be too brief to adequately and reliably classify the R&D according to the TOSSD criteria (see the interview with Ohid Yaqub). The TOSSD data collection also showed that manually screening the R&D projects only on the basis of this publicly-available partial data is very resource

[59] https://www.wto.org/english/tratop_e/trips_e/wto_background_e.pdf

intensive and will likely involve a low cost-benefit ratio. For example, out of EUR 1 billion reported by the EU in health research, the secretariat could flag EUR 90 million as focussed on accessibility and affordability. It would be difficult for the Secretariat to carry out this work for all providers.

- Additional information available to funders internally, for example on R&D proposals and contracts or funders' policy documents, may help in screening the projects. However, these are often confidential, meaning that only the reporters themselves would be able to carry out the screening. This raises the issue of whether sufficient resources are at their disposal. Ideally, in the longer term, information and data on access policies could be integrated in grant and contract documentation, for example in the form of questions and checkboxes to be completed by the grantee, so that it can be easily extractable from funders' internal information systems.
- Many access policies (e.g. technology transfers, differential prices, etc.) take place only after R&D funding was made available and products were developed. While the TOSSD reporting instructions address specifically this case and allow the retroactive reporting of R&D funding that has been followed by actions promoting access to innovations (see Box 4.2), in practice this can be challenging to do for reporters, particularly if the funding date is distant in time.

4.3.5. Clear national mandates and more operational reporting guidelines are needed to ensure the capacity of providers to report activity-level data on health R&D funding, in co-operation with the institutions responsible for international R&D statistics

Total public funding for health R&D is well measured, but not with the level of granularity sought in TOSSD. Public R&D funding is tracked in government budget allocations for R&D (GBARD) and gross domestic expenditure on R&D (GERD) statistics produced by the OECD and the UNESCO Institute for Statistics (see Box 4.5). While these statistics can be broken down by socioeconomic objective, including on health, they are in principle too aggregated for the purposes of TOSSD, which is based on activity-level data. This aggregate measurement would not allow, for example, the screening of R&D projects against the principle of access to health technologies, or tracking important sub-categories in health R&D, such as communicable diseases, non-communicable diseases or anti-microbial resistance. Therefore, while GBARD or GERD data could potentially be used provisionally as proxy data, depending on the eligibility choices of the International TOSSD Task Force (see options proposed below), **activity-level reporting, where possible, should ultimately be aimed at for TOSSD data to be useful.** For many R&D funders, in particular in health, project-level data on R&D funding are available with information on most of the TOSSD key fields, particularly for research grants (Bejraoui et al., 2020[45]). In order to align TOSSD with the internationally agreed statistical standards on R&D, but also to avoid any duplication of efforts, **it will be important that the TOSSD reporting on R&D is done in co-operation with the relevant institutions in charge of international R&D statistics.**

Box 4.5. International statistics on the public financing of R&D

The primary international bodies with responsibility for measuring R&D funding are the OECD, in particular the Science, Technology and Innovation (STI) Directorate, and the UNESCO's Institute for Statistics.

The main indicators are GERD, produced by both the OECD and UNESCO, and GBARD, produced by the OECD. GERD statistics measure total R&D expenditure within a country, including R&D funded from abroad, but excluding domestic funds for R&D performed outside the domestic economy.[1] Expenditure can be broken down across a number of variables, including the source of funds (e.g. the government sector), type of R&D (e.g. basic research, applied research and experimental development) and socio-economic objective (e.g. health). GBARD statistics measure total direct government support for R&D using data from government budgets. They cover all types of R&D and can be broken down only by socioeconomic objective, including health.

Note: [1] See https://data.oecd.org/rd/gross-domestic-spending-on-r-d.htm

The most important challenge faced by TOSSD reporters is the mandate for collecting data. While the primary TOSSD reporters are located in development agencies and institutions, most of the data related to R&D funding sit within other government entities, in particular R&D funding agencies and health ministries. The first TOSSD data collection in 2020 showed that the biggest challenge faced by TOSSD reporters is related to the mandate for collecting data from these other government entities, which are not necessarily involved in SDG reporting. A whole-of-government reporting mandate is all the more important that, as noted above, the screening of TOSSD R&D activities against the principle of access to health technologies can only be made by the R&D funders themselves. Recent developments, in particular through discussions in the G20 and other global fora, underscore how TOSSD can help serve as a tool for monitoring and measuring financing for global public goods, including pandemic preparedness. Such discussions can facilitate domestic engagement and the cross-governmental mainstreaming of TOSSD.

In order to be applicable to R&D funders, the TOSSD criteria will need to be more practical and the coverage of what is reportable clearer. Interviews with research funders and experts in the tracking of R&D funding highlighted the need to have more practical guidelines that would make reporting more feasible and easier for the reporting entities. The current criteria were viewed as too high-level and leaving too much room for interpretation. This is particularly the case for the criterion on "SDG-related and potentially applicable to…at least one TOSSD-eligible country". As explained in section 4.3.2, in order to facilitate reporting it may be easier to consider that this criterion is met by default for health R&D, leaving, however, the possibility for reporters to exclude any activity that they would not consider as aligned with it. Some experts also suggested that TOSSD reporting could be further facilitated by adopting some operational reporting practices, using for example an institutional approach to distinguish between R&D oriented towards knowledge and R&D oriented towards product development[60] (see the interview with Ohid Yaqub).

[60] Research carried out by universities could be considered as oriented towards the generation of knowledge, and R&D carried out by private enterprises could be considered as oriented towards the development of new products.

4.3.6. Options and recommendations for tracking R&D funding in Pillar II

R&D funders' promotion of access to health technologies could be tracked through a policy flag rather than an eligibility condition

Access to health innovations is a key enabler of "ensuring healthy lives for all" and an essential element of today's global public health policy. At the same time, access policies should not be made a strict eligibility criterion for the conceptual and practical reasons mentioned in section 4.3.4. Therefore**, one option that could be considered is to track policies for access to health technologies through a voluntary (at least in the short term) policy flag**, for example in the "key words" field. As explained above, screening manually relevant R&D projects against access policies is resource-intensive, and implementation would take time. Therefore, TOSSD should aim at progressive implementation by reporters. Ideally, in the medium term TOSSD reporting countries should aim to track access policies through tick boxes in R&D funders' grant systems or in R&D contract negotiations. Incentives may need to be put in place to encourage the completeness of reporting. A strong commitment from donors to report on access may also be needed.

Table 4.4. Proposed policy flag on access to health technologies

Relevant dimensions to promote access	Questions	Guidance
Availability	Have steps been taken to ensure that funded developments reach the markets most in need, in particular in developing countries?	• Will the products be registered in countries that need them, not just available for the travellers' market? • Will the innovation be licensed to companies in developing countries or placed in the global public domain?
Affordability	Have steps been taken to ensure that funded developments are affordable?	Affordability is promoted either directly or indirectly through pricing or IP strategies: • Examples of pricing strategies include agreements on affordable pricing, differential pricing or funding schemes aimed at delinking the price of medicines and the R&D costs (e.g. advanced market commitments) or *ex post* subsidisation of treatments in developing countries. • Examples of IP strategies include voluntary licences, technology transfers, licensing strategies such as non-exclusive licensing that promote competition, placement of innovations in the public domain.
Appropriateness	Is the R&D considering how to ensure that the funded development is suitable for the markets of developing countries?	• Are developing countries involved in the R&D process to ensure that resulting technology is appropriate for them? • Does the innovation require cold-chain storage, how many doses, how is it administered, etc.? The characteristics of innovations can generally be shaped through target product profiles.

Note: Draws on the principles proposed by the experts from Wellcome Trust.

In order to further operationalise the tracking of policies on access to health innovations, some options could be considered:

- "Access to health technologies" could be flagged by default on all funding provided to research performers known to have clear "equitable access" policies. For example, many not-for-profits and universities, but also some companies,[61] have these policies in place.[62] The identification of these R&D performers at the national level could be undertaken through regular surveys, for example.
- "Access to health technologies" could be flagged for all calls for proposals and funding schemes that have a focus on access policies.[63]
- "Access to health technologies" could also be flagged by default for funding to R&D in areas that are considered as non-patentable by countries (see section 4.3.4).
- Ideally in the medium term, questions on access to health technologies should be integrated into research proposals and R&D contracts, and tracked in funders' information systems in a way that is easily extractable.

R&D eligibility options that could be considered depending on the objective set for TOSSD Pillar II

Table 4.5 presents some options that the Task Force could consider for refining the scope of R&D funding in Pillar II. To illustrate the order of magnitude of R&D funding potentially captured in each these options, an estimation is provided using the United States and European Union as examples. To be comparable with historical and future levels of R&D we analyse 2019 data before the substantial COVID-19 R&D investments were made.

[61] For example, the Serum Institute in India has a clear focus on "the global need for cost-effective vaccines" (https://www.seruminstitute.com/research_devlopment.php).

[62] For example, the goal of the Genethon is to bring to patients innovative gene therapies "at a controlled and fair price" (https://www.genethon.com/our-commitment/access-to-treatments/); the Max Planck Institute of Psychiatry is "committed to the common good and not profit-oriented" (https://www.psych.mpg.de/2100059/the_clinic).

[63] For example the EU funding tender "New anti-infective agents for prevention and/or treatment of neglected infectious diseases (NID)" https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/sc1-bhc-15-2018.

Table 4.5. Options for counting official R&D funding in Pillar II

	Option 1: Health R&D funding "provided to promote the sustainable development of developing countries"	Option 2: R&D funding provided to promote global sustainable development, excluding "pure" basic research.	Option 3: R&D provided to promote global sustainable development
What is eligible?	• R&D funding for neglected diseases that affect primarily developing countries (malaria, tuberculosis, etc.) beyond what is captured in ODA.[1] • Contributions to international product development partnerships (PDPs) that are in co-operation with developing countries and are primarily focussed on equitable access in developing countries (e.g. ACT-A). • Any other R&D investment where access to health technologies in developing countries is a clear and important objective.	• Product development for all health technologies. • All applied health research. • Purpose-oriented basic health and biological research.	• Almost all health R&D is eligible. Reporters would still have the possibility to exclude activities they would consider as purely domestic.
Use of a policy flag on access to health technologies	• The policy flag could be used; however, the above coverage can already be considered as clearly focussed on the benefits to developing countries.	• Use the policy flag based on the three dimensions identified within access to health technologies.	• Use the policy flag based on the three dimensions identified within access to health technologies.
Applicability of the eligibility criteria and the flag on access to health technologies	Easy: • R&D funding for neglected diseases is already tracked in the G-FINDER survey, and data on contributions to international PDPs are easy to collect.	Difficult: • "Product development" and "Purpose-oriented basic research" are not categories that are readily available in current R&D funding data. The application of the eligibility criteria would need to be very practical and operational guidelines that could be developed with the support of a consultative group of health experts. • Incentives and mandate to apply the flag on access to health technologies would be needed.	Easy: • In terms of eligibility the data collection would be easy given that it would cover almost all R&D. • Incentives and mandate to apply the flag on access to health technologies would be needed.
Data sources	• G-FINDER ND survey. • Reporting by providers of their contributions to international PDPs or any other funding clearly focussed on developing countries.	• Reported by countries using publicly-available project datasets. • Reporting on government intramural research may need to be done on an institutional basis depending on the budgetary structure of the government research entities.	• Reported by countries using publicly-available project datasets. • Reporting on government intramural research may need to be done on an institutional basis depending on the budgetary structure of the government research entities.
Estimation of R&D funding covered using the US and EU as an example	• USD 2 billion[2]	• USD 20 billion[3]	• USD 38 billion[4]

Note: [1] Much of the global investments in R&D for neglected diseases are not captured in ODA either because they do not have the economic development and welfare of developing countries as their main objective, or because they are funded by providers that do not report on ODA.

