Evaluation of WHO's Normative Function

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Acronyms

ARV	Antiretroviral
CO	WHO Country Office
DFID	UK Department for International Development
DG	Director-General
EB	Executive Board
EML	List of essential medicines
FAO	Food and Agriculture Organization of the United Nations
FCTC	Framework Convention on Tobacco Control
GACC	Global Alliance for Clean Cookstoves
GAVI	Global Alliance for Vaccines and Immunization
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit
GPW	General Programme of Work
GRADE	Grading of Recommendations, Assessment, Development and Evaluations
GRC	Guideline Review Committee
HQ	Headquarters
ICMR	The Indian Council for Medical Research
INNs	International Nonproprietary Names
IRIS	Institutional Repository for Information Sharing
JPMS	Joint Programme Monitoring System (UNAIDS)
MS	Member States
NTD	Neglected Tropical Disease
QA	Quality Assurance
RO	WHO Regional Office
ToC	Theory of Change
UNEG	UN Evaluation group
USAID	United States Agency for International Development
WHA	World Health Assembly

Executive summary

Background and purpose

WHO was established as a specialised agency with the authority to adopt and approve normative instruments[1]. The Twelfth General Programme of Work of WHO (2014) specifies that, in its normative and standard-setting work, WHO is a science- and evidence- based organisation with a focus on public health. However, the term normative is not used in the WHO Constitution. The lack of a clear defining framework has posed problems in explaining and evaluating WHO´s normative function.

This report is the result of one evaluation in two phases. The first phase of the evaluation set out *"to review and develop a clear framework for defining aspects of normative work"*. During the first phase of the evaluation, four options for defining the normative work of WHO were identified: (i) a legal perspective, with normative products being those endorsed by the World Health Assembly; (ii) a policy process perspective, where normative is seen as both a product and a function; (iii) a global public goods perspective, with normative being understood as global functions of salience to all Member States; and (iv) a combined perspective, with a differentiation between core normative instruments and supportive normative functions. The combined perspective was the preferred option because it combines all the established legal instruments, Secretariat guidelines and other non-normative products (e.g. health trend assessments) with the execution of normative elements in all the core WHO functions.

Normative instruments include "products" encapsulating normative content in a written document, and functions, i.e. steps and activities in a normative process or in policy-making in general.

There are two broad groups of normative instruments: (i) conventions, regulations and recommendations endorsed by the World Health Assembly (WHA) or adopted by an equivalent body (e.g. Codex Alimentarius Commission); and (ii) a broad range of normative guidelines prepared by the Secretariat[2]. They are all placed on a continuum from the most to the least binding – from examples of international law to guidelines and recommendations.

This second phase of the evaluation focused on analysing selected normative products and the overall purpose was to provide recommendations for strengthening WHO´s normative function. The objective was not to assess the technical content of individual normative products, but to analyse and explore if, how and why they have played a role and contributed to a normative process and towards fulfilling WHO's normative function. The evaluation aimed to provide feedback and learning opportunities for the Secretariat and Member States. The exploration and analysis were guided by two broad questions:

- How to define WHO´s normative function in each of the products?
- What factors determine strength and effectiveness of the normative products?

The evaluation followed ten normative products from their initiation and design to dissemination and incorporation at country level.

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[1] The Organisation's primary function is defined as acting as the *"directing and co-ordinating authority on international health work".* Article 2 of the Constitution of WHO presents a list of twenty-two functions to assist WHO in fulfilling its objective (Article 1).

[2] All referred to as "normative products" in this document.

Sample of normative products

A sample of normative products was purposively selected and limited to ten, covering all the five relevant categories in WHO´s Programme Budget 2014 – 2015: (a) Communicable diseases, (b) Noncommunicable diseases, (c) Promoting health through the life course. (d) Health systems and (e) Preparedness, surveillance and response. As such, the sample of products has a broad coverage and varies significantly in form and substance.

1. Global health sector strategy on HIV/AIDS
2. Guidelines on the use of anti-retroviral medicines for the treatment and prevention of HIV infection
3. Roadmap for neglected tropical diseases
4. Global mental health action plan
5. Maternal, infant and young child nutrition comprehensive implementation plan
6. WHO Guidelines for Indoor Air Quality: Household Fuel Combustion
7. WHO Global Code of Practice on the International Recruitment of Health Personnel
8. WHO Model List of Essential Medicines (EML)
9. International Nonproprietary Names (INN)
10. International food standards developed and adopted by the Codex Alimentarius Commission

Methods

Three complementary methods were used for collecting data and information – document review, interviews and surveys among WHO staff and external stakeholders. No country visits were carried out so findings on country impact are limited.

Selected findings and conclusions

- There is a need to define what constitutes a normative product and function. It would be easier to limit normative to products, but functions add value in explaining WHO characteristics.

- The evaluation has analysed a broad variety of normative products of high technical quality reflecting the international norm- and standard-setting function of WHO. Some of the programmes are small, and not always well known either within or outside the Organisation, but represent and reflect core WHO functions.

- The preparation of normative products is not based on systematic analysis and assessment of needs and demands within WHO – resulting in a corporate plan defining in what areas normative guidance is needed. No decision is taken on what should be prioritised and how many normative guidelines should be produced within a given time period.

- The understanding of WHO´s normative function in the ten case studies and among people interviewed varied greatly. There was not one decisive variable, but a mix of contributing factors that influence relevance and effectiveness.

- Who initiated the normative process (extent and source of demand) was found to be important, but not in all cases. For at least two normative products, relevance and effectiveness were the results of perceived global usefulness (INN and EML) rather than strong partner and/or country demand. The best example is the INN Programme. Since its inception, the aim has been to provide health professionals with a unique and universally-available designated name to identify pharmaceutical substances. It originates from WHO´s core constitutional mandate and is a headquarters- and expert-driven normative activity – producing an international "public good" in which WHO´s mandate is not contested.

- The consultations leading up to a product were important, but again this was not true in all cases. The strategy, technical guidelines and roadmaps/implementation plans were all the

result of extensive internal and external consultations with stakeholders. It was not possible to quantify volume and assess quality of consultations, but the case studies illustrate serious intent and commendable practice in requesting feedback and involving stakeholders in consultative processes. However, the INN and EML are more headquarters- and expert-driven programmes that do not involve consultations with a broad group of external stakeholders in the development of the product, but rather with experts to ensure scientific rigor. Feedback from stakeholders is requested before approval. For those normative products, there is no correlation between high level of consultation and participation in design and their importance and impact.

- The ten case studies indicate that the more scientific-and evidence-based products have a higher, more direct effectiveness (level of knowledge, uptake and incorporation) than those with a stronger legal/formal backing and providing broader policy guidance. Higher levels of quality of evidence were as such associated with increased uptake in national guidelines. The two technical guidelines, the INN and EML, are based on WHO´s role as a scientific and evidence-based Organisation. Their effectiveness is not so much founded on formal status, but on WHO´s legitimacy and scientific authority and the technical quality of the products. The Global Code of Practice on the International Recruitment of Health Personnel is presented more as a political document despite the fact that it is underpinned by a substantial body of evidence. Its effectiveness was found to be mixed – partly because the objectives are long-term and complex to achieve. The strategy, roadmap and action plans have evidence-based technical elements, but serve another purpose than the technical guidelines.

- In terms of formal status, the two most "powerful" products in the sample are the Codes – the norms and standards from Codex Alimentarius Commission and the Global Code of Practice on the International Recruitment of Health Personnel. They are examples of constitutional "soft laws". The Global Code is an agreement approved by the World Health Assembly. The "strongest" and in practice most binding normative products are the INNs and the food safety and quality norms and standards, including food labelling standards, defined by Codex Alimentarius Commission. The INNs and the food safety and quality norms and standards are advisory but when used and adopted they often become mandatory in national or, as in the case of the European Community, international legislation.

- The report discusses how WHO implements normative products to ensure that they are followed. The Organisation has few tools and strategies for supporting the implementation of norms and standards after they are formulated and presented in a report. There is no legal power whereby WHO can order implementation and ensure compliance. Furthermore, there are seldom any additional resources and incentives for actors in the system to design interventions according to the strategies or guidelines. In most cases, external partners are motivated to act according to the guidance based on WHO´s credibility, awareness-raising and through information sharing.

- In all the ten cases, there was a stronger focus on the preparation, design and formulation of the normative product than on dissemination and follow up – having a negative impact on effectiveness. Dissemination and follow up were not ignored, but more time, resources and attention were dedicated to preparing a high-quality product than on the former. There is also limited data and information available on the actual level and effectiveness of dissemination and use. Most of the publications were not based on a "theory of change" – articulating what was required to initiate change - and consequently there were no systematic and comprehensive plans for promoting change and reform.

- All ten normative products provide evidence of results, but results are exceptionally varied. With few independent evaluations available, the documentation of results depends on

internal reviews and self-reporting. Given the lack of structured and systematic monitoring and independent evaluation of implementation, more results may actually have been achieved than those documented.

- Presenting figures and changes in global targets is the most common form of monitoring – based on global indicators. There is less monitoring of processes for implementing the normative products. Aggregate data provide useful information on overall trends, but changes in global figures can only exceptionally be attributed to a normative product.

- There is a major difference in effectiveness and documentation of results between normative products requiring "significant" and "complex" change, involving transformations in global and national health policies and practices, and those promoting "simple" technical changes and "incremental" reforms. Those with a high level of complexity have the greatest difficulty to document effectiveness. The concrete and evidence-based recommendations in the anti-retroviral guidelines can more easily document a high level of implementation and incorporation in country policies.