[2] The estimate is based on data extracted from the G-FINDER survey on neglected diseases (NDs), which includes contributions to international PDPs, many of which are focussed on NDs. However, it might not reflect all contributions to PDPs that aim at "equitable access" in developing countries, for example to CEPI which is not focussed on NDs. Based on the TOSSD and CRS databases, neither the EU nor the US provided funding to CEPI in 2019; a total of USD 66 million was provided by Germany, Japan and the United Kingdom, and USD 20 million was provided by the Bill & Melinda Gates Foundation.
[3] The figure is rough estimate of funding for product development and applied research, including USD 18 billion for the NIH, USD 1.270 billion for BARDA and USD 502 million for the EU commission. Basic research was generally excluded because it is not possible to identify "pure" basic research. To identify basic and applied research in the NIH data, we have used the agency's aggregate estimation shares (https://officeofbudget.od.nih.gov/pdfs/FY21/spending-hist/Basic and Applied FY 2003 - FY 2020 (V).pdf). BARDA's funding is focussed on product development. To identify the European Commission's funding for product development we have manually classified the EU's 2019 TOSSD data submission.
[4] Includes all R&D funded or performed by the NIH, all product development funded by BARDA, and all health R&D submitted by the EU in the 2019 TOSSD data collection.
Source: NIH (n.d.[46]), *ExPORTER*, https://exporter.nih.gov/; ASPR (2019[47]), *Fiscal Year 2019 Budget-in-Brief: Public Health and Social Services Emergency Fund*, https://www.phe.gov/about/aspr/Documents/BIB-2019.pdf; Policy Cures Research (n.d.[48]), *G-FINDER: tracking funding for global health R&D*, https://gfinderdata.policycuresresearch.org/; data submitted by the EU in the first TOSSD data collection.

Option 1 would measure R&D funding that can be presented as "promoting sustainable development in developing countries". It would include R&D on diseases that disproportionately affect developing countries and international product development partnerships clearly focussed on equitable access in developing countries (e.g. CEPI). While part of the funding captured in option 1 is already tracked in ODA – out of the USD 2 billion estimated for the European Union and United States from the G-FIINDER database, USD 63 million is provided by aid agencies – a very large part would still be additional to ODA. Indeed, although focussing on diseases that disproportionately affect developing countries, much of the R&D funding captured in the G-FINDER neglected diseases survey is not included in ODA because its primary objective is not the economic development and welfare of developing countries. Option 2 would measure R&D funding provided to promote global sustainable development, focussing on application-specific R&D, i.e. excluding "pure" basic research. This option would be difficult to implement, as it is not easy to distinguish between pure basic research and application-specific basic research. Option 3 would measure R&D funding provided to promote global sustainable development and would cover almost all health R&D. It would have the following advantages:

- Easy to implement in terms of scope of funding collected.
- Truly measures total official support for the SDGs.
- Provides incentives to invest in needed technologies through the very broad coverage of product development activities.
- Provides incentives for promoting access to health technologies in developing countries as the policy flag can be used to assess providers' efforts in this regard. However, incentives need to be put in place to encourage the completeness of this reporting.
- Would allow an understanding of how much total R&D funding is associated with policies on access to health technologies.
- Given that potentially all health R&D funding would be captured, this option would also allow the retroactive application of a flag in cases where the access action takes place only after the R&D funding is provided and reported.

Recommendations

In view of the above findings on the tracking of R&D funding in Pillar II, the International TOSSD Task Force could:

- Consider tracking the principle of access to health technologies through a policy flag rather than presenting it as a strict eligibility condition.
- Clarify the objective of Pillar II and revise the scope of R&D captured accordingly, preferably towards a global public goods and global sustainable development approach.

4.4. Tracking other global and domestic health expenditure as a contribution to international public goods

4.4.1. What is the issue?

In defining the scope of health-related activities in TOSSD Pillar II, the TOSSD Task Force has so far discussed only the treatment of health R&D. This section investigates the other domestic and global activities providing positive transboundary spill-overs that are sufficiently valuable to the international community to be considered as contributing to IPGs and included in TOSSD Pillar II. This is particularly relevant in light of the emerging data needs of the international community, following the COVID-19 crisis. We start first by addressing the global health functions before addressing domestic expenditure.

4.4.2. Tracking the financing of international health co-operation and co-ordination

There was a large consensus among the experts interviewed for allowing a very broad coverage of international health co-operation in Pillar II, although they emphasised again that this should be differentiated from support to developing countries (see for example the interviews with experts from WHO, the CGD, the AFD and with Olivier Weil).

The COVID-19 crisis illustrates more than ever that international co-operation is essential to ensure global health security. It also shows that national egoism, illustrated in vaccine nationalism, can be a significant barrier to global health security. Activities that help ensure health security at the international level should be encouraged in TOSSD. A number of initiatives have been recently proposed to remedy the shortcomings identified in the international health security system, including greater independence of WHO, the development of a new global health convention and the creation of a new health supervisory body (G20 High-Level Independent Panel, 2021[2]; Duff et al., 2021[49]). In addition, the experts interviewed emphasised the importance of supporting regional public health agencies, such as the Africa Centres for Disease Control and Prevention or the European Centre for Disease Prevention and Control, which play a key role in the international surveillance system.

International health co-operation can support the achievement of the SDGs through functions other than pandemic prevention or health security. For example, global functions for health are particularly needed to address the increasing burden of non-communicable diseases (Hatefi et al., 2018[50]), which represent nearly three-quarters of global deaths, and to address SDG target 3.3, which calls for reducing "by one-third premature mortality from non-communicable diseases through prevention and treatment…".[64] WHO's Department for the Prevention of NCDs plays an important role at the global level in contributing to this target. The experts interviewed from the WHO highlighted that they consider the entirety of the organisation's work as contributing to the 2030 Agenda. They also

[64] See https://www.un.org/sustainabledevelopment/health/.

referred to the classification of global functions for common goods for health developed by Schäferhoff et al. (2019[27]) and used as a reference by WHO (see Box 4.6).

Therefore, all activities that provide a framework for countries to co-operate on health matters should be encouraged and tracked in TOSSD. The current TOSSD reporting instructions do allow for such a broad coverage, as the main eligibility criteria for international co-operation counted in Pillar II are that it contributes to one of the SDGs and is implemented in co-operation with developing countries.

However, the interviewees also emphasised that these activities should be seen from their global nature and not as focussing on developing countries' benefits. It is important to recognise that global functions for Common Goods for Health benefit all countries, not developing countries in particular. In addition, the share of international organisations' work and expenditure that can be considered as benefiting particularly developing countries is already captured in ODA.

Box 4.6. Classification of global function for global common goods for health

Global Common Goods for Health (GCH) are defined by WHO as "population-based functions or interventions that require collective financing, either from the government or donors based on the following conditions:

- Contribute to health and economic progress;
- There is a clear economic rationale for interventions based on market failures, with focus on (i) Public Goods (Non-Rival, Non-Exclusionary) or (ii) large social externalities."

In a series of influential papers, a group of researchers have proposed a methodology for measuring the financing of global CGH. In the most recent paper, which was commissioned by the WHO, Schäferhoff et al. (2019[27]) have developed a classification of international funding for GCH that draws on the three global functions proposed by The Lancet Commission on Investing in Health (Jamison et al., 2013[51]), which have been further classified into a several sub-categories. "Global functions" are "characterized by their ability to address transnational issues" as opposed to "country-specific functions", which refer to "disease control activities that will benefit that country alone." Table 4.6 shows the classification now used by WHO as a reference for the financing of GCH.

Table 4.6. Classification of global functions for global common goods for health

Function	Sub-function
Global function: Provision of global public goods	Research and development for health tools
	Development and harmonisation of international health regulations
	Knowledge generation and sharing
	Intellectual property sharing
	Market-shaping activities
Global function: Management of negative regional and global cross-border externalities	Outbreak preparedness and response
	Responses to antimicrobial resistance (AMR)
	Responses to marketing of unhealthful products
	Control of cross-border disease movement
Global function: Fostering of global health leadership and stewardship	Health advocacy and priority setting (convening policy makers for negotiation and consensus building)
	Promotion of aid effectiveness and accountability

Source: Schäferhoff et al. (2019[27]), *International Funding for Global Common Goods for Health: An Analysis Using the Creditor Reporting System and G-FINDER Databases*, https://doi.org/10.1080/23288604.2019.1663646; Jamison et al. (2013[51]), *Global health 2035: A world converging within a generation*, https://www.doi.org/10.1016/s0140-6736(13)62105-4.

4.4.3. Tracking domestic financing for global health security

In 2018, domestic public spending on health – not counting health research – reached USD 4.9 trillion (WHO, 2020[52]). How much of this spending benefits other countries and can considered as contribution to global public goods?

TOSSD Pillar II could track domestic spending on health security as a contribution to global public goods

The COVID-19 pandemic has illustrated that global public goods such as health are only provided if every country contributes. This global public good nature can best be seen from the angle of health security or pandemic preparedness. The G20 summit underlines that investments in global health and health security are broader social and macroeconomic investments in global public goods.[65] However, COVID-19 has also confirmed that these global public goods were largely underfunded and that almost all countries were unprepared for global public health emergencies (G20 High-Level Independent Panel, 2021[2]).[66]

Most of the experts interviewed advocated for capturing domestic spending on pandemic preparedness and health security in TOSSD Pillar II. The G20 High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response calls on countries to "define and track budgetary expenditures on outbreak prevention and preparedness". National surveillance, diagnostic capacities as well as immunisation[67] were viewed as essential by many (WHO, CGD, etc.). Some interviewees also emphasised the essential role of pharmaceutical regulation agencies in protecting public health, including at the global level. Many countries rely on other countries' approvals, either through Mutual Recognition Agreements (MRA) or unilateral reliance. For example, 13 regulatory authorities in Latin America accept relying on marketing authorisations issued by the European Medicines Agency, the United States Food and Drug Administration, and Health Canada; Argentina, Australia, Brazil, Chile, Japan, Mexico, and Switzerland are also used as a reference by some Latin American and Caribbean (LAC) regulators (Durán et al., 2021[53]). Combating anti-microbial resistance was also mentioned as very important for global health security. In addition, the pandemic has demonstrated again the importance of the One Health approach, which integrates animal and human health, to better prevent and address pandemics.

However, the experts also emphasised that there might be definitional issues in some of these concepts – for example surveillance can also be classified as research by national public health agencies – and recommended referring to the international frameworks in place for addressing health security and communicable diseases.

At the global level, **health security is regulated by the International Health Regulations (IHR)**, which provide an "overarching legal framework that defines countries' rights and obligations in handling public health events and emergencies that have the potential to cross borders".[68] Countries are required by the IHR to develop certain minimum core public health capacities to prevent, detect and rapidly respond to public health threats. These **core health security capacities are best defined in the Joint External Evaluations (JEE) indicators**, which are used to assess progress made (Table 4.7). The Global Preparedness Monitoring Board (GPMB) and the G20 High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response

[65] https://global-health-summit.europa.eu/rome-declaration_en.

[66] Just before the crisis hit the world, the Global Health Security Index had already shown that "most countries have not allocated funding from national budgets to fill identified preparedness gaps." See https://www.ghsindex.org/wp-content/uploads/2019/10/2019-Global-Health-Security-Index.pdf.

[67] In the United Nations General Assembly Political Declaration on Equitable Global Access to COVID-19 Vaccines UN member states pledged to treat "COVID-19 vaccination a global public good by ensuring affordable, equitable and fair access to vaccines for all".

[68] See https://www.who.int/health-topics/international-health-regulations#tab=tab_1.

have recently proposed a list of the **core capacities included in pandemic prevention, preparedness and response** (see Table 4.7).[69] Health security is a broader concept than pandemic preparedness, which does not include, for example, anti-microbial resistance.

In order to fully capture and encourage all domestic spending that contributes to global public goods for health, TOSSD Pillar II could include expenditure on health security as defined in the JEE. TOSSD could also rely on existing efforts to track these expenditures.

Table 4.7. Scope of activities included in health security and pandemic prevention, preparedness, and response

JEE health security indicators	GPMB's key capacities for pandemic prevention, preparedness, and response	G20 High-Level Independent Panel capacity for pandemic prevention and preparedness
Prevent	**Prevention and preparedness**	**Robust surveillance and detection networks**
National legislation, policy and financing	One Health surveillance and risk assessment	One Health surveillance and risk assessment
IHR coordination, communication and advocacy	Immunisation	Data and information sharing
Antimicrobial resistance	Health system capacity and access	R&D on future and emerging infectious diseases
Zoonotic disease	Pandemic planning and exercising	Building resilience in health systems
Food safety	Data and information sharing	Immunisation
Biosafety and biosecurity	Norms, standards, evidence-based policy, technical support	**Health system capacity and access**
Immunization	R&D on future and emerging infectious diseases	Pandemic planning and exercising
Detect	Clinical trial and regulatory capacity	Norms, standards, evidence-based policy, technical support
National laboratory system	Mechanisms for ensuring advanced equitable access to countermeasures	Community engagement and trust
Surveillance	Supply chain networks and stockpiles	**Supply chains for medical countermeasures**
Reporting	Community engagement and trust	R&D on future and emerging infectious diseases
Human resources	Governance and coordination	Clinical trial and regulatory capacity
Respond	Surge financing mechanisms	Mechanisms for ensuring advance equitable access to countermeasures
Emergency preparedness	**Response**	Supply chain networks and stockpiles
Emergency response operations	One Health surveillance and risk assessment	Surge financing mechanisms
Linking public health and security authorities	Health system	
Medical countermeasures and personnel deployment	Emergency development of diagnostics, vaccines, and therapeutics (in response to actual outbreaks)	
Risk communication	Manufacturing of counter measures	
IHR related hazards and points of entry	Procurement, logistics, and distribution of medical products and supplies	
Points of entry	Procurement, logistics, and distribution of vaccines, diagnostics and therapeutics	
Chemical events	Knowledge generation and communication	
Radiation emergencies	Governance and co-ordination	

[69] The G20 High-Level Independent Panel proposal is a reduced list of the components identified by the GPMB.

Source: WHO (2016[54]), *International Health Regulations (2005): Joint External Evaluation Tool*, https://apps.who.int/iris/bitstream/handle/10665/204368/9789241510172_eng.pdf;jsessionid=79805F5F938EDCE76AFD6D878D072B77?sequence=1; G20 High-level Independent Panel (2021[2]), *A Global Deal for Our Pandemic Age*, https://www.g20.org/wp-content/uploads/2021/07/G20-HLIP-Report.pdf.

TOSSD should use existing data and current efforts to better track health security expenditure

The primary framework for measuring national health expenditure is the System of Health Accounts (SHA), managed by WHO and the OECD (see Box 4.7). The SHA expenditure framework was not designed to track health security in particular but health expenditure in general. Therefore the SHA categories do not exactly match those of the JEE indicators. In addition, the SHA is only concerned with human health and does not capture animal health, which is central to health security and the "One Health surveillance".

Box 4.7. The OECD and WHO System of Health Accounts (SHA) current expenditure data

Health expenditure is primarily tracked through the OECD and WHO System of Health Accounts (SHA), which is a global standard used by many countries. Expenditures are counted when the primary purpose aims at "improving, maintaining and preventing the deterioration of the health status of persons and mitigating the consequences of ill-health through the application of qualified health knowledge" (OECD/Eurostat/WHO, 2017[55]). Through its various classifications, the SHA captures the flow of health financing from revenue raising to the purchasing of health care.

Tracking health security through the classification of health care functions (ICHA-HC)

In terms of objectives pursued, current health expenditures are presented by health function, including curative care, long-term care, medical goods, preventive care and governance, and health system and financing administration. Each function is further divided into several sub-functions. The OECD and WHO are developing a mapping between the SHA sub-functions and the JEE indicators. Some of the sub-functions included, particularly in preventive care, can be fully, or almost fully, linked to the JEE health security indicators. These include "immunisation programmes", "epidemiological surveillance and risk and disease control programmes", "preparing for disaster and emergency response programmes" and "food and drinking water interventions", although the latter is usually not reported in health accounts. It is important to note that while the OECD database allows tracking at the sub-function level, the WHO database shows only current expenditure at the function level.

Tracking public health expenditures through the classification of health care financing schemes (ICHA-HF)

The SHA is primarily structured around the classification of health care financing schemes (HF), which are financing arrangements through which individuals or groups of the population obtain health services. The main breakdown is between government/compulsory contributory health care financing schemes, which are made mandatory by law and aim to ensure access to basic health care for the whole society or a large part of society; and voluntary health care payment schemes, which provide access to care based primarily on the discretion of private actors.

Strictly speaking, the financing schemes classification does not track public expenditures, which can span several schemes. Public spending is tracked through the revenues of financing schemes classification (FS), which provides information about the funding sources of health care spending. However, the FS classification cannot be linked to the health functions and hence the JEE indicators. Therefore, in order to identify public spending on health security, the HF classification needs to be used as a proxy. A relatively good proxy for public expenditures is the sum of government and social health insurance schemes.

Potential issues of double counting between SHA and other TOSSD reporting

Current health expenditures do not include health R&D, which is in principle captured as a memorandum item to the separate capital account, although in practice there is little reporting on this item. Therefore, including SHA current health expenditures in TOSSD would not entail double counting issues, health R&D is reported separately by TOSSD providers.

Efforts are being undertaken currently by the OECD and WHO to map the JEE and SHA categories and use the SHA data as proxy for health security expenditure. Some SHA health care functions can be fully, or almost fully, linked to the JEE health security indicators (see Box 4.7). Other SHA activities are only partially mapped to the JEE indicators. Discussions with OECD experts on health accounts indicated that many countries are not able to break down these categories, and that efforts will need to be pursued to get more detailed data. Some JEE indicators, for example on animal health, go beyond the SHA, which is focussed only human health. To further decide how to distribute expenditure to JEE and how to measure the health security expenditure beyond health, the OECD and WHO are planning some pilots in selected countries. In the SHA, public, or "official", expenditures are in principle tracked through the revenues of financing schemes; however, this classification cannot be linked to health care functions and thus the JEE health security indicators. Therefore a relatively good proxy for public expenditures, that can be linked to the JEE health security indicators is the sum of government and social health insurance schemes in the health care financing schemes classification (see Box 4.7).

TOSSD Pillar II should use existing frameworks and include SHA public expenditures that are fully or almost fully mapped to the JEE indicators and which are already tracked for many countries. An estimation of these expenditures for 21 countries that already report to the OECD at the health care sub-function level, shows that they amounted to approximately USD 13.3 billion in 2019 (see Table 4.8). Further improvements in the tracking of health security through the SHA could also be reflected in TOSSD. Finally, TOSSD could also allow countries with the capacity to track health security expenditures currently not (well) reflected in the SHA to do so. The added value of TOSSD is that it will present these expenditures complemented by other health expenditures that contribute to global public goods for health, in particular R&D, global functions for health and cross-border flows to developing countries. It will also present these expenditures alongside other contributions to global public goods, such as climate mitigation.

Table 4.8. Estimation of national public expenditures on health security for selected countries in 2019, USD million

Country	Immunisation programmes	Epidemiological surveillance and risk and disease control programmes	Preparing for disaster and emergency response programmes	Total
Belgium	8	159	13	180
Costa Rica	4	12	..	15
Czech Republic	74	..	..	74
Denmark	64	18	..	83
Estonia	5	18	1	24
Finland	35	..	..	35
France	174	567	56	797
Germany	2 428	3 233	..	5 661
Greece	14	66	..	80
Iceland	11	3	1	15
Korea	605	1 191	6	1 802
Latvia	12	4	..	16
Lithuania	17	16	2	35
Luxembourg	9	0	..	10
Mexico	248	323	12	583
Poland	42	178	..	220
Russia	356	595	19	971
Slovenia	26	14	..	40
Sweden	252	34	..	286
Switzerland	..	457	..	457
United Kingdom	1 151	749	..	1 900
Total	5 535	7 637	110	13 284

Note: Current expenditures from government and social health insurance schemes were used as a proxy for public expenditures.
Source: OECD statistics on Health Expenditure based on the SHA https://stats.oecd.org/.

Recommendations

As in previous sections, the scope of global and domestic health expenditure that could be included in Pillar II will depend on the overall objective of TOSSD and Pillar II:

- If the overall objective of TOSSD Pillar II is to measure financing that promotes the sustainable development of developing countries, we recommend not including any of the above expenditures.
- If the overall objective of TOSSD Pillar II is to track expenditures that promote global sustainable development and IPGs, we recommend including (i) all expenditures at the global and regional level to promote international health co-operation; and (ii) domestic expenditures that contribute to global health security, using the OECD and WHO health accounts as data sources, and allowing countries to report additional contributions to health security currently not (well) tracked in the SHA.

5 Tracking the contributions of philanthropic organisations to global health

5.1. What is the issue?

TOSSD is designed to mainly capture public, or "official", financing for the implementation of the SDGs. However, the role of private finance, particularly from philanthropic organisations, in implementing the SDGs is also recognised in the 2030 Agenda.[70] Philanthropic foundations are particularly active in the area of health. In this chapter we investigate the relevance of including a satellite indicator of philanthropic financing in the TOSSD framework, using health as a case study.

5.2. Philanthropic organisations contribute considerably to improving global health and well-being

5.2.1. Philanthropic foundations provide considerable financing to support health sustainability, both in developing countries and at the global level

Philanthropic financing for health is very large. For example, in 2019, total grants provided by the Bill & Melinda Gates Foundation (BMGF) amounted to nearly USD 3.5 billion, out of which, USD 2.1 billion (60%) was provided to support health objectives. The BMGF was also the third largest donor of WHO in 2018-19, contributing USD 455 million. In the fiscal year 2019-20, the Wellcome Trust foundation provided nearly USD 1.5 billion of grants, almost all of which focussed on health research.

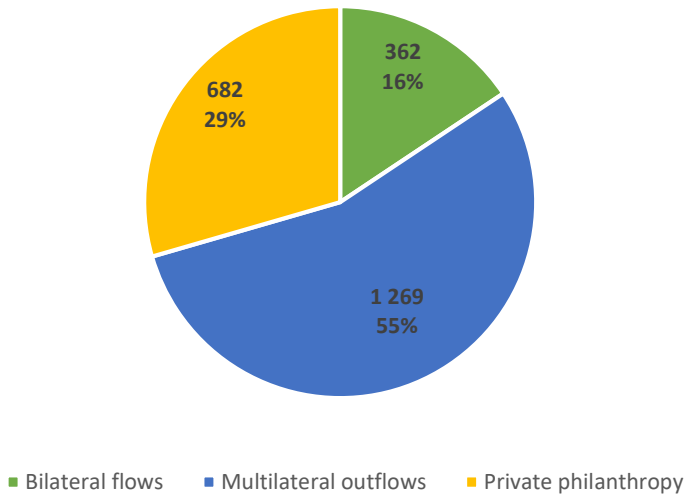
Philanthropic foundations' contribution to development co-operation is important, particularly in the health sector. Philanthropic foundations have long been recognised as key contributors in areas critical to developing countries, such as infectious disease control or medical research (OECD, 2003[56]). While the number of development finance providers in the health sector has increased substantially since 2000,[71] health-related development finance remains very concentrated among a few donors, with private philanthropic foundations among the key players (OECD, 2021[57]). Figure 5.1 illustrates the importance of

[70] See Paragraph 41 in (United Nations, 2015[66]): "We acknowledge the role of the diverse private sector, ranging from micro-enterprises to cooperatives to multinationals, and that of civil society organizations and philanthropic organizations in the implementation of the new Agenda".

[71] The number of entities reporting their health-related disbursements to the OECD's Creditor Reporting System (CRS), for example, has grown from 27 in 2 000 to 86 in 2018 - See Figure 3.2 in (OECD, 2021[57]), https://www.oecd.org/development/financing-transition-in-the-health-sector-0d16fad8-en.htm.

philanthropic foundations is supporting developing countries' health sector; it shows that philanthropic foundations – including the BMGF, the Wellcome Trust, the Children's Investment Fund Foundation, and the David & Lucile Packard Foundation – represented nearly 30% of all health-related development finance in India between 2017 and 2019, which was more than the resources provided by bilateral providers (16%).

Figure 5.1. Health-related development finance from external providers in India, 2017-2019, USD million



Note: The figures are shown in 2019 USD prices.
Source: Authors' calculations based on the OECD Creditor Reporting System (database), https://stats.oecd.org/.

The COVID-19 crisis has further highlighted the critical role of private foundations in global health. Philanthropic foundations have been actively participating in finding global solutions and providing funding to the fight against the COVID-19 pandemic. A survey carried out in 2020 by the OECD-DAC indicated that private foundations committed approximately USD 1.6 billion as an immediate response to the COVID-19 crisis (OECD, 2020[58]),[72] including support to developing countries and to global public goods (e.g. COVID-19 R&D), of which USD 491 million was allocated directly to developing countries. The survey also highlighted that private philanthropic foundations responded to the crisis by extending non-financial support in the form of large-scale fundraising, engagement with political leaders as well as flexibility towards grantees, continuation of usual pay-out or various kinds of technical assistance. Overall, since the beginning of the COVID-19 crisis the BMGF has committed USD 1 billion of grants and mobilised USD 750 million in guarantees, forgivable loans and other financing from its Strategic Investment Fund.[73]

[72] The survey covered only the expenditures from January to April 2020.

[73] See https://www.gatesfoundation.org/ideas/articles/covid19-faq.