- The Global Code of Practice on the International Recruitment of Health Personnel is on the other side of the continuum. It is not only about a disease or the health sector, but about the politically sensitive issue of international migration – a multi-sectoral issue that goes beyond the health sector and, as such, long-term results are much more difficult to measure. However, the Global Code has in place a system for monitoring intermediate outcomes.

- Detailed costs of preparing the normative products were not available for the cases studied. Voluntary funding was made available in two of the cases (according to available information) and mostly from bi-/multi-lateral donors. In most of the cases, the work was carried out with internal staff and financial resources. There was limited funding for follow up and implementation of the normative products.

- There is no single and simple answer to what determines strong and effective normative products. There are lessons to learn and share, but each case requires its own "theory of change" and a strong implementation plan. It should also be emphasised that other explanatory factors could have been included in the analysis, such as, for instance, type and level of managerial support to normative processes and products. Several of the people interviewed referred to a lack of recognition, low visibility and weak senior-level support to WHO´s normative programmes and activities.

Recommendations
1. WHO should prepare a policy paper defining its normative instruments (normative products and functions). It should also prioritize and prepare stronger and more effective normative instruments. This could mean fewer publications but, even more importantly should include an active deliberation of how to ensure their normative strength and effectiveness.

2. Normative instruments could be defined as follows:
   - **Core normative products** are international public goods. Such products are per definition global, but the regional and country levels play important roles in their preparation, validation and application. There are several categories of normative products, each with its own characteristics:
     o *Constitutional normative products* – conventions/regulations/regulatory recommendations approved by the World Health Assembly or by an equivalent body (e.g. Codex Alimentarius Commission). Such products vary in form and substance. They are sometimes binding legal instruments. WHO adopts the normative products via its constitutional authority.

- o *Scientific and technical normative products* – norms and standards set by the Secretariat for a broad range of thematic areas, based on scientific evidence and advice from leading technical experts.
- o *Health trend assessments* such as the annual World Health Statistics, Global Burden of Disease, Risk and Injury, World Malaria Report, Maternal Mortality, Countdown 2015, etc. (international public goods).

- **Supportive normative functions** – normative elements of WHO core functions.

3. WHO should also prepare a plan for the development of normative products based on an assessment of demands and needs and in line with WHO´s corporate priorities for achieving a higher level of coherence between the normative products.

4. Guiding principles and agreed quality assurance procedures should be established for the design, formulation and dissemination/follow-up of all normative products. It would be appropriate if all normative products, including strategies, roadmaps and global action plans, were based on agreed standards and reviewed independently, as is the case for technical guidelines. The GRADE approach to assessing quality of evidence for recommendations could, with adjustments, be used for all normative documents – not only technical guidelines.

5. WHO should give equal attention to products and process and shift attention and resources from preparation of normative products to the entire normative processes, encompassing assessment of needs, initiation, design and preparation, dissemination and use, adaptation and incorporation in health policy and practices, feedback and learning. They should also be appropriately and adequately budgeted.

6. Normative functions in WHO should be funded through sustainable funding and not only through voluntary and more unpredictable funding. Funding of normative products exclusively through voluntary funding, including from the private sector, should be avoided.

7. Systems and plans for monitoring and evaluation should be more standardised and streamlined. There is a need to shift focus from assessing quality of normative products and their recommendations to documenting effects. High quality monitoring should be combined with independent evaluations.

8. There should be a follow up to this evaluation: (i) assessing WHO´s normative functions from a country perspective, in order to better understand how and to what extent WHO´s normative work is relevant and makes a difference in countries; (ii), assessing the global scope of WHO´s normative work in terms of size and number of normative programmes, activities and funds utilised; and (iii) assessing and analysing the actual and changing profile of what WHO does as a normative Organisation.

CHAPTER 1: INTRODUCTION

1.1. Background

WHO was established as a specialised agency with the authority to adopt and approve normative instruments[3]. The Twelfth Programme of Work of WHO (2014) specifies that in its normative and standard-setting work, WHO is a science- and evidence-based organisation with a focus on public health. WHO´s legitimacy and technical authority lie in its rigorous adherence to the systematic use of evidence as the basis for all policies. However, the term normative is not used in the WHO Constitution. The following definition was developed in the context of WHO reform (Executive Board Paper EB 130/5 Add.1):

"*The phrase "norms, standards and conventions" is used to denote a wide range of WHO's work that is informed by country needs, but that benefits countries and partner organisations collectively rather than individually. This range includes producing global health trend assessments, prequalification of medicines and vaccines, treatment protocols and legal instruments such as the WHO Framework Convention on Tobacco Control. These elements are not all "normative" in the strict sense of the word, but the term is used here as a shorthand to describe these aspects of WHO's work. The activities concerned are, for the most part, consistent with the economic definition of global or regional public goods".*

The lack of a clear defining framework has posed problems in explaining WHO´s normative function and to evaluate its normative work. This report is the result of one evaluation in two phases. The first phase of the evaluation set out *"to review and develop a clear framework for defining aspects of normative work"*. During the first phase of the evaluation, four options for defining the normative work of WHO were identified: (i) a legal perspective, with normative products being those endorsed by the World Health Assembly; (ii) a policy process perspective, where normative is seen as both a product and a function; (iii) a global public goods perspective, with normative being understood as global functions of salience to all Member States; and (iv) a combined perspective, with a differentiation between core normative instruments and supportive normative functions. The combined perspective was the preferred option because it combines all the established legal instruments, Secretariat guidelines and other non-normative products (e.g. health trend assessments) with the execution of normative elements in all the core WHO functions.

Normative instruments include "products", encapsulating normative content, and functions, i.e. steps and activities in a normative process or in policy-making in general.

There are two broad groups of normative instruments: (i) conventions, regulations and recommendations endorsed by the World Health Assembly (WHA) or adopted by an equivalent body (e.g. Codex Alimentarius Commission); and (ii) a broad range of normative guidelines prepared by the Secretariat[4]. They are all placed on a continuum from the most to the least binding – from examples of international law to guidelines and recommendations.

The evaluation defined WHO´s normative function as a combination of:
- **Core normative products** – defined as international public goods including the normative conventions, regulations, recommendations, Secretariat guidelines and health trend assessments.

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[3] WHO is an international intergovernmental organisation composed of 194 Member States. The objective, structure and legal capacities of the organisation, including its capacities to adopt and approve normative instruments, are established by the treaty upon which it is based, and it is the starting point for understanding the role of WHO in global health governance (Solomon, undated).

[4] All referred to as "normative products" in this document.

- **Supportive normative functions** – defined as the normative elements in all core WHO functions. In other words, core functions defined in the General Programme of Work have both normative and non-normative elements. This applies to all three levels: global, regional and country.

Three alternatives for an evaluation were suggested: (a) A global evaluation of WHO´s normative work, (b) a country/regional evaluation or (c) an evaluation of specific normative products or functions. In the following discussion with the Evaluation Office, it was decided to focus the evaluation on a sample of normative instruments linked to outputs and indicators in the Programme Budget 2014-2015.

This is as such a global evaluation focussing on selected normative products and processes. The sample of normative products are used to assess the entire normative process from the initiation and design of a new normative product through the formulation and approval to dissemination, adaptation, incorporation in country health policies and practices and finally feedback and learning. This is not a country-based evaluation assessing the ultimate health impact of normative work. Such an evaluation would have required a different design and approach.

1.2. Purpose and objectives for the evaluation

The overall purpose of the evaluation was to strengthen WHO´s normative function through an assessment of specific normative processes and products. The main interest and focus was to analyse and explore if, how and why they have played a role and contributed to a normative process and towards fulfilling WHO's normative function, and not to assess the technical content of individual normative products. The exploration and analysis were guided by two broad questions:

- How to define WHO´s normative function in each of the products?
- What factors determine strength and effectiveness of the normative products?

The evaluation followed the normative products from their initiation and design to dissemination and incorporation at country level. The evaluation aimed to provide feedback and learning opportunities for the Secretariat, and Member States.

The more specific objectives for the evaluation were to (evaluation criteria in brackets):
1. Assess the background, source and demand – to what extent the normative products are based on expressed needs and priorities (relevance).
2. Assess design and formulation of the normative products – to what extent criteria and standards for development of normative products in WHO as a science-based organisation are adhered to (quality, relevance).
3. Assess costs, quality and systems for quality assurance and approval – to what extent costs are reasonable, the development process has QA systems in place and products meet quality requirements (quality, efficiency).
4. Assess plans and processes for dissemination of the normative products – to what extent the products reach their intended audiences (outcome – effectiveness).
5. Assess adaptation and incorporation at country level – to what extent the normative products have been adapted to country contexts and incorporated in health policies and practices (outcome – effectiveness).
6. Assess systems and processes for feedback and learning – to what extent monitoring and evaluation have provided feedback and learning (learning, effectiveness).

The discussion of the products' normative character will be based on the analytical categories presented in Chapter 2. Different criteria for defining normative, will have implications for what products will be categorised as normative, partly normative or rather something else. The

concluding chapter seeks to summarise the discussion and recommend a classification and way forward.