5.2.2. Beyond their financial contribution, philanthropic foundations play an important role in shaping international co-operation for health

Philanthropic foundations have initiated many international partnerships aimed at addressing global health challenges. Examples include:

- The Coalition for Epidemic Preparedness Innovations (CEPI), a global partnership to develop vaccines and stop future epidemics, was launched in 2017 by the governments of Norway and India, the Bill & Melinda Gates Foundation, the Wellcome Trust, and the World Economic Forum.
- The Access to COVID-19 Tools (ACT)-Accelerator, a global collaboration to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines was launched by WHO, the European Commission, France and the Bill & Melinda Gates Foundation in April 2020?
- The Therapeutics Accelerator initiative[74], part of the Access to COVID-19 Tools Accelerator, was launched by the Bill & Melinda Gates Foundation, the Wellcome Trust and the MasterCard Impact Fund. Other foundations that contributed to this initiative included Alwaleed Philanthropies, Avast Foundation, Chan Zuckerberg Initiative, EQT Foundation, Michael & Susan Dell Foundation and some high-net-worth individuals.
- The Bill & Melinda Gates Foundation played a key role in the creation of Gavi, the Vaccine Alliance, including a major financial contribution as seed money. It is also one of the partners leading the Global Polio Eradication Initiative, a public-private partnership aimed at eradicating polio worldwide.

5.2.3. Philanthropic foundations typically aim to contribute to global public goods

Philanthropic organisations are significantly focussed on global access to health technologies and "open science". The experts from the Wellcome Trust interviewed for this pilot highlighted that open access to publications, data, software, and materials is a key requirement of all their grants. In addition, they have also developed specific policies aimed at promoting equitable access to healthcare interventions (see the interview with the Wellcome Trust in section 6.12). The Bill and Melinda Gates Foundation has developed global and humanitarian licence terms which require that the technologies developed with BMGF resources are made available and accessible at an affordable price to the people most in need living in developing countries and within the United States.[75]

Philanthropic foundations often seek to address market failures by supporting R&D for health technologies characterised by high social demand but insufficient commercial incentives to attract industrial R&D. Examples include R&D to develop an Ebola vaccine or products to combat anti-microbial resistance. The Wellcome Trust focusses typically on these neglected R&D topics (see the interview in section 6.12). The Bill and Melinda Gates Foundation is known to focus particularly on neglected tropical diseases.[76]

[74] https://www.therapeuticsaccelerator.org/.

[75] "Within the Global Health and Global Development programs our beneficiaries are the people most in need living in developing countries and within U.S. Programs they include low income students, students of colour and first-generation college students, and the educational systems serving these communities." See https://www.gatesfoundation.org/about/policies-and-resources/global-access-statement.

[76] See https://www.gatesfoundation.org/our-work/programs/global-health/neglected-tropical-diseases.

5.3. TOSSD could introduce a satellite indicator to track the philanthropic financing of the SDGs, which is currently only partially captured in international statistics

While philanthropic financing for global health is essential, it is only partially tracked in international development finance statistics. Private philanthropy for development, i.e. philanthropy focussed on issues primarily affecting developing countries, is relatively well tracked in the CRS.[77] However, although major philanthropies active in developing countries are included in the tracking, the coverage could be further improved, for example by including private foundations from emerging economies. For example, Chinese philanthropy has great potential in terms of contribution to the SDGS[78]. In addition, current statistics do not include philanthropic financing for global issues such as climate action and medical research (cancer, genomics). For example, while the Wellcome Trust granted around USD 1 billion of funding in 2019,[79] only USD 324 million (32%) was captured in the CRS.

There is a high demand for tracking private philanthropy in TOSSD. Previous TOSSD pilots have already shown the high demand in recipient countries for having a better picture of philanthropic financing in their countries (Delalande et al., 2020[42]).The experts interviewed in this pilot also confirmed the need to track more globally the contributions of philanthropic actors to advancing global health objectives (see the interviews with experts from the WHO and the Wellcome Trust in Chapter 6). The need for tracking private grants was also emphasised by the UN Working Group on Measurement of Development Support established by the Inter-Agency and Expert Group on the Sustainable Development Goal Indicators.

Therefore, **TOSSD could introduce a satellite indicator to track the philanthropic financing of the SDGs, which is today only partially captured in international statistics.** At the second meeting of the International TOSSD Task Force in December 2017, Task Force members had already started discussing[80] the usefulness of complementing the TOSSD statistical framework with additional "satellite" indicators to provide a broader picture of developing countries' total resource receipts. Now that the Task Force has finalised a second version of the TOSSD reporting instructions, it could be appropriate to resume discussions on the relevance of having these additional satellite indicators.

Recommendations

In view of the above findings, the International TOSSD Task Force could envisage capturing philanthropic financing for the achievement of the SDGs, particularly health, in a satellite indicator.

[77] See https://www.oecd.org/dac/financing-sustainable-development/development-finance-standards/beyond-oda-foundations.htm.

[78] See the Report of the Asian Venture Philanthropy Network on "Philanthropy in China" https://www.rockefellerfoundation.org/wp-content/uploads/Philanthropy-in-China-Web-Version-April-5-2019-FINAL.pdf.

[79] See grant funding data from the Wellcome Trust https://wellcome.org/grant-funding/funded-people-and-projects#grant-funding-data-63a0 and https://stats.oecd.org/.

[80] See the background paper discussed at the meeting at: http://www.oecd.org/dac/financing-sustainable-development/development-finance-standards/How-will-TOSSD-reporting-be-done-in-practice.pdf.

6 Experts' views on TOSSD and the tracking of global health expenditure

6.1. The perspective of experts from the World Health Organisation

The World Health Organisation (WHO) is the United Nations entity responsible for global public health. The organisation leads in particular the "global efforts to give everyone, everywhere an equal chance to live a healthy life." Several interviews were carried out with experts from WHO[81], who spoke in their own capacity and not on behalf of the organisation.

Regarding the financing of international public goods (IPGs) (TOSSD Pillar II), the experts interviewed highlighted a number of important definitional issues:

- They first referred to a number of definitions and categories used as a reference by WHO and that may be interesting to consider in TOSSD, including the definition of common goods for health (CGH),[82] which draws on the concept of public goods but not only; the definition of health security which captures the transboundary element of public health; and the global functions identified as contributing to global CGH (Schäferhoff et al., 2019[27]) (see section 6.5).
- They also raised questions on the link made in TOSSD between IPGs and developing countries. There should be a very clear distinction between supporting IPGs and supporting the sustainable development of developing countries as these are two different agendas with two different objectives. In addition, the requirement for IPGs to provide "substantial benefits" to developing countries may be difficult to operationalise and again misleading in suggesting that they support particularly developing countries. IPGs that benefit specifically developing countries are already captured in official development assistance (ODA). For the additional element that TOSSD aims to capture, i.e. global public goods, we should consider that it benefits all, not just developing countries. In a GPG approach, we should consider that everyone contributes and everyone benefits. For example, the global functions of WHO do not benefit only developing countries, but all countries.

[81] Interviews were carried out with John Grove, Director of Quality Assurance for Norms and Standards who also has experience in health statistics; Adam Taghreed, who leads the WHO Global R&D Observatory; Susan Sparkes, health financing technical officer; Ke Xu, health financing technical officer; and Marjolaine Nicod, Coordinator of the WHO Universal Health Coverage 2030.

[82] See https://www.who.int/health-topics/common-goods-for-health#tab=tab_1.

- The experts also noted that the current eligibility rules of TOSSD Pillar II may leave too much room for interpretation, and that more clarifications on what is counted or not may be helpful in providing a common understanding of the scope of the measure.

Regarding the eligibility rules that apply specifically to counting R&D funding as a contribution to IPGs, the experts told us that they generally make sense from a policy perspective although they may be too restrictive and difficult to operationalise.

In the area of health, it might be easier to consider for reporting purposes that almost all R&D meets criterion "a)" of the R&D eligibility rules (see Box 4.2), i.e. all health R&D contributes to the SDGs and is potentially applicable to at least one developing country. The SDGs promote the improvement of human health and well-being in general, and therefore all R&D contributes to this objective. In addition, in terms of the transnational applicability of the research, even certain types of implementation or health systems research that may aim to answer domestic questions can inform other countries with similar contexts if publicly available.

As regards criterion "c)" of the R&D eligibility rules (see Box 4.2), it is very important to track policies on access to health technologies; however, making these policies a condition for counting public R&D funding in TOSSD may be too restrictive. In particular:

- TOSSD would fill an important information gap if it could track R&D funders' policies that promote global access to health technologies. Access to health technologies in developing countries is a key dimension in the SDG framework. In addition, the COVID-19 pandemic has introduced a new push for equitable access because of the need to respond very quickly across borders.
- It is equally important to enforce the equitable access principle and hold countries accountable. Too often, equitable access principles are announced but not enforced.
- A potential challenge for this tracking is that there is no one-size-fits-all approach in how governments look at the issue of access to health technologies. The regulation is quite different across the board. While many countries do have mechanisms in place to promote this, more in-depth research with various stakeholders would be needed to identify and classify all the different approaches.
- While it would be important to track whether R&D funding is tied to conditions on access to health technologies, TOSSD should also capture public funding for health technologies that is not tied to these conditions for several reasons:
    - Many of these technologies eventually become widely available through other mechanisms related to procurement policies or market dynamics that decrease the production costs.
    - The relevance of conditioning R&D funding to access or affordability will depend on the type of R&D funded. For example, funding for very early stage R&D cannot be linked to access yet because the outcome is unknown. Conditions on access or affordability make more sense when funding is provided for the later product development stage.
    - We need to keep the right incentives to develop the technologies needed to address global health challenges. Before making a technology widely available it needs to be developed.

In addition to public support, it would also be important to track funding provided by private foundations as this represents a very important part of support in the health sector.

WHO experts emphasised some challenges in operationalising the R&D criteria, in particular the multiplicity of national actors that may hold data and information on potentially eligible R&D funding, which will make the completeness of the reporting difficult. TOSSD may need to set up criteria to promote completeness of reporting, including on equitable access policies.

Should international health co-operation be captured in TOSSD Pillar II as a contribution to IPGs? The experts commented that they definitely consider the global functions of WHO (e.g. international health regulations or public health surveillance) as contributing to the SDGs and IPGs. In addition, these global functions undoubtedly contribute to the achievement of the SDG agenda, which differs from the Millennium Development Goals (MDGs) agenda in its global nature.

Should other types of national expenditure that contribute to global health security be included in TOSSD Pillar II? For example, the experts emphasised that national health surveillance and diagnostics are very important factors of global health security. However, definitions of these categories would need to be clarified as they might be different from country to country. For example, the US Centers for Disease Control and Prevention (CDC) classify health surveillance as research.

Regarding the cross-border flows Pillar of TOSSD (Pillar I), WHO experts highlighted that it would fill an important data gap if it could show the actual funding received in the field. Top-level donor reporting reflects the funding put in the system, but not the resources actually received in the field. For example, health services providers (e.g. NGOs) retain a significant part of the funding as administration costs, and only a share of the total funding goes to the actual project. The experts told us that it would be interesting to unpack even further the USD 20 billion collected in TOSSD Pillar I for 2019.

6.2. The US National Institutes of Health, the largest global funder of biomedical research

The US National Institutes of Health (NIH) is the largest funder, and one of the most important performers, of biomedical R&D at the global level. Interviews were carried out with representatives from the NIH Office of Technology Transfer[83] and the Fogarty International Center.[84]

The mission of the NIH is to "seek fundamental knowledge about the nature and behaviour of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability". The NIH total budget is around USD 40 billion a year. Around 83% of this budget funds extramural research performed outside the NIH, while the remaining 17% goes on spending at the NIH, including intramural research (11%) and other types of administrative costs.[85] The NIH is part of the broader Department of Health and Human Services (HHS), which includes other agencies that have their own R&D budget to deliver their own mandate. [86]

In general, the consultations with the NIH revealed that **a large part of R&D funded or performed by the agency would be eligible under the current TOSSD Pillar II R&D rules** (see Box 4.2) as it is **primarily aimed at generating new knowledge that will be freely accessible at the global level.** A very important part of the NIH's mission and role is to support basic biomedical research, which represents around 52% of its total budget.[87] The NIH considers that public funding must give high priority to basic science given its high benefits to society – both in terms of enhancing the stock of biomedical knowledge and enabling

[83] We interviewed Tara L. Kirby, Director of the Office of Technology Transfer; Mark L. Rohrbaugh, Special Advisor for Technology Transfer; and Alina Predescu, Health Science Policy Analyst, Office of Science Policy [MR and AP].

[84] An interview was carried out with Christine F. Sizemore, Director of Fogarty's Division of International Relations.

[85] See the NIH extramural and intramural funding for 2019 https://report.nih.gov/nihdatabook/category/1.

[86] Other HHS agencies and offices that have R&D budgets include the Biomedical Advanced Research and Development Authority (BARDA), which funds product development by pharmaceutical companies, the Centers for Disease Control (CDC), the research of which relates to health security, and the Food and Drug Administration (FDA) which focusses on regulatory science and safety issues.

[87] See Basic and Applied FY 2003 - FY 2020 (V).pdf (nih.gov)

the development of new technologies – and because of the insufficient commercial incentives to invest in this research – due to the uncertainty and often long time needed for the returns to materialise.[88] There are many examples of health innovations made possible by NIH-funded basic research, including the two vaccines for COVID-19 that use the Messenger RNA (mRNA) sequence of the SARS-CoV-2 stabilised spike protein discovered by NIH scientists.[89]

While the NIH does not directly consider the affordability of the health technologies that result from its funding, its intramural research programme promotes affordability indirectly through the emphasis placed on competition and technology transfers to developing countries

Inventions arising from NIH-funded extramural research are owned by the recipient of the funds and the US Government has little impact on how they are licensed, such as whether there is preference for US industry or on the affordability of the final product. In general, beyond the obligation to provide free public access to scientific publications, report to the NIH, and comply with laws and regulations, there are few other conditions associated with most NIH awards. Strict upfront government conditions and requirements are typically included in R&D contracts,[90] which represent only around 8% of the NIH total budget.[91] Most extramural funding is provided through grants based on research proposals and terms of award which do not include the strict requirements involved in contracts. Grants can be funder-driven and associated with specific calls aimed at responding to certain policy objectives, but in most cases they support unsolicited research, meaning that the researcher or investigator has submitted the research proposal on his or her own with no specific targets established by the NIH. Research solicited by the NIH[92] represented only 25% of its 2019 extramural funding.

Intramural research is carried out by NIH researchers and any resulting intellectual property (IP) is by law owned by the US government. The consultations with the NIH revealed that while the NIH used to have a "reasonable pricing" clause from 1989 to 1995,[93] **today the agency does not consider affordability issues when it licenses its own technologies to pharmaceutical firms**. There are several reasons for this, including (i) the lack of mandate and expertise; (ii) the fact that NIH inventions are typically licensed at a very early stage in the R&D process with high uncertainty on whether they will actually lead a commercialised drug, which makes the consideration of affordability difficult and irrelevant in most cases; and (iii) the agency prioritises the likelihood that the invention is successfully developed into a drug and brought to the market, in a context where the probability of finding a licensee is very low, which puts the agency in a weak negotiation position (US Government Accountability Office, 2020[59]).

However, NIH licensing procedures do promote competition indirectly through the emphasis placed on competition (US Government Accountability Office, 2020[31]) First, the NIH and the HHS in general give priority to non-exclusive licences. Exclusive licences are granted only in cases where this is considered necessary to incentivise the risky development of approved health technologies from NIH

[88] See https://science.sciencemag.org/content/351/6280/1405.1.full

[89] For more examples and information on the impact of NIH research, see Our Knowledge | National Institutes of Health (NIH).

[90] R&D contracts are initiated by the NIH and driven by the need to respond to specific programmatic goals and the NIH clarifies up front what are the research goals and the government requirements, including product requirements. See https://www.niaid.nih.gov/grants-contracts/closer-look-contracts

[91] See https://report.nih.gov/nihdatabook/category/1

[92] NIH solicited grant applications are submitted in response to Requests for Applications (RFA).

[93] See https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf

inventions. However, before granting an exclusive licence, the NIH has mechanisms in place to ensure that competition is not undermined. An Exclusive License Consultation Group, which includes officials from the NIH, CDC and FDA, reviews plans to license any technology on an exclusive basis, and looks to ensure that granting an exclusive licence would not undermine competition. The NIH also promotes competition through the limitation of exclusive licences to specific purposes or fields of use as opposed to granting a general right for all fields and uses. All proposed exclusive licences are posted for public comment and possible objections, which may include competing licence applications.

In addition, the NIH often seeks to transfer technologies to developing countries. The agency's experts told us that they have developed strategies to license and transfer NIH technologies to institutions in developing countries to meet local and regional needs and support developing countries' access to these technologies (Salicrup, Harris and Rohrbaugh, 2005[38]). Although this is not undertaken systematically, there are numerous examples of NIH technology transfers to developing countries, such as Argentina, Brazil, Chile, China, Egypt, Indonesia, Korea, Mexico, India, South Africa and other Sub-Saharan African countries, for diseases such as HIV/AIDS, tuberculosis, rotavirus, malaria or dengue. NIH experts also emphasised that the NIH is a strong supporter of certain diseases that are rare in the United States but not in developing countries (e.g. tropical diseases).

On the basis of the current TOSSD rules, most of the NIH intramural programme and a substantial part of its extramural research would be eligible under Pillar II

The **NIH intramural programme** would be largely eligible under the current TOSSD Pillar II rules, as it is **mainly focussed on basic science, and when inventions are made: (i) NIH licensing procedures promote competition; and (ii) strategies to transfer health technologies to pharmaceutical firms in developing countries are often actively sought.** From the interviews with NIH experts, it appeared that the agency's intramural research is primarily focussed on basic science rather than the development of new health technologies and, in general, it is rare that patented inventions arise from the intramural programme.[94] However, as explained above, when this happens the NIH licensing practices do promote competition, which would make its intramural research compliant with the current TOSSD Pillar II eligibility rules.[95] In particular, the NIH gives priority to non-exclusive licences, which are specifically mentioned as eligible in TOSSD. The NIH intramural programme would also be eligible to TOSSD through the *ex post* technology transfers to developing countries that the agency often actively seeks. Therefore, should the current TOSSD R&D rules be maintained, the project-level data on the NIH intramural research programme, which are already publicly available, could potentially be included in full in Pillar II.

In principle, a large part of this NIH-funded extramural research would also be eligible under the current TOSSD Pillar II rules given its focus on knowledge generation; however, filtering what is eligible will be challenging. As explained above, there are no conditions on the affordability of health technologies associated with NIH awards. However, a large part of NIH extramural funding would still be eligible because in the vast majority of cases it is not directly related to the development of new products, and rarely leads to patented inventions. NIH experts told us that the agency's extramural funding generally goes to research and academic institutions rather than private companies, with a very small share going to small businesses (around 3% of total R&D funding, see Table 6.1), as required by federal law. In addition, they emphasised that although there may be more patents and drugs resulting from extramural

[94] From 1980 to 2019, the Department of Health and Human Services obtained 4 446 patents, of which 94 were licensed to pharmaceutical companies. These licences were used in the development of 34 drugs approved by the US Food and Drug Administration (US Government Accountability Office, 2020[31]).

[95] According to the TOSSD reporting instructions on R&D, contracts "associated with conditions that aim at promoting competitive manufacturing, for example through non-exclusive licensing" are eligible under TOSSD Pillar II (See Annex E of the TOSSD Reporting Instructions, https://www.tossd.org/docs/reporting-instructions.pdf).

applied research compared to the intramural programme, in general it is rare that NIH grants directly lead to patents, and even when inventions are made these are generally still at the very early research stage, before any product development. The typical research outcome of NIH grants would rather be scientific publications that can sometimes be cited in patents. This was confirmed by Ohid Yaqub, an expert in research policy and biomedical innovation who is very familiar with NIH funding data, and who added that there can also be an issue of underreporting by NIH grantees of the patents arising from the research (see section 6.3).

However, the NIH funding data do not allow the strict identification of what would be eligible under the current TOSSD rules. The NIH does not distinguish between knowledge-generation and product development in its funding, except for small business grants, which can be considered as related to product development. In addition, the NIH information system does not distinguish between basic research and applied/translational research, which could be used as (imperfect) proxies. These categories would need to be ascertained manually for each project based on the publicly available abstracts. NIH experts noted some definitional challenges in classifying these categories as each organisation and scientific discipline has a different definition of where basic science ends and applied/translational research starts. Thus, if there is any classification of these categories at the NIH it is done at the level of individual institutes. Therefore, given that the typical outcome for the vast majority of NIH awards is an openly-accessible scientific publication rather than a patent or health product, a possible solution could be to include NIH extramural grants in full.

The NIH also has a substantial cross-border programme that would be eligible under TOSSD Pillar I

Although the NIH mission is mainly focussed on domestic funding, the agency does also have a substantial cross-border programme, which provides support to many developing countries. While the Fogarty International Center is the only NIH entity whose mission is focused exclusively on international research and capacity building, all NIH Institutes and Centers support international research, primarily through international collaborations on US awards but also to a lesser degree directly through grants organisations outside the United States. The Fogarty International Center executes its global mandate by "supporting and facilitating global health research conducted by U.S. and international investigators, building partnerships between health research institutions in the U.S. and abroad, and training the next generation of scientists to address global health need".[96] As a whole, in 2020 the NIH granted approximately 300 awards directly to institutions located in developing countries, for a total amount of USD 124 million,[97] with USD 84 million through research grants,[98] USD 9.8 million through R&D contracts, and USD 30 million for research training and capacity-building.

[96] See https://www.nih.gov/about-nih/what-we-do/nih-almanac/fogarty-international-center-fic

[97] See https://report.nih.gov/award/index.cfm

[98] Including research project grants and research centres grants.

Table 6.1. Indicative assessment of the eligibility of NIH funding categories under the current TOSSD R&D eligibility rules

NIH funding mechanism	Total cost (USD	Share	TOSSD eligibility assessment
NIH intramural programme			
Intramural research	4 167	12%	The intramural research programme would be largely eligible under TOSSD Pillar II as it is mainly focussed on basic science, and when inventions are made: (i) the NIH licensing procedures promote competition; and (ii) strategies to transfer health technologies to pharmaceutical firms in developing countries are often actively sought. In addition, a rapid look at the 2019 intramural project data shows that research topics are generally applicable to developing countries (e.g. "Molecular and Pathophysiological Study of Parkinson's Disease").
Extramural funding for organisations in the US or high-income countries			
Research grants (including project grants, research centres and other research grants)	27 248	76%	A large part of the extramural research grants should be eligible under TOSSD Pillar II provided that the research project is deemed "applicable to developing countries", which as discussed in section 6.1 may hold true for almost all biomedical R&D. The reason is that in the vast majority of cases, NIH-funded extramural research is not directly related to the development of new products: • Basic research represent a significant part of NIH extramural funding, • Applied or translational research is generally not directly related to the development of new products. • In general, it is rare that NIH extramural grants directly lead to patents. They would rather result in scientific publications that get cited in patents.
R&D contracts	1 691	5%	R&D contracts can be related to the development of new products and their inclusion would need to be assessed on a case-by-case basis.
Research grants and contracts to small businesses	1 125	3%	Funding to small businesses can be related to the development of new products and its inclusion would need to be assessed on case-by-case basis.
Training (individual and institutional)	837	2%	The eligibility of R&D training to TOSSD has not yet been addressed by the TOSSD Task Force.
Others	475	1%	Not assessed.
Interagency agreements	139	0%	Not assessed.
Construction grants	69	0%	The eligibility of R&D capital expenditures to TOSSD has not yet been addressed by the TOSSD Task Force.
Cross-border flows to developing countries			
Research grants and contracts to organisations in developing countries	143	0%	Cross-border support to developing countries is fully eligible under TOSSD Pillar I.
Total	35 894	100%	

Note: The data include only R&D projects supported by the NIH and not any other operating costs.
Source: NIH, (n.d.[46]), *NIH ExPORTER database*, https://exporter.nih.gov/.

6.3. Ohid Yaqub, researcher specialised in research policy and biomedical innovation

Ohid Yaqub is an academic researcher specialised in research policy and biomedical innovation. His research interests include R&D funding. Given the methods used by Ohid Yaqub in his research, his perspective was very relevant for TOSSD. In particular, part of his research is based on R&D project tracing, which involves connecting research inputs such as funding to research outputs such as publications and patents. The interview with Ohid Yaqub focussed on the R&D eligibility rules.

For there to be "substantial benefits" to developing countries from TOSSD R&D, open access to scientific publications and intellectual property arrangements are relevant, but other issues are also pertinent.