The analysis of the question about normative strength and effectiveness is based on certain assumptions or hypotheses of what are the most important determining factors. From the list of objectives above, the following factors are considered important and will be discussed[5]. The list is not exhaustive and several other factors such as e.g. type and level of managerial support could have been discussed. The factors discussed are:

- Source and extent of demand for normative action.
- Process for developing the normative product and level of involvement of and consultation with stakeholders.
- Quality of the normative product.
- Level of ambition – or expected scope of change – "significant" and complex change of global policies or "simple" technical reforms.
- Normative strength – level of binding and non-binding characteristics.
- Extent of effective dissemination and reach (whether the product is available among target groups).
- Evidence of relevance and results (adaptation/incorporation/changes in practices) based on available data and information.
- Effective systems for monitoring and evaluation progress and non-compliance – reporting and enforcement mechanisms.

1.3. Evaluation framework and questions

The following model presents the phases and processes in the life cycle of a normative product and what steps and questions the evaluation covers. The evaluation will seek to identify and explore salient issues and challenges in each of the phases.
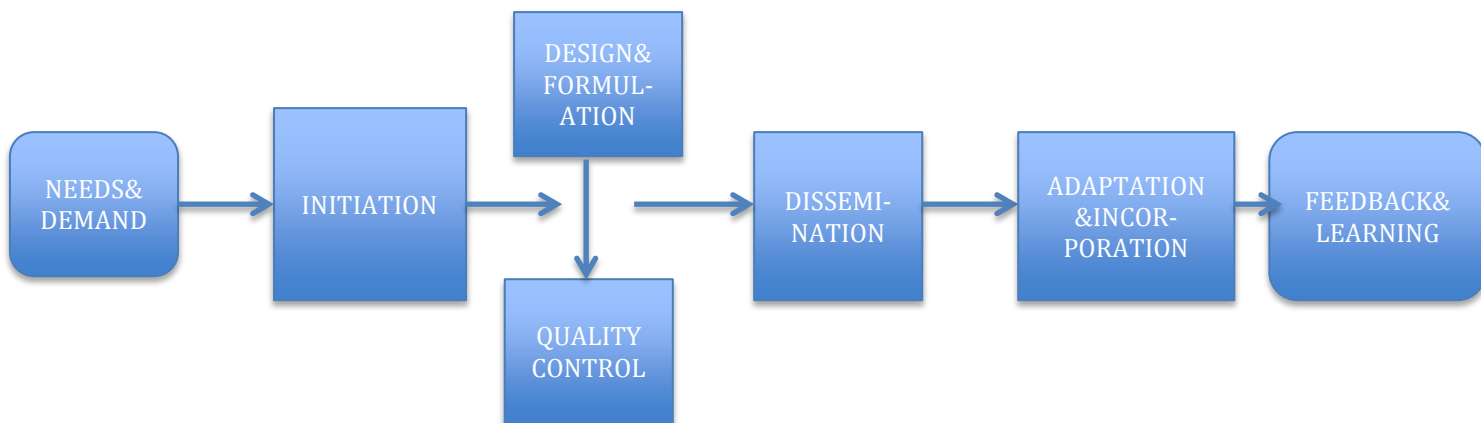
Based on a selection of normative products, the evaluation covers the following processes and questions. The case studies have tried to respond to all questions, but some questions are more relevant in certain cases and not in others.

1. **Initiation**
   - What was the demand for the normative product?

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[5] The selection of variables is influenced by strategic planning literature Bryson, J.M. (2004) Strategic Planning for Public and Not-for Profit Organizations. New York: John Wiley, and Mintzberg, H. (1994) *The Rise and Fall of Strategic Planning*. New York: The Free Press. See also Kal Raustalia (2004) Form and substance in International Agreements. UCLA Law School and Chayes&Chayes (1993). On Compliance, The MIT Press.

- Who suggested developing the normative product (Secretariat, Member States, Regional offices (RO), country offices (CO)?
- How were needs and relevance assessed before deciding that a normative product was required?
- What were the functions of Headquarters (HQ), RO, CO and Member States in the initiation phase?
- What other stakeholders had a role in this phase?

2. **Design and formulation**
   - How was the normative product prepared?
   - Who played what roles in the preparation?
   - What partnerships were established?
   - What was the level of participation by HQ, RO, CO and Member States and other stakeholders?
   - What was the cost of the product and what costs were included in the budget?

3. **Quality assurance and quality**
   - What were the QA systems and procedures?
   - What roles did external/internal experts play?
   - What dimensions/aspects of the normative products were reviewed?
   - How and by whom were the normative products approved?
   - What were the roles of HQ, RO, and CO in the quality assurance and approval process?
   - Are QA processes and approval explained in the report?
   - What is the quality of the normative product in terms of format, reader/user friendliness, presentation of evidence and recommendations? [6]

4. **Dissemination**
   - What plans were prepared for dissemination?
   - Are such plans included in the report?
   - To what extent have the normative products reached intended users?
   - Was any theory of change/dissemination strategy developed (explaining linkages between the production of the normative product and expected outputs and outcomes)?
   - How was the normative product disseminated (e.g. online, printed copies) and to whom?
   - Was any follow up planned/carried out (presentations, introductions, press releases etc.)?
   - What were the roles of HQ, RO and CO in dissemination?

5. **Relevance and results**
   - To what extent is the normative product found relevant to country needs and priorities?
   - To what extent is the normative product available and known among country partners?
   - What has been the role of RO and CO in the introduction and adaptation of the normative product?
   - What did WHO provide to country partners in terms of technical guidance, capacity building etc.?
   - To what extent has the normative product influenced or been incorporated in country health policies and practices and to the extent possible global level stakeholders (e.g. GAVI, Global Fund, UN agencies)?

6. **Feedback and learning**
   - Have the normative products and processes been systematically monitored?

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[6] Technical quality of evidence and recommendations will not be discussed – only to what extent they meet requirements for how normative products should be prepared and be presented.

- What evaluations have been carried out?
- What other feedback and learning mechanisms have been in place?
- What roles have HQ, RO and CO played in capturing the lessons?

1.4. Sample of normative products

The sample of normative products to be assessed was selected from the categories of interventions in WHO´s Programme Budget 2014–2015. The normative products are referred to in outcome and output indicators in the work plan. There are also targets – e.g. targets for how many countries that should develop national HIV/AIDS strategies in line with the global health sector strategy on HIV/AIDS. The roles and expected deliverables of country and regional offices and HQ are also specified. With such a sample, all activities identified at the indicator-level in the Programme budget should be completed and outputs delivered by 2015. As such, data and information about progress and achievements should be available in reports from the Secretariat and other available sources for monitoring programme budget implementation.

Because of constraints on time and resources for the evaluation, the sample of normative products was purposively selected and limited to ten covering all the five relevant categories in WHO´s Programme budget 2014-2015 such as: (a) Communicable diseases, (b) Noncommunicable diseases, (c) Promoting health through the life course. (d) Health systems and (e) Preparedness, surveillance and response. Preference was also given to normative products with baselines and targets in the Programme budget. As such, the sample of products has a broad coverage and varies significantly in form and substance[7].

Table 1: Sample of normative products

Normative product	Output indicator	Baseline	Target
Communicable diseases			
1. Global health sector strategy on HIV/AIDS	Number of countries that have developed and are implementing national HIV/AIDS strategies in line with the global health strategy on HIV/AIDS	-	57/57 (2015)
2. Guidelines on the use of anti-retroviral medicines for the treatment and prevention of HIV infection.	Number of countries that have adopted/adapted 2013 guidelines on the use of anti-retroviral medicines for the treatment and prevention of HIV infection.	NA	57/57 (205)
3. Roadmap for neglected tropical diseases.	Number of disease endemic countries adopting and implementing neglected tropical disease national plans in line with the road map to reduce the burden of priority neglected tropical diseases.	40/125 (2013)	100/125 (205)
Noncommunicable diseases			
4. Global mental health action plan.	Number of countries with a national policy and/or plan for mental health that is in line with the 2013-2020 global mental health action plan.	60/194 (2013)	70/194 (2015)
5. Maternal, infant and young child nutrition comprehensive implementation plan.	Number of countries that are implementing national action plans based on the Maternal, infant and young child nutrition comprehensive implementation plan.	-	-
Promoting health through the life-course			
6. Guidelines for	Number of countries that have developed new	20/194	30/194

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[7] Programmes commented that some of the output indicators were outdated or not known/used by the programme.

environmental and occupational health risks: *WHO Guidelines for Indoor Air Quality: Household Fuel Combustion (2014)*	or revised existing policies or national standards based on WHO guidelines for environmental and occupational health risks.	(2012)	(2015)
Health systems			
7. The WHO Global Code of Practice on the International Recruitment of Health personnel	Number of countries that have an investment plan for scaling up and/or improving training and education of health workers in accordance with national health needs.	30/5(2012)	35/57 (2015)
8. WHO Model List of Essential Medicines (2015)	Countries enabled to develop, or update, implement, monitor and evaluate national policies on better access to health technologies, and to strengthen evidence-based selection and rational use of health technologies.	-	-
9. International Nonproprietary Names. (Focus on 1-2 products)	Develop and support the application of global technical guidelines norms and standards, including for traditional and complementary medicines.	-	-
Preparedness, surveillance and response			
10. International food standards developed and adopted by the Codex Alimentarius Commission (1963)	Support the work of the Codex Alimentarius Commission to develop, and for countries to implement, food safety standards through the Codex Alimentarius Commission.	-	-

1.5. Methods

Three complementary methods were used for collecting data and information – document review, interviews and surveys. The steps and use of methods in the evaluation process were:

1. **Document search and review:** The evaluation started with a comprehensive search for and review of all documents related to each of the ten normative products. In addition to the normative products, global, regional and country level progress/annual/completion reports and governing body documents were also collected and reviewed[8].

2. **Document assessment:** The Inception Report envisaged a separate assessment of each normative product focusing on aspects of quality. However, this was only completed for the technical guidelines since the format was not applicable to the strategies, roadmaps and action plans. The two evaluators read all reports and agreed on the scoring.

3. **Secretariat interviews:** Meetings and interviews with WHO staff involved in the preparation and implementation of the normative products obtaining feedback to the entire list of evaluation questions.

4. **Regional/country feedback:** Feedback was collected from a sample of country/regional offices and external partners through an online survey and/or by using existing data and information. The questions focused on their involvement in the preparation of the normative products and assessment of relevance, adaptation and incorporation.

5. **Selected Skype/telephone interviews:** Interviews were conducted with a sample of external stakeholders identified for each normative product[9].

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[8] Annex 3: References
[9] Annex 2: People interviewed

1.6. Methodological challenges and limitations

This evaluation of normative work was challenging for several reasons:

- Data and information was not consistently available for answering all evaluation questions, such as for instance, costs, participation, dissemination, etc. The response from staff and stakeholders to requests for information and interviews was also variable.
- The evaluation did not include visits to countries and was dependent on desk studies and feedback from interviews with stakeholders.
- The sample of normative products was heterogeneous. This evaluation included only a sample – making a comparative assessment difficult.
- The normative products are different in length, design and substantive content. As such, it is difficult to assess the products based on similar criteria.
- There are multiple determinants for outcomes of any normative product, e.g. when a national government adopts a health policy or a new treatment practice. There is no direct causal link between WHO´s normative guidance and intended outcomes.
- Normative work involves both products and processes in which the end result follows from successful processes, e.g. when building consensus for a global standard or strengthening political will for the implementation of an international norm.
- Normative work takes a long time to show long–term results (impact). Several of the normative products in the sample are prepared in recent years. Impact is rarely visible within the timeframe of an organisation´s programme cycle. Hence, focus remains on outcomes and contribution of normative products to outcomes.

Re: Survey questionnaires and interviews

In addition to telephone interviews, online survey questionnaires were sent out, targeting relevant stakeholders in 6 of the 10 cases [10]. This was a useful method to collect data and to gather wider perceptions beyond WHO staff. The implementation of the survey was through the online survey tool called Survey Monkey. This helped to ensure that the invitation email to complete the survey guaranteed anonymity and that responses were handled securely.

Stakeholder lists were provided from WHO departments, some of which consisted of RO/CO staff, others included external stakeholders (UN organisations, NGO´s research institutes etc.). It was important to reflect a cross-section of stakeholders, but the team was also reliant on each WHO department selecting a sufficient number of, and the most relevant, people.

It was not feasible within the limitations of this assignment to collect data through surveys from all ten cases, in some cases it was more suitable to conduct telephone interviews. Further, some WHO departments provided contact lists at a late stage, which limited the time frame in the data collection phase.

Gaining access to people for Skype interviews proved difficult in some cases. The response was varying, quite a few did not respond to our requests (both WHO staff and external stakeholders). The response rate to the survey questionnaires was overall relatively good (after 2 and 3 reminders), but for a few cases it was lower (e.g. HIV and Indoor air quality guideline). Possible explanations for this may be that surveys are perceived as more convenient and flexible/time effective than organising a phone interview.

The questionnaires were tailored to each stakeholder group. In one case (HIV guidelines/strategy), the population of stakeholders was so large that a small, but carefully chosen, sample was used. Otherwise, the team reached out to all stakeholders on the lists

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[10] Notably for: Mental Health Action Plan 2013-2020, International food standards developed and adopted by the Codex Alimentarius Commission, NTD Roadmap, ARV guidelines/HIV strategy, Comprehensive Implementation Plan on maternal, infant and young child nutrition and Guidelines for indoor air quality.

provided (from all departments), either via requests for Skype interview or via survey questionnaires.

The survey questionnaire included quantitative, but mostly qualitative questions (with opportunities for the respondent to provide open-ended responses). It sought to measure the relevance, demand, quality and dissemination of the normative products, but also qualitative aspects and perceptions regarding the products and potential use, expected results.

The response rate for the questionnaires was relatively good, in most cases more than 50% response rate[11]. Marketing Companies estimate that for general surveys of medium length, the response rates tend to be lower than 10 percent when there is no "invitation incentive", i.e. incentive to answer[12]. Low response rate may indicate that respondents do not feel obliged to answer, or they are not interested or involved. Extending upon the argument, if they consider it useful and relevant, it will be important for them to reflect this by providing feedback (via an online survey/interview).

It is worth noting that survey and interviews measure people´s opinions and perceptions about what has happened and is likely to happen. Such information is useful and important, but the subjective dimension of the response has its limitations.

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[11] Total response rate for survey questionnaires: Mental Health: 61,5%, Codex: 70%, Nutrition: 55%, Indoor air guideline: 33%, NTD: 22%.

[12] See for example: "Survey response rates", Peoples Pulse; http://www.peoplepulse.com.au/Survey-Response-Rates.htm

CHAPTER 2: DEFINING WHO´S NORMATIVE FUNCTION

2.1. Understanding what is normative

As mentioned before, the term normative is not used in the WHO Constitution. However, WHO was established as an intergovernmental organisation with the authority to adopt and approve normative instruments. The Organisation's primary function is defined as acting as the *"directing and co-ordinating authority on international health work"*. Article 2 of the Constitution of WHO presents a list of twenty-two functions to assist WHO in fulfilling its objective (Article 1). It specifies three types of legal instrument which can contribute to the achievement of the objective: conventions and agreements; regulations; and recommendations.

The Eleventh General Programme of Work (2006–2015) refers to WHO´s Core Functions (reaffirmed in the current Twelfth General Programme of Work (2014–2019):

(a) Providing leadership on matters critical to health and engaging in partnerships where joint action is needed.
(b) Shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge.
(c) Setting norms and standards, and promoting and monitoring their implementation.
(d) Articulating ethical and evidence-based policy options.
(e) Providing technical support, catalysing change, and building sustainable institutional capacity.
(f) Monitoring the health situation and assessing health trends.

There are normative elements in the above functions as will be explained later.

2.2. Normative instruments, products and functions

When trying to define "normative", it is useful to clarify what is meant by normative *instruments, products* and *functions*. Instruments refer in most cases to "products" encapsulating normative content. However, they also include functions, i.e. steps and activities in a normative process or in policy-making in general. In other words, the term normative refers to and covers both products and processes. The aspiration is to make the two lists as comprehensive as possible. This may help to understand where differences of opinions and disagreements are and provide a basis for reaching consensus or at least an agreement of how normative work should be understood. The difference of opinion depends to a large extent on the choice of a "narrow" or "broad" choice of instruments, but also on conflicting views on what products and functions are truly normative. The evaluation explored such issues and questions.

Normative products

There are two broad groups – those normative products (conventions, regulations and recommendations) endorsed by the World Health Assembly or adopted by an equivalent body (e.g. Codex Alimentarius Commission) and on the other hand normative guidelines prepared by the Secretariat. They are placed on a continuum from the most to the least binding – from examples of international law to guidelines and recommendations[13]. As a universal public health agency, WHO was granted extensive powers in its Constitution to set health related norms and standards. The Constitution provides for three legal instruments:

(a) Conventions – adopted by the World Health Assembly with respect to any matter within the competence of the organisation. The only international convention adopted so far has been the WHO Framework Convention on Tobacco Control (FCTC). Conventions fall

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[13] "It is useful to visualise these norms as a spectrum, ranging from treaties legally binding on those states that ratify them to broad, largely rhetorical goals" (Sills 2002).

under Article 19 in the Constitution, are legally binding instruments for all Member States and require a two third majority in the WHA to be decided.

(b) Regulations – adopted by the World Health Assembly under Article 21 and 22 of the Constitution in five specific areas designed to prevent the international spread of disease. They enter into force for all Member States by a specified deadline, except for those members who either reject the regulations or file a reservation. WHO has adopted two regulations: The International Health Regulations and the International Classification of Diseases.

(c) Regulatory recommendations – adopted by the World Health Assembly as recommendations and non-binding standards such as "codes" being the most formal manifestation of WHO´s "soft law": The International Code of Marketing of Breast-milk Substitutes, the Global Code of Practice on the International Recruitment of Health Personnel and Codex Alimentarius – a joint programme between WHO and FAO and a broad range of global strategies, such as the Global Health Sector HIV/AIDS Strategy, Malaria Control Strategy, etc. [14]

The second large group and by far the largest group– which is not endorsed by the World Health Assembly - consists of all guidelines and standards developed by the Secretariat based on a general grant of authority by the Governing body. *"A WHO Guideline is any document developed by WHO containing recommendations for clinical practice or public health policy. A recommendation tells the intended end-user of the guideline what he or she can or should do in specific situations to achieve the best health outcome…(…..)..Guidelines are the fundamental means through which the Organisation fulfils its technical leadership role in health"* (WHO Handbook for Guideline Development 2014). The number of conventions, regulations and regulatory recommendations are relatively few, while the Secretariat with support from committees of independent experts prepares each year a large number of technical guidelines and normative products in all areas relevant to WHO (approx. 50 per year).