R&D, even when written up into a publication that is "open access", is not always easily accessible because local capabilities and infrastructure may be needed on the part of the reader/user of the research, in order to extract value from it and appreciate its possible applications. Conversely, there may be research that is not "open access" but that still nevertheless provides substantial benefit for developing countries. Researchers' publication choices are affected by a variety of factors, and research can be applied in a variety of ways (Yaqub, 2020[60]). More generally, a major rationale for undertaking R&D is not only to increase the stock of knowledge, but also to maintain it and develop an ability to absorb new R&D undertaken elsewhere. As such, the open access criteria, simply and on their own, may lead to inappropriate inclusions and exclusions from TOSSD.

Similarly, although intellectual property arrangements on R&D can mean reduced access in developing countries, it should be emphasised that its primary function is to incentivise their development in the first place. Advance market commitments (AMC) are not necessarily about low product prices, but rather about encouraging product development when there is no commercial incentive. Under such conditions, other approaches to improving access can be highlighted, such as differential pricing across markets/countries/buyers, or the potential use of compulsory licensing arrangements (Hassan, Yaqub and Diepeveen, 2010[61]). Moreover, it is possible to conceive that some organisations may seek intellectual property ownership as a form of defensive patenting, precisely because it wants to keep it open and widely shared. Or some organisations may even seek to import and re-purpose R&D from developing countries (Fry et al., 2011[62]). So intellectual property protection, simply and on its own, may lead to inappropriate inclusions and exclusions from TOSSD.

Ohid Yaqub stressed that a major challenge is related to the availability of data describing R&D that could potentially be used to determine whether the R&D meets TOSSD criteria.

For Ohid Yaqub the TOSSD criteria seemed ambitious given the type of data available on R&D funding. The publicly-available grant data that could be used to apply the criteria include basic project information (research organisation, project description, etc.) as well as the funding schemes and policy documents where funders specify certain policy objectives or targets. However, this may be too brief to adequately and reliably classify the R&D. Having access to more comprehensive information on the research projects would help, but this may be restricted by non-disclosure and confidentiality constraints. In addition, even with all the data and information available on R&D projects, it still might not be easy to classify these projects very accurately in the different TOSSD eligibility categories ("product-oriented", "knowledge-oriented", "non-exclusive licences", etc.).

An alternative would be an institutional approach, looking at the nature of the institution performing the R&D: if the R&D is performed by a biotech or a pharmaceutical firm then it's probably about product development, if it is performed by a research institution then it's probably more knowledge-oriented. In general, research done in universities and research institutes does not lead to patents but rather to scientific publications which might then get cited in patents.

Ohid Yaqub also told us that if the criteria are to be applied by the funders themselves, with a strong mandate to do so, then their application might be more feasible as they may have some additional information internally that could help classify the projects.

6.4. The International Genomics Institute, a research institution that aims at "bringing cutting-edge research to the public"

The International Genomics Institute (IGI) is a non-profit academic research organisation founded by Jennifer Doudna, the 2020 co-nobeliste, with Emmanuelle Carpentier, for her work on the CRISPR gene editing. The mission of the IGI is "to bridge revolutionary genome-editing tool development to affordable and accessible solutions in human health, climate, and agriculture". Interviews were carried with Melinda Kliegman, IGI Director of Public Impact, and Lea Witkowsky, a science policy analyst at IGI looking at the regulatory, ethical and societal dimensions of biotechnology development and adoption.

Similarly to a number of other experts interviewed, IGI emphasised first the importance of clarifying the overall objective of TOSSD Pillar II.

A strict application of the TOSSD sustainability criteria ("…no substantial detrimental effect is anticipated on another target…") could be difficult, even in health R&D

The IGI emphasised that the "sustainability" of biomedical research is subjective and highly dependent on culture, values and interpretation. Biomedical R&D can sometimes have a negative impact on the other sustainability dimensions included in the SDGs. Concerns have been raised for instance on the social outcomes that might be caused by medical progress made in human genetic editing. While human genetic editing would be considered an important advancement for those suffering from debilitating neurodegenerative diseases, others, including in the deaf community for example, have opposed the use of genome editing to prevent and treat deafness as they do not see deafness as a disease but rather as a fundamental part of their identity and culture.

Current TOSSD R&D criteria may give too much importance to basic research as opposed to product development

Some basic research might be related to the SDGs but may not be as critical to saving lives as health technologies. IGI experts told us that by definition most basic research does not have an applied function and they would not consider that type of basic research as much a public good as a drug that can save lives. They stressed that the TOSSD Secretariat should verify whether the reported basic research is actually applicable to developing countries.

While it would be prudent to tie public funding to conditions on affordability and access, this is difficult to do in the current R&D funding model

For IGI, ideally public funding should be tied to conditions on access and affordability, and more stipulations should be included on IP sharing and affordability. However, the current R&D funding model makes this difficult. Government funding is mostly focused on upstream academic research that can lead to important discoveries and inventions, but that are usually still at a very early stage in the product development process. Translation from laboratory inventions to actual treatments that patients can use can be difficult, uncertain and costly, hence the need for strong incentives, through the expectation of high profits, for pharmaceutical firms to step in and invest in this development. As a result, very rarely are there conditions on affordability associated with technology transfers from universities or government laboratories to pharmaceutical manufacturers. However, some universities have started to impose such conditions, for instance the IGI (and the University of California system in which the IGI is housed) generally retains the rights to humanitarian access of its intellectual property in low-and middle-income countries, and research rights are always retained.

The IGI experts told us that ideally, public funding should also fund technology translation so that it can impose conditions that promote the public interest. One way to generate funding for such a mechanism in the United States would be for the NIH to retain some small portion (~2%) of profits made by companies whose patents are based on NIH funded research. This funding could then be used to fund more research, non-profits committed to delivering treatments at an affordable or low-cost, or could remain with the commercial entity if they divert some portion of profits to treat low-income patients.

The experts highlighted that the capacity of the current model to translate laboratory inventions to accessible treatments is increasingly challenged, as concerns are raised in the public on the affordability of some new health technologies, especially around genomic therapies[99] which is IGI's main area of work. Particularly concerning are cures for lethal diseases discovered at academic research institutions that are not translated or further developed by commercial companies because they are not expected to generate a large profit.

The IGI is currently exploring new models to translate inventions to affordable and accessible treatments

The IGI sees these issues as a market failure and is currently exploring new models to translate inventions to affordable and accessible treatments. The California Institute for Regenerative Medicine (CIRM), a public funding agency, awarded the IGI and the University of California with multiple grants, for a total of approximately USD 37 million, to develop gene therapies for sickle cell disease and advance these therapies to clinical trials, which are ongoing.[100] As sickle cell disease primarily impacts those living in low- and middle-income countries, the IGI's vision is a safe, *in vivo*, minimally invasive treatment that can be delivered at the bedside. If such a treatment can be developed at a public university using only philanthropic and public funding, it will be critically important that it is widely accessible and affordable, and thus a global public good.

The IGI has also developed a non-exclusive, no-fee, royalty free licence to make new technology developed during the COVID-19 pandemic – to aid in the diagnosis and treatment of the disease – widely accessible to any entity working on this disease globally.

6.5. The perspective of experts from the United Nations International Institute for Global Health

The UN University International Institute for Global Health (UNU-IIGH) is the UN think tank dedicated to global health. It was established in 2005 and is based in Kuala Lumpur, Malaysia. Interviews were carried out with several experts from UNU-IIGH.[101]

Regarding the cross-border flows Pillar of TOSSD (Pillar I), the UNU-IIGH emphasised the importance of capturing South-South flows and South-North flows. While South-South Cooperation (SSC) is important in the health sector, it is not properly captured today. For example, a public-private partnership including the Malaysian Ministry of Health and Egyptian firms has recently developed a new hepatitis C drug that will provide an affordable treatment for millions of patients still waiting for access to

[99] See for example https://www.nature.com/articles/d41586-019-03709-8.

[100] https://www.cirm.ca.gov/our-progress/disease-information/sickle-cell-disease-fact-sheet.

[101] Interviews were carried out with Pascale Allotey, Professor and Director of UNU-IIGH; Michelle Remme, Research lead, Research Fellow; and Lavanya Vijayasingham, Post-doctoral Fellow.

these treatments in developing countries.[102] In addition, the experts interviewed also noted that it would be important to track cross-border South-North flows (e.g. doctors sent by Cuba), and that Pillar I should not be limited to developing countries. They also highlighted some innovative financing mechanisms that can be used for health financing in developing countries (Atun et al., 2016[19]).

The UNU-IIGH experts interviewed told us that TOSSD would indeed fill a key information gap if it could track the public financing of health-related global public goods (TOSSD Pillar II). However, it needs to be clear that this is different from financing in support of developing countries. All countries benefit from, and should contribute to, global public goods. It would also be important here to reflect the contributions made by the Global South, for example through the financing provided to the global funds.

On the coverage of TOSSD Pillar II, the experts confirmed that basic health research is important for sustainable development and should be captured if the knowledge is globally and freely available. On potential additional areas to be included, they mentioned the work of drug approval agencies, which is often used as a reference in developing countries.

6.6. The perspective of health experts from the Organisation for Economic Co-operation and Development (OECD)

The OECD provides evidence-based policy advice to its members on a number of issues, including health. The OECD Health Division leads on health-related work, which includes the analysis of "policies that improve access, efficiency, resilience and quality of health care". Interviews on TOSSD were carried out with several experts from the OECD's health division,[103] and focussed on the second Pillar of TOSSD, the financing of international public goods.

The objective of measuring the financing of international public goods needs to be clearer and more explicit. For the OECD experts, the end goal of the TOSSD Pillar II measurement framework was not sufficiently explicit in the TOSSD reporting instructions. Transparency should not be an end in itself but always serve a broader policy objective.

Regarding the measurement of health R&D funding, they generally agreed with the introduction of the "access to health technologies" principle, although emphasised some operational challenges.

The OECD advocates for including provisions for IP sharing and technology transfers in publicly-funded contracts for the development of products addressing health emergencies (OECD, 2021[33]). OECD research has also emphasised that the best way to ensure access to health technologies in developing countries is to apply differential pricing (OECD, 2018[4]), although some experts interviewed emphasised that differential pricing can be an imperfect solution as they do not reflect the price disparities within countries and across income groups.

OECD experts also emphasised a number of issues relating to the implementation of the equitable access policies, beyond official announcements. First, even when governments do include conditions on affordability and access in their R&D funding, they often have difficulties in following up and ensuring that these conditions are complied with. In addition, R&D conducted by pharmaceutical firms is often characterised by a certain lack of transparency, in particular regarding the actual R&D cost. It was noted for example that while some pharmaceutical firms have pledged to sell their COVID-19 vaccine at cost, it is not possible to know if this is really the case.

[102] See https://dndi.org/press-releases/2021/first-hepatitis-c-treatment-developed-through-south-south-cooperation-registered-in-malaysia/

[103] Interviews were carried out with Ruth Lopert, Senior Health Economist; Nick Tomlinson, Global Health Advisor; David Morgan, Head of the OECD Health Accounts Unit; and Michael Mueller, Health Policy Analyst.

Regarding the operationalisation of the TOSSD criteria, several issues were mentioned. First, it was noted that the criteria leave some room for interpretation, and that this might lead to inconsistencies in what is reported by the various R&D funders. TOSSD should also seek to ensure also consistency in interpretation and provide more guidance on what is eligible. For example, the argument could be made that all health innovations become accessible for all at some point, even if not during the first years. Moreover, it was noted that often the promotion of developing countries' access to health technology takes place only after the R&D funding was provided and the invention was made. The experts asked then whether it would not make sense to only record R&D funding in TOSSD Pillar II retroactively, once the equitable access has materialised. However, this approach would only include "successful" R&D, which is not the spirit of as it is an input and not an output measure.

On other health public spending that can potentially be counted in TOSSD as a contribution to IPGs, the experts interviewed stressed the importance of domestic spending on health surveillance and immunisation. This spending undoubtedly provides global transboundary benefits through control of communicable diseases. The OECD statistics on health expenditure and financing and the WHO Global Health Expenditure database already include data on immunisation that could potentially be used in TOSSD.

6.7. Policy Cures Research, tracking funding for R&D on global health issues

The G-FINDER project is conducted by Policy Cures Research[104] to track annual investment in R&D for new products and technologies designed to address the persistent global health challenges that disproportionately affect the world's most disadvantaged people. The flagship survey of the G-FINDER project is the Neglected Diseases (ND) survey, which focusses on under-funded infectious diseases that disproportionately affect developing countries and for which there is insufficient or no commercial interest. In addition, the G-FINDER project covers emerging infectious diseases (EIDs), based on the priority diseases as defined in the WHO Blueprint, and sexual and reproductive health (SRH) issues affecting developing countries.