To what extent are there other normative products?
(a) **Joint normative products:** There are examples of guidelines developed in collaboration with external organisations. International food standards developed and adopted by the Codex Alimentarius Commission is such a joint guideline between FAO and WHO and is also a normative product for WHO. A guideline produced by an external organisation with technical contributions from WHO should not be classified as a WHO normative product. It is a minimum requirement that the guideline is prepared jointly and adheres to basic principles for WHO guidelines.

(b) **Resolutions adopted in the Governing bodies of WHO:** WHO resolutions are not considered binding decisions in a strict international legal sense, but they often have considerable force, as well as specific requirements, as an international political matter, especially when constituted as "strategies" or "codes" (Solomon undated). However, the content of the resolutions varies according to the nature of approval sought, and usually addresses different stakeholders – be it Member States, partners and the Secretariat.

(c) **Global health trends assessments:** Examples are the annual World Health Statistics, Global Burden of Disease, Risk and Injury, World Malaria Report, Maternal Mortality, Countdown 2015. Strictly speaking, such reports are mainly descriptive – not normative. The normative

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[14] The term "code" describes a more complex health-related recommendation and has only been used twice in WHO´s history. It appears to be reserved for matters of relatively greater political relevance than "strategies". In contrast to Codes, WHO has approved strategies on a large number of health matters since 1948.

element from WHO´s perspective could be the development of standards, protocols, systems and channels for global reporting that allow for comparative analysis between countries and regions. However, such outputs are international public goods – even if they are not normative – an issue to be discussed later.

Documents not considered normative are (Handbook for Guideline Development 2014):
- Documents that state established principles (e.g. WHO Constitutional issues, human rights).
- WHO Secretariat reports and other papers submitted to the Governing bodies.
- Information documents that report facts, describe evidence or document or review existing practices and interventions.
- Documents containing standards for manufacturing health technologies, such as pharmaceuticals and vaccines.
- "How to" documents such as operational manuals or implementation guides and tools.
- Documents that describe standard operating procedures for organisations and systems.

A more complex issue is to what extent all normative products are in fact normative – or is it only those that meet scientific criteria and standards – given that WHO is a science- and evidence-based organisation? There is for instance a huge difference in the sample of normative products between strategies/roadmaps/actions plans on the one hand, and the technical guidelines on the other. A radical solution would be to narrow down basic WHO normative products to conventions, regulations and recommendations passed through the World Health Assembly. Or, as an alternative, limit WHO´s norm- and standard-setting role only to include evidence-based guidelines (prepared according to strict quality criteria/procedures and cleared by the Guideline Review Committee). The evaluation studied the alternatives based on the analysis of the ten case studies. The table provides a summary of normative products:

Table 2: Types of normative products

	Products	Examples	Characterics
WHA based	1. Conventions	Framework Convention on Tobacco Control (2005)	Falls under Article 19 in WHO´s Constitution Legally binding instruments Require two thirds majority in WHA
	2. Regulations	The International Health Regulations (1956) International Classification of Diseases	Falls under Article 21&22 in WHO´s Constitution Legally binding instruments Require simple majority in WHA Member States may opt out in advance Limited to five areas: (a) Sanitary and quarantine requirements (b) Nomenclatures with respect to diseases, causes of death and public health practices (c) Standards with respect to diagnostic procedures (d) Standards with respect to safety, purity and potency of biological and pharmaceutical products (e) Advertising and labelling of pharmaceutical products.
	3. Regulatory recommen-dations	Codes, strategies or plans of actions such as: - International Code of Marketing of Breast Milk	All matters within WHO´s competence Codes reserved for matters of greater political significance (used only twice) Adopted more than 20 strategies

		Substitutes (1981) - Global Code of Practice on the International Recruitment of Health Personnel (2010) - Codex Alimentarius (food standards) (1963) - Global Strategy to Reduce the Harmful Use of Alcohol - Global Immunisation Strategy - Malaria Control Strategy	Presented as WHA resolutions Require simple majority Not legally binding Falls under Article 23 in WHO Constitution
Secre-tariat based	4. Scientific and technical normative products	Technical guidelines and standards on e.g. immunisation, safe motherhood, financing, malaria, etc. List of essential medicines Guidelines to prequalify medicines	Presented by the Secretariat Based on WHO´s scientific/technical credibility Non-binding instruments
	5. Health trends assessments	Annual World Health Statistics, Global Burden of Disease, Risk and Injury, World Malaria Report, Maternal Mortality, Countdown 2015, etc.	Descriptive – not normative, but public goods of benefit to all countries

Normative functions

Normative functions refer to processes and imply that normative work covers more than products. A guideline or strategy do not exist in a vacuum, but are developed and used in an iterative process with partners, regional and country realities. However, what functions are normative? The choice is again between a broad definition – including the entire policy process or a narrower focus on selected functions. There are basically three steps or phases in any policy process:

(a) **Problem identification** – in which WHO identifies trends, anticipates and analyses health problems based on scientific knowledge and research.
(b) **Policy formulation and development** – in which WHO translates experience and insights into normative instruments - recommendations and guidelines.
(c) **Policy implementation and follow up** – in which WHO disseminates and advocates for agreed norms and standards, supports adaptation and capacity strengthening in countries and monitor implementation.

WHO seems to limit "normative" to the second phase or function – to the formulation and production of normative products, e.g. regarding the definition of normative:

"The phrase "norms, standards and conventions" is used here to denote a wide range of WHO's work that is informed by country needs…… This range includes producing global health trend assessments, prequalification of medicines and vaccines, treatment protocols and legal instruments such as the WHO Framework Convention on Tobacco Control".

By contrast, the UN Evaluation group (UNEG 2013) uses the following definition:

> *"Normative work in the UN is the support to the development of norms and standards in conventions, declarations, regulatory frameworks, agreements, guidelines, codes of practice and other standard setting instruments, at global, regional and national level. Normative work may also include support to the implementation of these instruments at the policy level, i.e. their integration into legislation, policies and development plans".*

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This definition combines the notion of developing instruments for the collective benefit of countries with the technical support needed for implementation into a single value chain. Linking normative to the formulation of normative products, is simple and intuitive. However, such a formal definition excludes what others perceive as normative and may leave an impression of normative as exclusively a global function – detached from regional and country influence and involvement. A normative process is more dynamic and iterative. A middle way is to argue that each step in the policy process contains normative elements – to a smaller or larger extent. From such a perspective, it is not sufficient to focus on the middle phase – the formulation of norms and standards. What is occurring in the preparatory and follow up phases is not empty of normative substance.

Overarching roles and functions of the three levels of the organisation have been developed (Report of the Task Force 2012). The functions are not corresponding directly to the phases and steps in the policy process (identification, formulation and implementation), but represent what WHO has used in the 11th and 12th General programme of Work and are as such more relevant. There are normative elements in each of the core functions.

1. Providing leadership on matters critical to health and engaging in partnerships where joint action is needed.
2. Shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge.
3. Setting norms and standards, and promoting and monitoring their implementation.
4. Articulating ethical and evidence-based policy options.
5. Providing technical support, catalysing change, and building sustainable institutional capacity.
6. Monitoring the health situation and assessing health trends.

- **Providing leadership on matters critical to health:** Providing leadership per se is not normative, but becomes normative when linked to promotion and advocacy for global norms and standards. WHO leadership plays also a role in defining the need and agenda for new normative instruments. Again, it is a matter of choice whether to call substantive leadership on such issues normative or not.

- **Shaping the research agenda:** Research is in itself not normative or prescriptive – rather the opposite – because of its inherent and continuous search for new and alternative answers and hypotheses. However, there are normative elements in the research process: (a) Shaping and defining the research agenda – setting priorities for what to study, (b) Setting standard definitions and procedures for research, (c) Recommending research designs and methods.

- **Setting norms and standards and promoting and monitoring their implementation:** This is the simple function – clearly normative while the latter: promoting and monitoring their implementation is more questionable. Promoting and advocating for specific norms and guidelines – is different from developing them, but still an important part of a normative process – in which WHO is prescriptive and seeks to convince countries about the value and merit of certain solutions. Monitoring the actual implementation is a technical data collection and reporting process, but the formulation of standards and methods for monitoring have normative elements.

- **Articulating ethical and evidence-based policy options:** This entails leading the formulation of public health policies, strategies and plans and establishing principles and rules for global public goods for health. This is from one perspective, a subset of no 3. (Setting norms and standards), but the focus is on providing options to countries and the global community. The normative element is to present what the viable alternatives are, but

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in a process oriented manner. On the other hand, if this were happening in a dialogue between WHO and a Minister of Health in country X, it would most often be called technical cooperation.

- **Providing technical support, catalysing change, and building sustainable institutional capacity:** This function seeks to summarise what is called technical cooperation at country level – often defined as the antidote to normative work. However, when opening the "black box" of technical cooperation – there are several normative elements, such as:

    o Adapting international commitments and normative instruments.
    o Setting priorities for a country cooperation strategy.
    o Promoting implementation of best practices.
    o Influencing regional and global policies and programmes.
    o Providing evidence and feedback in the preparation of norms and standards.

Financing and supporting the implementation of country programmes and projects are the clearest examples of the opposite of normative. However, some could argue that all norms and standards originate from and are informed by experience and insights from processes of implementation. They do not exist or are formulated in a global vacuum. Such an argument could justify involvement in innovative experimental implementation as part of a broader policy process, while replication and scaling-up fall outside with no or marginal normative relevance.

- **Monitoring the health situation and assessing health trends:** The collection, aggregation, validation, analysis, dissemination and use of data and information are not normative. However, the development of guidelines and methodologies for surveillance, health information systems and evaluations, have normative elements.

The next table provides a summary of the findings[15]:

Table 3: Types of normative functions

	What is not normative	**Normative content/elements**
1. Providing leadership on matters critical to health	Technical and managerial support Coordination Convene meetings	Promotion and advocacy of health and normative products Setting the agenda for new normative instruments (being a catalyst)
2. Shaping the research agenda	Data collection Aggregation and analysis Synthesis and presentation	Shaping and defining the research agenda Setting standards definitions, procedures for research Recommending designs and methods
3. Setting norms and standards and promote and monitor their implementation	Collecting monitoring data and information	Lead in the setting norms and standards Promoting and advocating norms and standards Formulating standards and methods for monitoring
4. Articulating ethical and evidence-based policy options	Backstop regional/country offices	Presenting viable options Lead health policy dialogue Adapt strategies and plans to apply global norms and standards
5. Providing technical support, catalysing change, and building sustainable institutional capacity	Financial and technical support Project implementation/ execution – replication/ scaling up Training/capacity strengthening Service delivery Lead emergency response Backstop regional/country offices	Adapting global norms and standards Setting country priorities Promoting best practices Providing evidence and feedback
6. Monitoring the health situation and assessing health trends	Data collection (data bases) Aggregation and analysis Synthesis and presentation	Developing guidelines and methodologies for surveillance, health information systems and evaluation

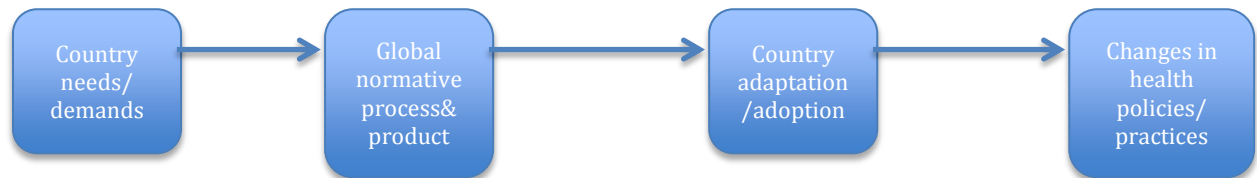## 2.3. Theory of change for normative products

There is no explicit theory of change (ToC)[16] in and for WHO´s normative products - largely because such a theory was not required and many of the products were prepared before such a concept became common. However, based on a review of the normative products and other WHO documents, it is possible to identify the main elements and construct ex post an implicit theory of change (or rather theories of change). It could help to clarify what is expected to happen in order to reach expected results and to discuss the underlying assumptions.

(a) There is a *limited/narrow "theory of change"* which basically implies that normative products are prepared by WHO headquarters with support from technical experts and consultations with WHO regional/country offices. The major outcome is a high-quality document with strong recommendations based on solid evidence. Such a document is made

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[15] See Report of the Task Force on the roles and functions of the three levels of WHO (2012) for a more complete overview.

[16] A Theory of Change (ToC) is a description and illustration of how and why a desired change is expected to happen in a particular context. It is focused on mapping out or "filling in" what has been described as the "missing middle" between what a programme or change initiative does (its activities or interventions) and how these lead to desired goals being achieved.