From the interviews carried out with the G-FINDER team, it appeared that the main differences between the G-FINDER survey and TOSSD are related to their scope:

- In terms of diseases covered, the scope of the G-FINDER survey is very limited compared to TOSSD. The G-FINDER neglected disease survey excludes R&D that is primarily commercially-motivated or that is focused on technologies likely only to be suitable for high income country settings-, while TOSSD is based on a global public good approach and includes all diseases "applicable" to developing countries, including those with an incidence in both developing and advanced countries. The G-FINDER team see the limited scope of the surveys as a strength of their data. By limiting the scope to diseases that disproportionately affect people in poor countries, they ensure that the R&D captured particularly benefits developing countries. This restriction does not, however, apply to the G-FINDER EID survey, which includes all R&D funding for priority EIDs such as COVID-19, regardless of its commercial motivation and donor country impact. This reflects a view that EID R&D is a truly global public good, and is subject to a general, global failure of market incentives for sufficient expenditure on preventing uncertain, future, global losses.
- In terms of type of R&D, the G-FINDER surveys are focussed on product development and basic health research related to the diseases and health areas within its scope, partly explaining why they cover a very small part of overall public funding for R&D (e.g. in 2019 only USD 2.1 billion of

[104] Policy Cures Research is a global health think tank with a long and pioneering history in global health R&D data collection and analysis. See https://www.policycuresresearch.org/about-us/.

R&D funding from the NIH was captured across the G-FINDER surveys out of a total budget of USD 36 billion).

- In TOSSD, the scope is rather limited through the principle of access to health technologies in developing countries. In the G-FINDER surveys the issue of access to health technologies is not directly taken into account – the survey instead assumes that product development primarily motivated by the needs of developing countries will ultimately result in developing nations' access to the resulting products.
- R&D areas not covered by the three surveys, but which the G-FINDER team considered important to track, include non-communicable diseases, implementation research, research for policy and health systems strengthening, research into optimal delivery of non-product or existing product interventions and into the creation of non-pharmaceutical interventions, and general therapies such as painkillers and nutritional supplements. These restrictions partly reflect a deliberate decision to adopt a specific focus on biopharmaceutical interventions as the subject matter of the G-FINDER survey, and partly the difficulty of determining whether each specific example of these kinds of intervention is sufficiently motivated by, or targeted at, particular neglected pathogens. A project such as TOSSD, which is aimed at measuring overall healthcare funding, would resolve many of these questions of demarcation, but would answer a different question to the narrow, specific query to which the G-FINDER survey aims to provide a detailed, accurate answer.

The G-FINDER team recommended adopting a more practical and detailed approach in the TOSSD reporting instructions. For the G-FINDER team the TOSSD criteria appeared too high-level and may need to be more detailed to be operational. Reporters need very clear and granular examples on what should be included or not, ideally with concrete examples to illustrate. The G-FINDER ND survey, for example, includes 35 pages of very granular instructions with examples[105]. In addition, leaving room for interpretation may lead to inconsistencies across the data reported by the various R&D funders. If, despite the detailed instructions, the reporter still has doubts on whether an activity should be included, the reporter is requested to still report it to the G-FINDER team, who will determine whether it is eligible. In order to operationalise the high-level criteria of the ND survey, the G-FINDER team relies on an international Advisory Committee of 17 experts in neglected disease and R&D. A similar approach could be explored for TOSSD.

Finally, the G-FINDER team highlighted the significant amount of resources needed to collect the data.

In order to isolate the in-scope funding from large databases, such as the US NIH RePORTER, the Policy Cures Research team initially uses keyword searches on project names and descriptions to identify funding that potentially relates to one of the pathogens covered by the G-FINDER survey. All potentially in-scope grants – whether extracted by the G-FINDER team from publicly available databases, or reported to the survey by participants – are then individually compared to the survey's scope restrictions based on grant descriptions (including abstracts where available) and independent research conducted by the Policy Cures Research technical team. Where insufficient detail exists to make informed decisions on inclusion, the G-FINDER team typically follows up with the reporting organisation directly. This scope checking process is coupled with the cross-checking of grants reported by both funder and recipient, in order to validate scope allocation decisions, and to eliminate double-counting.

A lot of engagement needs to be undertaken every year to make sure that past reporters continue to send their data, but also that new participants are included in the surveys, especially newly formed organisations or new market entrants. This engagement work requires the recruitment of several research assistants located in different parts of the world. In addition, for some funders the G-FINDER team allocates

105 See https://policy-cures-website-assets.s3.ap-southeast-2.amazonaws.com/wp-content/uploads/2021/05/14174443/y13_2020_G-FINDER_ND_RD_scope.pdf.

supplementary resources to support them compile the data. For example, a staff member is sent to India for several months every year to support Indian reporters respond to the survey. In addition to the engagement work, substantial resources are needed to process and validate the data, including adjusting reported amounts to a common currency, querying reporters on apparent discrepancies, and cross-checking reports from funders and recipients to ensure consistency and avoid double-counting. By gathering data consistently over several years, the survey team is able to develop an understanding of how the data "ought to" look and can effectively interrogate submitted data against a historical standard.

6.8. The perspective of health experts from the French development agency

The French Development Agency (AFD) is the public financial institution in charge of implementing the development co-operation policy defined by the French government. Interviews were carried out with Christophe Paquet and Agnès Soucat,[106] two AFD health experts who brought a particularly interesting perspective on TOSSD as they have expertise and experience in both development co-operation and public health policy, which makes their viewpoint relevant to both Pillar I and Pillar II of TOSSD.

The AFD experts recommended clarifying the objective of Pillar II and advocated for a global public good perspective where all countries are beneficiaries. On the general definition of TOSSD, they stressed that promoting GPGs is different from promoting the sustainable development of developing countries. The public good and the common good argument is different from the equity argument. A GPG approach would answer the question of how much the world spends on core functions that are public goods or for which there is a global market failure, many of them to ensure global health security, which is different from the question of how much providers of development finance spend to support developing countries as a solidarity approach. In a GPG approach, it does not make sense, and in fact it is not possible, to break down the benefits to capture the portion that benefits **to** particular developing countries. Public goods are equitable by definition as they are not dividable and not excludable. What can be roughly estimated is what is spent **in** developing countries; the corresponding financing is already included in ODA (e.g. ODA coefficients applied to global organisations such as WHO). The general definition of TOSSD is therefore key to determine what will be covered in the measure. WHO has provided a definition of common goods for health and defined five categories of functions that can be used as a basic guidance (WHO, 2021[63]).

As far as GPGs are concerned, the AFD experts made the following comments on their coverage:

- National health systems are not part of GPGs per se, but a pre-requisite. They are the backbone of the global health system. They need to be either included or excluded in full.
- Basic research should not be included because the research topic is unknown. TOSSD Pillar II should have some boundaries, and it is better to include R&D directed towards the development of new health technologies, which will have a clear impact, rather than basic health research

[106] Christophe Paquet holds the position of Evaluation Manager in the Evaluation and Knowledge Capitalisation Department and was the former Head of the Health and Social Protection Unit of the French Development Agency (AFD). Previously, he managed the International and Tropical Department at the former French National Institute for Public Health Surveillance, while participating in several missions for WHO during epidemics of international importance, such as SARS in 2003. He also conducted several humanitarian missions with Médecins Sans Frontières (MSF) in Central America, Thailand and Sudan. Christophe Paquet specialised in communicable and tropical diseases and participated in the creation of Epicentre, an MSF epidemiology research group and WHO Collaborating Centre. Agnès Soucat is the current Head of the Health and Social Protection Unit of the French Development Agency (AFD) and the former Director of the Department of Health Systems Governance and Financing at WHO. Prior to that, she was Director of Human Development at the African Development Bank and Lead Economist at the World Bank. She is a recognised researcher on issues related to health financing, including common goods for health, and was a commissioner of the 2013 "Lancet Commission on Investing in Health".

- Regarding international health co-operation and coordination, they recommended including all activities that establish a framework for countries to discuss and co-operate on health issues. They stressed in particular the importance of promoting international health regulations, including at the global (WHO regulations), regional (e.g. EU health regulations) and national level, particularly as the COVID-19 crisis has shown how national self-interests can prevail.
- National surveillance systems are essential to ensure global health security, and therefore could be considered for inclusion in TOSSD Pillar II. However, national surveillance systems can be broad, including, for example, the central public health agency, regional surveillance entities, laboratories that have a diagnostic mission and some laboratory functions in the hospital system. Therefore, it might be complicated to draw a line.

Regarding the first Pillar of TOSSD (cross-border flows to developing countries), the AFD experts emphasised the need to focus on national health systems and the importance of tracking South-South Co-operation and migrants' remittances. Providers of cross-border support should prioritise the strengthening of national health systems to ensure a sustainable and long-term path towards better health outcomes in recipient countries. Today, many providers have their specific tropisms and tend to focus on the eradication of specific health diseases rather than supporting the health system as a whole.

In terms of tracking, it would be important that TOSSD Pillar I captures South-South Cooperation so that all providers can be compared. However, it should be noted that SSC is not always free (for example in some cases technical support provided by doctors has been traded with oil). Finally, migrants' remittances in the health sector can be very important in terms of volume, and not much data exist on this today. It should be noted, however, that the economic literature has shown that these remittances can both have a positive relief effect and potential adverse impact given the overall lack of co-ordination (e.g. the construction of new health facilities with no doctors to operate them).

6.9. Olivier Weil, a researcher specialised in health financing in developing countries

Olivier Weil is an Associate Professor in the Health and Development team of the Conservatoire National des Arts et Métiers (Cnam), a major French higher education and research institution under the supervision of the Ministry of Higher Education. As a medical doctor and public health specialist, he is in charge of the Global Health section of the Specialised Master's Degree, as well as the Global Health Specialisation Certificate. His professional career has focused on the issues of maternal health and the strengthening of health systems in low- and middle-income countries, issues that he has mainly addressed through action research programmes and evaluation approaches. Olivier Weil is also a Senior Health Specialist at Mott MacDonald in London, where his current main research themes are the financing, organisation and quality of obstetric and neonatal care.

Olivier Weil generally agreed on the need to track contributions to health-related IPGs in TOSSD Pillar II, as this constitutes a major information gap today.

On the specific eligibility rules applicable to R&D funding to be counted as a contribution to IPGs (see Box 4.2), he made several comments:

- Olivier Weil stressed that that there may be an issue with the purpose of the research: does it really contribute to the sustainable development of developing countries? If the focus is really only on developing countries, TOSSD should find other sub-criteria.
- On the coverage of basic research, Olivier Weil told us that it would need to be either included or excluded in full because it will be difficult to distinguish between "beneficial" and "non-beneficial" basic research. An "optimistic" approach – according to which the majority of basic research brings

large benefits to the world population – would include all basic research. However, he noted that the total amounts potentially captured in this area would be very large.

- On the criteria that apply to the generation of new knowledge, Olivier Weil told us that it is very important to apply and enforce the principle of open access to make scientific knowledge truly a global public good. However, he emphasised that putting knowledge in the public domain does not mean that it will benefit developing countries. The primary issue in many developing countries is not necessarily the access to knowledge, but the capacity to perform any research. Without such capacity it will be difficult for developing countries to benefit from the knowledge.
- On the criteria that apply to the development of new products, he emphasised that if the focus is really on the benefits that accrue particularly to developing countries, then the eligibility could be linked to international research partnership mechanisms such as the Coalition for Epidemic Preparedness Innovations (CEPI) or the International Partnership on Microbicides (IPM),[107] which involve developing countries and have a clear focus on access to health products in these countries. He also noted that international procurement (e.g. UNICEF) and delivery (e.g. Gavi) mechanisms have proven key to delivering health services that are affordable and accessible in developing countries. As an example, he mentioned the Human Papillomavirus Vaccine (HPV), the price of which is tiered based on the recipient country income group.[108]

Olivier Weil stressed that international health co-operation (e.g. international norm-setting, health surveillance) is essential for global health and should be counted in TOSSD as a contribution to IPGs. However, he also emphasised that these are global activities for the benefit of everyone and it will be difficult to ascertain the fraction that actually benefits developing countries.

On domestic health expenditure, Olivier Weil would include health surveillance in TOSSD Pillar II, but not the broader strengthening of national health systems, in which there is no or limited impact on the circulation of communicable diseases. He also stressed that the issue of antimicrobial resistance is a major global public health concern, and that national efforts to combat the circulation of microbes resistant to antibiotics, in particular in the agriculture and food sector, do clearly contribute to IPGs and could be covered.