available electronically and circulated in hard copies to countries and global partners. The use and impact of the normative product is expected to follow from the high-quality of the document, leadership and authority of WHO and country needs for guidance. The role of regions is capturing country needs, adaptation and capacity strengthening. Change and results happens through "diffusion" (guidance and recommendations are supplied) – without a clear and explicit plan for implementation, dissemination and follow up.

```
┌──────────┐      ┌──────────┐      ┌──────────┐      ┌──────────┐
│ Country  │      │  Global  │      │ Country  │      │Changes in│
│ needs/   │ ───▶ │normative │ ───▶ │adaptation│ ───▶ │ health   │
│ demands  │      │process&  │      │ /adoption│      │policies/ │
│          │      │ product  │      │          │      │practices │
└──────────┘      └──────────┘      └──────────┘      └──────────┘
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(b) Such an approach is for obvious reasons not satisfactory or sufficient. Hence, there are efforts to encourage and prepare *a more advanced "theory of change"* including an active dissemination strategy. The ToC on the next page presents a more elaborate theory and includes elements referred to in some of the normative products and the Handbook for Guidelines Development.
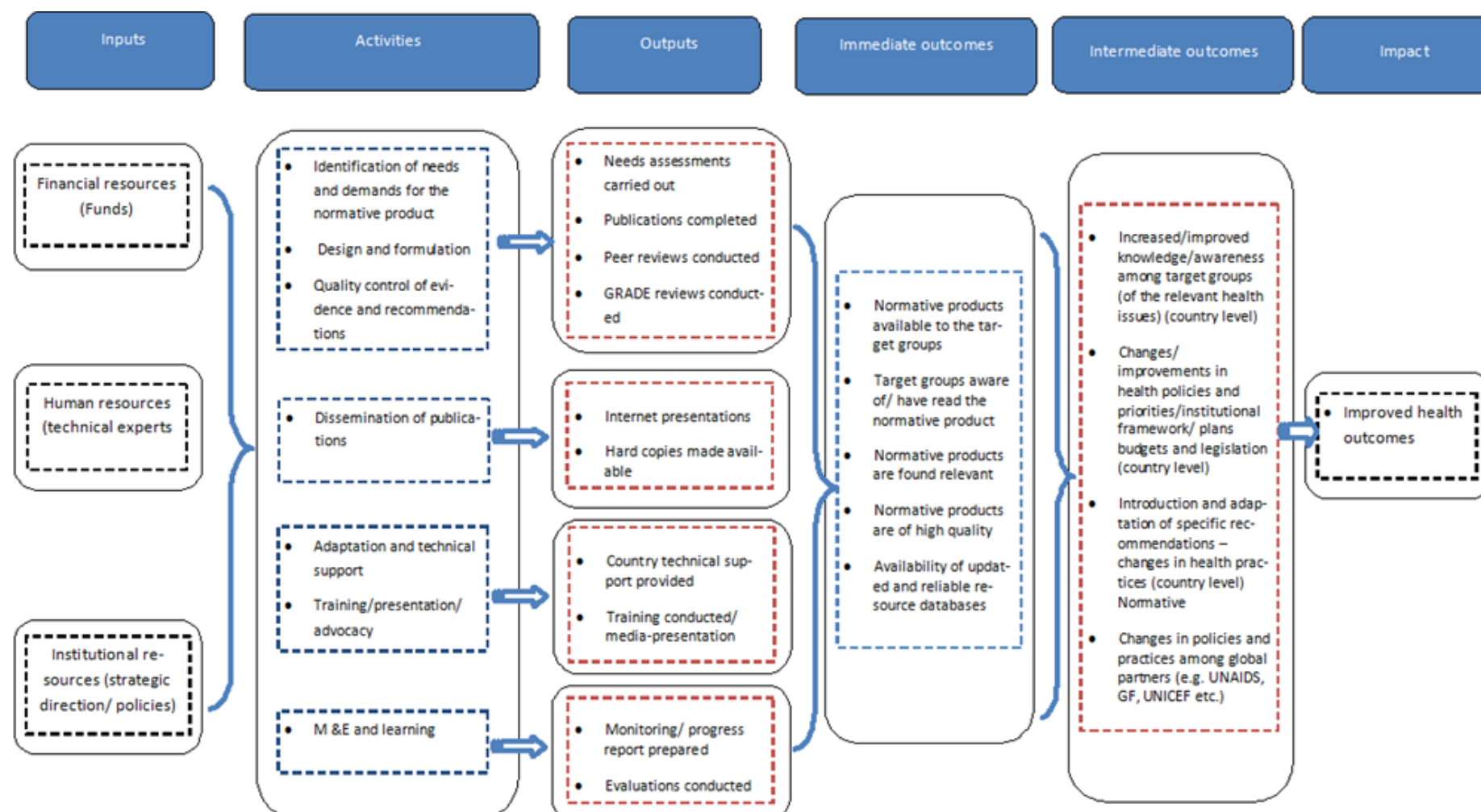
Such a ToC can help to assess a broader range of success factors – what contribute to active utilisation of the normative products and ultimately incorporation of their recommendations in country health policies and practices.

A major limitation in this framework is the missing external context in which the normative product is introduced and supposed to play a role (and sometimes limited role) in a complex and long-term process of change. Since this is not a country evaluation, the importance of contextual factors will not be included in this evaluation.

The challenge is to get a handle on and understand the causal linkages between a normative product with a set of recommendations and the expected outcomes and impact – or changes in health policies and practices.

It is naive to expect that changes in health outcomes can be explained and attributed to WHO guidelines and implementation plans alone. The relevant and interesting questions are *how* and to what extent normative guidance (processes and products) contribute to *change* and *improvements* in health policies and practices. Such normative processes and products are certainly not unimportant or unnecessary, but they are always part of a broader "causal package".

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Theory of change for normative products

Inputs	Activities	Outputs	Immediate outcomes	Intermediate outcomes	Impact

Inputs

- Financial resources (Funds)
- Human resources (technical experts)
- Institutional resources (strategic direction/ policies)

Activities

- Identification of needs and demands for the normative product
- Design and formulation
- Quality control of evidence and recommendations
- Dissemination of publications
- Adaptation and technical support
- Training/presentation/ advocacy
- M &E and learning

Outputs

- Needs assessments carried out
- Publications completed
- Peer reviews conducted
- GRADE reviews conducted
- Internet presentations
- Hard copies made available
- Country technical support provided
- Training conducted/ media-presentation
- Monitoring/ progress report prepared
- Evaluations conducted

Immediate outcomes

- Normative products available to the target groups
- Target groups aware of/ have read the normative product
- Normative products are found relevant
- Normative products are of high quality
- Availability of updated and reliable resource databases

Intermediate outcomes

- Increased/improved knowledge/awareness among target groups (of the relevant health issues) (country level)
- Changes/ improvements in health policies and priorities/institutional framework/ plans budgets and legislation (country level)
- Introduction and adaptation of specific recommendations – changes in health practices (country level) Normative
- Changes in policies and practices among global partners (e.g. UNAIDS, GF, UNICEF etc.)

Impact

- Improved health outcomes

CHAPTER 3: FINDINGS AND ANALYSIS

3.1. Synopsis of normative products

Ten normative products were selected as case studies from WHO´s Programme Budget 2014-15. This was a purposive and not representative sample of products, but it covers a broad range of thematic areas and varies widely in form and substance:

- All five categories in WHO´s work plan are included: Communicable diseases, Noncommunicable diseases, Promoting health through the life course, Health systems and Preparedness, Surveillance and response.
- Two technical normative guidelines developed in line with rules and procedures from WHO´s Handbook for Guideline Development (2014):
    - Guidelines on the Use of Anti-retroviral Medicines for the Treatment and Prevention of HIV infection (2013 and 2016).
    - WHO Guidelines for Indoor Air quality: Household Fuel Combustion (2014).
- One global strategy:
    - Global Health Sector Strategy on HIV/AIDS (2011-2015).
- Three roadmaps/implementation/action plans for thematic areas:
    - Roadmap for Neglected Tropical Diseases (2012).
    - Global Mental Health Action Plan (2012).
    - Maternal, Infant and Young Child Nutrition Comprehensive Implementation Plan (2014).
- Two global codes:
    - WHO Global Code of Practice on the International Recruitment of Health Personnel (2010).
    - International food standards developed and adopted by the Codex Alimentarius Commission
- Two drug related regulatory mechanisms:
    - International Nonproprietary Names (INNs).
    - WHO Model List of Essential Medicines (2015).

The sample is suitable for discussing the two overall questions in this evaluation: What is a normative product in WHO and what factors determine their relevance and effectiveness? The variation in products provides an opportunity to explore how WHO´s normative function are defined – based on different perspectives and criteria. The case studies support an assessment of what works and what is less effective.

Chapter 1.2. explained a group of internal and external factors influencing effectiveness. The products exhibit a wide range of variation on all relevant variables. Several were initiated internally by WHO – others were demanded and requested by Member States. The process for developing normative documents varied from extensive, long-term consultations at all levels to expert decisions taken in Geneva. Some are negotiated as semi-legal agreements ("soft law") and endorsed by the World Health Assembly while a majority are approved internally and published by the Secretariat. A few represent something new which had previously not been done by WHO - by providing the first global guidance in their topic area, while others build on previous work and evidence - consolidating other existing normative work.

Some products contain substantive obligations that require significant demanding policy changes, others require little or simply ratify status quo ante. And some contain rules and regulations to monitor and report on compliance and non-compliance, others create no review structure at all. Some are highly technical and prepared based on scientific standards while

others are more "political" and/or provide recommendations with less empirical evidence or at least available evidence in the reports. Some are long documents (up to 300 pages) – others short lists (3-5 pages). A few are actively disseminated and supported by technical support and additional funding – others are just made available for target audiences – increasingly only electronically. Some case studies demonstrate high relevance and results among global partners and in countries – in terms of incorporation in national health policies and practices – others are not able to verify and document country results.

The following factors were found important for the assessment of relevance and effectiveness (as mentioned the list is not exhaustive):

Factors influencing relevance and effectiveness
- Source and extent of demand for normative action.
- Process for developing the normative product and level of involvement of and consultation with stakeholders.
- Quality of the normative product.
- Level of ambition – or expected scope of change – "significant" and complex change or "simple" – from global policy change to reforms in technical solutions.
- Normative strength – level of binding and non- binding characteristics.
- Extent of effective dissemination and reach (whether the product is available among target groups).
- Evidence of relevance and results (adaptation/incorporation/changes in practices) based on available data and information.
- Effective systems for monitoring and evaluating progress and non-compliance – reporting and enforcement mechanisms.

3.2. Initiation

The questions are to what extent the normative guidelines were based on assessment of needs and strong demand and who articulated such demand (extent and source of demand). The assumption is that those factors influence level of ownership and subsequently relevance and results. In many of the cases, it was possible to identify demand and source of demand in the documents, while in others such information was not available. Major findings from the ten case studies are:

There is no evidence that needs and demands for normative products were based on systematic analysis and assessment within WHO – resulting in a corporate plan defining in what areas normative guidance is needed. In other words, there is no decision on what should be prioritised and how many normative guidelines should be produced within a given time-period. The initiative is in more than half of the cases taken by individual departments (Annex 1). All products are well justified in their own right so this evaluation is not able to assess if too many or too few guidelines are developed.

However, it could be argued that the production of normative documents should have been more strategic and selective – not only because of the high costs in developing a normative product, but primarily for focusing on fewer priorities within the organisation. Preparing strategies and guidelines has to some extent become a way for attracting attention and recognition to a certain area of work. In fact, several of the case studies suggested that the normative product functioned as an advocacy tool – gaining both internal recognition and above all, raising awareness globally on neglected issues (e.g. indoor air guidelines, mental health and neglected tropical diseases). In some cases the issue was well understood, but the guidelines provided evidence-based guidance on the solution to a well-known public health issue. Departments in WHO use the normative products also for positioning themselves in terms of

funding, and in this sense, a "successful" normative product could increase the level of resources internally and externally.

*"The action plan and the accompanying Resolution – a first in the history of WHO – represent a formal recognition of the importance of mental health for WHO´s 194 member countries. As such, it focuses international attention on a long-neglected problem". (*Global Mental Health Action Plan *case study)*

More than half of the products in the sample were initiated internally by WHO, others followed requests from Member States, but often in combination with external events and changing environments. Regional and country offices appear to have played a minimal role in the actual initiation of normative products, but generally had some kind of involvement throughout the process- albeit to varying degree.

- The two technical guidelines are examples of headquarters driven processes and products. The guideline on indoor air quality was a new area and product for WHO – recommending effective interventions for reducing indoor air pollution[17].
- The guideline on ARV treatment was also initiated by WHO, but the revised and updated guideline from 2016 followed from changing needs and opportunities for treatment.
- The initiation of the HIV/AIDS strategy for the health sector (2016-21) came also from the Secretariat – recognising the need to develop a more comprehensive strategy covering also viral hepatitis and sexually transmitted infections.
- WHO´s Director General launched in 2010 the first WHO report on neglected tropical diseases to demonstrate progress and challenges ahead – setting the scene and preparing the ground for the new "roadmap".

Normative products also originate from expressed demands from Member States through the World Health Assembly and Executive Board. The Global Mental Health Action Plan was developed as a direct consequence of a discussion by the WHA in May 2012 on global burden of mental disorders and the need for a comprehensive, coordinated response from health and social sectors at the country level. More specifically, the process started with a proposal by Member States to include an agenda item on mental health at the Executive Board meeting of the WHO in January 2012.

*"The Global Mental Health Action Plan was developed as a direct consequence of a discussion by the WHA in May 2012 on global burden of mental disorders and the need for a comprehensive, coordinated response from health and social sectors at the country level). (*Global Mental Health Action Plan *Case study)*

In a similar vein, at the request from Member States, WHO with the broad participation of many stakeholders developed the "Comprehensive Implementation Plan on Maternal, Infant and Young Child Nutrition" (endorsed by WHA in 2012).

In one case, the initiative emerged partly outside WHO and WHO was encouraged to take on the work with developing a Global Code on a politically controversial issue such as health worker migration – an unusual normative area for WHO. The initiative was attributed to the intervention of African ministers of health since African health ministers tabled a draft resolution that called upon the WHO DG (in the 2005 WHA) to ensure that such a Code was developed. Member States called on WHO in 2004 and 2005 to develop such a Code of practice (Resolutions 57.19 and 58.17).

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[17] The Programme commented that three sets of Guidelines for Indoor Air Quality were recommended in the AQ Guidelines, Global Update. Therefore, this was actually a group of scientists and experts who drove their development. WHO has had an ongoing programme of work on indoor air pollution for many years prior to the Guidelines development.