Finally, on the first pillar of TOSSD – cross-border flows to developing countries – Olivier Weil noted that TOSSD would fill an important data gap as today there is little transparency on South-South providers' contributions to health.

6.10. Marco Schäferhoff, tracking the financing of global common goods for health

Marco Schäferhoff is the Managing Director and Co-Funder at Open Consultants and has over 15 years of experience in global health financing and policy. He has worked with various global health institutions such as Gavi, the Global Fund, the Bill & Melinda Gates Foundation, WHO, the Joint United Nations Programme on HIV/AIDS (UNAIDS) and several major donor governments. Marco Schäferhoff has worked on measuring global official financing for health in the past two decades, including with the Lancet Commission on Investing in Health. He is the lead author of the influential paper "International Funding for Global Common Goods for Health" (Schäferhoff et al., 2019[27]).

[107] See https://www.ipmglobal.org/about-ipm.

[108] See https://www.unicef.org/supply/sites/unicef.org.supply/files/2020-03/human-papillomavirus-vaccine-HPV-supply-and-demand-update.pdf.

Marco Schäferhoff was in general very supportive of TOSSD Pillar II and emphasised that it would fill a key data gap by tracking on a systematic basis the global contributions to health-related IPGs. He himself worked on this issue and proposed a methodology for measuring the financing of global common goods for health using the Creditor Reporting System (CRS) and G-FINDER databases (Schäferhoff et al., 2019[27]). He emphasised that capturing the contributions of China to global health would be a particularly great asset for TOSSD.

However, he expressed some reservations on the specific criteria that apply to the R&D funding counted as contributing to IPGs.

Marco Schäferhoff supported the inclusion of R&D funding in the IPG Pillar of TOSSD, but considered the TOSSD criteria at the same time too broad and restrictive.

Marco Schäferhoff recommended reducing the scope to cover only diseases that affect disproportionately developing countries. He referred to the methodology he used in his paper where the scope was limited to neglected diseases (ND). He recommended using the definition of NDs of the G-FINDER survey (see Box 4.3), which is regularly updated and sufficiently narrow, and not the one of WHO which is too large. For Marco Schäferhoff, eligibility should also be limited to product development as opposed to basic research.

On the contrary, the TOSSD R&D criteria may be too restrictive by excluding many health technologies that do not comply with TOSSD criteria related to the public domain or affordability in developing countries (see Box 4.2). For example, while the criterion on non-exclusive licensing can be helpful in some situations, it may exclude some important technologies developed under exclusive licences. He mentioned the example of a tuberculosis vaccine that was developed by GlaxoSmithKline (GSK) until phase 2b and then licensed to the Bill & Melinda Gates Medical Research Institute which will ensure that the product is accessible to a large population in developing countries.

He also pointed out the difficulties in operationalising the existing R&D criteria.

Marco Schäferhoff supported the inclusion of other global and domestic health expenditures in TOSSD Pillar II.

In addition to R&D funding, Marco Schäferhoff told us that he would include a number of other domestic and international expenditures and referred to his classification of funding for global common goods for health (GCH) (see Box 4.6), which includes outbreak preparedness and response, responses to antimicrobial resistance (AMR) control of cross-border disease movement, and health advocacy and priority setting. In addition, he emphasised the very important role played by drug approval agencies such as the US Food and Drug Administration (FDA), the approvals of which are used as reference in many developing countries.

Regarding TOSSD Pillar I – cross-border flows to developing countries – Marco Schäferhoff emphasised the importance of better capturing South-South flows, and expressed a preference for including support for IPGs in recipient countries in Pillar II.

Marco Schäferhoff emphasised the importance of increasing the coverage of South-South providers in international statistics. He mentioned, for example, the important support that India provides to African countries in the area of health. He also supported the inclusion of official mechanisms to mobilise private finance for developing countries.

In terms of the delineation between Pillar I and Pillar II, Marco Schäferhoff expressed a preference for including cross-border support for IPGs (e.g. pandemic preparedness) in Pillar II rather Pillar I. For example, donors' contributions to the fight against the Ebola crisis in Western Africa should be viewed first as a GPG because a further outbreak of the epidemic would have had negative consequences for all.

6.11. The perspective of experts from the Centre for Global Development

The Centre for Global Development (CGD) is a global think tank that "works to reduce global poverty and improve lives through innovative economic research that drives better policy and practice by the world's top decision makers". One of CGD's specialist areas is global health policy. Interviews were carried out with several experts from the CGD.[109]

The CGD brought a health expertise that is very relevant to the TOSSD discussion on IPGs through two different angles: global health security and pandemic control. The Centre has developed a new measure of Commitment to Global Health[110] as part of its Commitment to Development Index (CDI).[111] In addition, the CGD, along with Bruegel, have formed the Project Team of the new G20 high-level independent panel on the financing of global commons for pandemic preparedness and response (PPR),[112] and led in particular on the drafting of the Panel's report.

TOSSD would fill a key data gap if it provided a comprehensive picture of public funding for global health.

The experts from CGD mentioned the difficulty in accessing reliable and comprehensive data on public financing for global health, including on pandemic preparedness. They highlighted that currently the data are either missing or highly disparate and fragmented, with different sources using different methodologies and approaches. TOSSD would make a major contribution to the international health policy discussions, in particular at the monitoring level, if it was able to provide comprehensive and comparable data on public funding for global health.

Regarding the TOSSD R&D criteria (see Box 4.2), **the CGD told us that while they can be relevant for promoting access to health technologies in developing countries, a less restrictive approach may be better for incentivising more spending on health R&D.**

The interviewees acknowledged the problem of inaccessible health technologies in many developing countries. One of the four health-related indicators included in the Commitment to Development Index aims to measure the extent to which national policies promote access to medicines through trade agreements and restrictions on intellectual property rights.[113] They were supportive of the principle of open access and acknowledged the need to promote IP policies, such as non-exclusive licensing, that maximise the public benefit, and funding schemes, such as advance market commitments (AMC), that aim to address market failures.[114]

However, CGD experts also emphasised that in order to encourage a virtuous cycle with incentives for countries to spend more on health R&D, a less restrictive approach for counting R&D may be needed. In addition, access to medicines can be encouraged through channels other than R&D policy, for example

[109] Including Masood Ahmed, President of the Board of Director; Ian Mitchell, Senior Fellow and Director of Development Cooperation in Europe; Amanda Glassman, Executive Vice President of CGD and expert in health financing; and Beata Cichocka, Research Assistant focusing on the Commitment to Development Index.

[110] See https://www.cgdev.org/page/about-cgd.

[111] See https://www.cgdev.org/cdi#/.

[112] See https://pandemic-financing.org/.

[113] The other three health-related indicators include global health security, financing for international organisations, research and development. In the forthcoming CDI, a new health component will be added which will add indicators on vaccination rates; international health cooperation and export restrictions on food and medical goods.

[114] For example, to incentivise investments in COVID-19 R&D in the initial phase² of the pandemic, the CGD made a proposal that includes an AMC mechanism, the requirement for product developers to "license their vaccines out to generic producers at low or zero cost" and the application of differential pricing schemes (Silverman et al., 2020[67]).

through procurement. They recommended tracking equitable access policies rather than mandating them as a strict eligibility criterion.

The interviewees recommended including in the TOSSD measure other domestic and international expenditures that contribute to health security and pandemic preparedness, although they stressed some definitional challenges.

They recommended including broad coverage of international health co-operation (e.g. international health regulation, international health surveillance), although expenditure may be captured already in ODA and/or the financing of international organisations. Coverage should also align with the definition of pandemic preparedness and response proposed by the G20 high-level independent panel, or other international processes that become codified.

The interviewees particularly supported the inclusion in TOSSD Pillar II of certain domestic expenditures that contribute to both global health security and global pandemic preparedness, with positive spill overs globally. This included surveillance and detection networks and disease prevention capabilities such as immunisation. Other areas of domestic action relative to global public goods would be with reference to the fight against anti-microbial resistance (one of the dimensions covered in CGD's global health security indicator).

Finally, the interviewees highlighted a range of definitional issues surrounding the above categories, as well as the value of common standards in addressing policy action and expenditure (for example on the consistent measurement of antibiotic use in animals between countries).

They also noted that a widely accepted and robust measure of "international public good" expenditure by countries that covered global health alongside things like R&D and peacekeeping, could be an important measure of international effort that would be distinct from but complement ODA.

6.12. Wellcome Trust, one of the major global philanthropic organisations specialised in health

The Wellcome Trust is one of the largest global charitable foundations. It is focussed on health research. An interview was carried out with Alice Jamieson, Senior Policy & Advocacy Advisor; Chloe Watson, Global Policy & Advocacy Advisor; and Richard Hartlaub, Policy Officer.

The Wellcome Trust experts thought that TOSSD should track the contributions of private foundations given their major contribution to the SDGs, in particular in the health sector.

Most philanthropic actors explicitly aim to contribute to the SDGs. The contribution of private foundations is particularly powerful in the health sector, with funding amounts often larger than a number of governments, notably in health R&D. Therefore, it would make sense to track the funding provided by philanthropic foundations in TOSSD, even if in a separate or satellite indicator. It would be useful to distinguish between international and country-specific foundations or between the different financial instruments, e.g. non-returnable grants or equity investments.

Regarding the general definition of TOSSD Pillar II – financing of IPGs – the Wellcome Trust experts questioned whether IPGs should focus on developing countries or be conceived from a global perspective. They confirmed, as other experts, that forecasting the benefits in developing countries is likely to be very challenging. Rather than specifically focusing on developing countries, there needs to be a space for research for developing and developed countries' needs, such as a universal flu vaccine, antivirals and COVID-19 products. For example, ODA budgets that only cover activities that address health needs in developing countries are not sufficient to properly address the COVID-19 pandemic, and there is a need to incentivise more international co-operation and measure these contributions. In general, it

remains extremely challenging to mobilise support for IPGs – this could be improved by defining IPGs more broadly, which would ensure that they include more diseases that rich countries tend to care about.

The Wellcome Trust experts told us that TOSSD criteria for R&D funding are relevant, but advocated for an eligibility approach based on principles rather than strict criteria to accommodate the different types of funding, products and organisations that can be involved.

The experts pointed out that research funding data is annually published on Wellcome Trust's website. The foundation seeks to address barriers in the market for products that do not seem to have great commercial potential but that are nevertheless important, e.g. the Ebola vaccine or antibiotic innovation.[115]

They found the TOSSD criteria for R&D relevant and made some suggestions. They supported the inclusion of basic research in TOSSD as it is a principle requirement for innovation for sustainable development.

Regarding the criterion of "open access" to scientific publication and research data, the experts suggested broadening the category to include all the outputs of research, which may include data, but also original software or materials such as cell lines. The Wellcome Trust has long been a champion of open access. It is a condition of all their grant funding and extends beyond publications to include, for example, data, software, and materials.

Regarding the development of health technologies, the Wellcome Trust has published its own "approach to equitable access to healthcare interventions".[116] The experts emphasised that it is difficult to prescribe a one-size-fits-all model that promotes equitable access in developing countries as this depends on the stage of the research and the context. Different models and approaches may be needed for different product areas and geographies. Therefore they recommended following a flexible and principle-based approach that could draw on the following principles:

- Availability: Will the recipient take appropriate steps to ensure funded developments reach the markets most in need (e.g. ensuring products are registered in countries that need them, not just available for the travellers' market)?
- Affordability: What steps will the funding recipients take to ensure that funded developments are affordable to those most in need (e.g. pricing strategies, licensing of IP)?
- Appropriateness: Are the recipients considering how to ensure that the funded development is suitable for the setting in which it is intended to be used (e.g. does it require cold-chain storage, how many doses, how is it administered)?

The Wellcome Trust's approach to access is guided by its equitable access statement. It uses the principles within this statement and a range of tools to ensure products whose development it supports stand the best chance of reaching those who need them. These tools are tailored to the nature of the funding, products, stage of development and organisations involved, and include a mix of contractual mechanisms (e.g. strategies that reflect ability to pay) as well as ensuring that IP rights are applied appropriately to deliver public health benefit.

The Wellcome Trust is supportive of the role transparency can play in promoting equitable access and has highlighted the need for greater transparency around the steps taken by funders of R&D to support access, including on access conditions attached to public funding.

[115] See https://wellcome.org/news/were-backing-amr-action-fund-what-it-means-antibiotic-innovation

[116] See https://wellcome.org/what-we-do/our-work/access-healthcare-interventions/wellcomes-approach-equitable-access-healthcare-interventions.

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