In some cases, relevance and effectiveness follow directly from immediate use and perceived usefulness rather than strong partner and/or country demand. There are at least two global headquarters based cases: INN and Essential Medicines List. The best example is the INN programme. Since its inception, the aim has been to provide health professionals with a unique and universally available designated name to identify pharmaceutical substance. It is found useful as an international pharmaceutical "language". WHO´s mandate and responsibility are not contested and pharmaceutical companies accept, support and even fund the programme.

The list of essential medicines (EML) – advising countries on the selection of essential drugs - falls also in the same category, but is slightly different. It originates from WHO´s core constitutional mandate and derives from a WHA resolution in 1975 and reviewed by the EB in 2001. This is a headquarters and expert driven normative activity – producing an international "public good". It has not been difficult to argue that such a list is needed. Essential medicines play an important role in improving access to medicines for most of the world's population. The concept of a carefully selected list of medicines of assured quality that meet the majority of health care needs of a community has proved to be an effective and affordable solution for the treatment of common ailments. The list is used because it is found useful and intuitively relevant.

"A rationally selected national EML is an absolute necessity for any public sector-driven health system, and should also form the basis for any attempt at providing universal health coverage. An EML should form the basis for the design and implementation of a sustainable benefit package for any national health insurance system. The WHO Model List provided a unique normative document, which should form the basis for local (national or sub-national) considerations". (Interview external stakeholder, EML case study)

The international food standards developed and adopted by the Codex Alimentarius Commission have become the global reference point for consumers, food producers and processors, national food control agencies and the international food trade and based on scientific recommendations from global expert committees. The need for standards and the request for scientific advice come from Codex members.

3.3.   Design and formulation

The questions are related to the process of designing and formulating the normative product – who led the process, what was the level of consultation and participation and what supportive groups were in place.

If there is one lesson to be learned from the theory of strategic planning, it is that the process whereby a strategic plan is constructed is of utmost importance. This is not to say that everyone must be involved or that full participation is required (Bryson 2004). However, if a plan is to be implemented and have a likelihood of both buy in and high use, it is a very good idea to bring key expertise to the process, to include some of the actors that are meant to implement the strategy, to be reasonably transparent, to start and bring the process to an end, and to take the necessary decisions to implement the strategy quickly.

Such a lesson has been accepted by WHO, but it is interesting to see the significant variation in processes of design and formulation. Major findings from the ten case studies are:

The process of developing the normative product is made explicit and transparent in six of the documents – in most cases briefly and in others in detail (e.g. ARV guidelines and Indoor Air Quality Guidelines) (Annex 1). For the others information is available in other background documents or not at all.

The strategy, technical guidelines and roadmaps/implementation plans were all the result of broad and extensive internal and external consultations with stakeholders. It has not been possible to quantify volume or verify the quality of consultations, but the case studies illustrate serious intent and commendable practice in requesting feedback and involving stakeholders in consultative processes.

"The latest strategy (2016-21) was prepared through a broad consultative process that led to the draft strategy. It involved all key partners, including Member States, organisations of the United Nations system and other multilateral agencies, donor and development agencies and initiatives, civil society, non-governmental organizations, scientific and technical institutions and networks, and the private sector. Numerous stakeholder consultations were held, and more than 100 Member States participated in consultations held in all WHO regions in the period April–July 2015. To supplement those consultations and ensure the broadest participation, the Secretariat hosted a public online consultation for a six-week period from April to June 2015. An official technical briefing on the three strategies (viral hepatitis, HIV and sexually transmitted infections) was held during the Sixty-Eighth World Health Assembly". (Guidelines on ARV case study)

The process of designing and formulating the normative products are in all cases led by headquarters staff. The ARV guidelines development process included WHO regional and country staff participating in scoping meetings, the Guidelines Development Group meetings and peer review processes. Regional dissemination meetings were organised by Regional Offices, which included regional and country office staff along with national HIV programmes and partners. Also, regional and country office staff have taken an active (and often leading) role in supporting country adaptation of global guidelines. Whereas HQ staff took the lead, significant numbers of regional and country office staff were involved in the overall process.

For the Global HIV Strategy regional offices took a lead in organising regional consultations an then in the development of regional action plans, of which some were noted or adopted by the respective WHO Regional Committee.

"After the resolution process began an iterative, but intensive and wide-ranging consultation and drafting period. The consultative process involved WHO Member States, but also non-governmental organizations, WHO collaborating centres and other academic institutions. The draft prepared by the WHO Secretariat was then made available for comment to all interested parties via a web-consultation and was used for global and regional consultation meetings. To conclude the work, the WHO Secretariat submitted a final draft through the Executive Board, for consideration by Member States. Following revision and its approval by the Executive Board in January 2013, the final draft was submitted to, and adopted by the WHA in May 2013." (Global Mental Health Action Plan Case study)

The process for developing the Global Code on International Recruitment of Health Personnel was lengthy, but also broad – both inside and outside WHO:

"The Global Code of Practice on the International Recruitment of Health Personnel was the culmination of efforts by many different actors…… There was a long maturation period for the Code. The health ministers had already in 2004 asked the DG to develop a Code. The process was seriously protracted, until in 2010 the Code was adopted. Development and drafting of the Code were led by the World Health Organization's Department of Human Resources for Health and a potential framework for the proposed Code was first presented by WHO/HRH at the Global Forum on Human Resources for Health in Kampala in March 2008. The Code was negotiated at various levels and finally adopted by WHA in 2010". (Global Code Case study)

The two technical guidelines are the only two normative products adhering strictly to the rules in the Handbook for Guideline Development and all supportive groups are in place such as Steering Development Group, External Review Group etc.:

"The document provides in the introduction a detailed overview of who were involved in the preparation of the document and how the process of formulation, review and quality control was organised. The reader can easily follow how and why a recommendation is developed, by whom and on what basis. The process followed strictly the procedures outlined by the Guidelines Review Committee. The process was supported by four separate external Guideline Development Groups comprising 108 individuals and an external Peer Review Group of over 100 individuals….. A full draft of the guidelines was circulated for comment to members of the Guideline Development Groups and the external Peer Review Group". (ARV guideline 2013 Case study)

It is noteworthy that the International Nonproprietary Names and Essential Medicines lists are more headquarters and expert-driven programmes in the preparation and formulation of the products that do not involve consultations with broad groups of external stakeholders, but rather with technical experts in the relevant fields to ensure scientific rigour. However, the proposed INNs are shared with stakeholders for comments. For those normative products, there is no correlation between level of consultation and participation in design and their importance and impact.

"WHO is the Secretariat for the Expert Committee on Selection and Use, the group of experts responsible for revising and updating the Model List of Essential Medicines. …… Committee members are selected from WHO Expert Advisory Panels based on equitable geographical representation, gender balance and professional competencies to provide a representation of different approaches and practical experience from all regions of the world. As such, this is a typical headquarter mechanism with no mandatory links to regional and country offices. Normative work is carried out centrally with support from international experts". (Essential Medicines List case study)

Detailed costs for preparing the normative products were not available for the ten cases studied[18]. Voluntary funding was made available in two of the cases (according to available information) and mostly from bi-/multilateral donors. In most of the cases, the work was carried out with internal staff and financial resources. There was in most cases no or limited funding for follow up and implementation of the normative products. In the Global Code for International Recruitment on Health Personnel, there was a substantial budget, but the funds were later not made available. Significant funds were made available for regional dissemination meetings for the 2013 and 2016 ARV guidelines.

"The expected budget was not made available to the Secretariat so the implementation was supported by general resources and much more limited than expected". (Global Code case study)

"The guidelines project was funded by Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH, Health Canada, The Indian Council for Medical Research (ICMR), the United Nations Foundation Global Alliance for Clean Cook stoves (GACC) and the UK Department for International Development (DFID) (guidelines p.intro). There is however no funding secured for follow up of the guidelines". (Guidelines for air quality case study)[19].

In one case, there was a systematic costing of the implementation of the plan:

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[18] Several programmes commented later that costs could be estimated if needed.
[19] The programme added that: WHA Resolution 68.8 specifically requests MS to implement the Guidelines and accordingly Norway provided funds to WHO in helping to implement this resolution. Hence, indirectly there has been a small amount of funds provided for follow-up.

"A costing of the implementation has further been done by the World Bank, summarizing the analysis of the costs, impacts, and investments needed to achieve the targets (four of the six targets costed thus far) and how governments, donors, the private sector, foundations, and others can come together to finance these at scale. Key message in the latter is that reaching the targets will require an average annual investment of $ 7 billion over the next 10 years. This is in addition to the $ 3.9 billion the world currently spends on nutrition annually". (Comprehensive Implementation Plan on Maternal, Infant and Young Child Nutrition Case study)

3.4.   Normative strength

What kind of normative instruments are represented in the sample and how legally binding and strong are they? In terms of formal status, the two most "powerful" products in the sample are the Codes – Codex Alimentarius and the Global Code of Practice on the International Recruitment of Health Personnel. They are examples of constitutional "soft laws". The Global Code is approved by the World Health Assembly.

On the other hand, the "strongest" and probably most binding normative product is the International Nonproprietary Names (INN). The INNs are in principle advisory and only approved internally by the DG[20], but when used and adopted they often become mandatory in national or, as in the case of the European Community, international legislation. The same is true for the food safety and quality norms and standards set by Codex Alimentarius Commission, which have legal ties with the WTO SPS and TBT Agreements.

The Essential Medicines List is also strong, but for other reasons:
"The WHO Model List is well-known and the TRS is eagerly awaited every two years. The Model List is also relied upon by a number of countries that lack the capacity to develop their own list….. Nationally, it provides a means to express the outcome of a rational selection process, which is unbiased and evidence-informed. At a global level, the major benefits are normative, enabling and persuasive, as an expression of global consensus around what should be an absolute minimum for all health systems". (Interview external stakeholder, EML case study)

The formally "weakest" are the technical guidelines prepared, approved and submitted by the Secretariat – without any discussion and approval by the World Health Assembly.[21] However, they are the only products guided by the Handbook for Guideline Development and are of high technical quality.

The strategy for HIV/AIDS, Roadmap for neglected tropical diseases, Global mental health action plan and Maternal, infant and young child nutrition comprehensive implementation plan all fall in a middle category. They are approved by the World Health Assembly, but they do not have the scientific/technical qualities as the guidelines and there are no established mechanisms to ensure compliance.

The case studies provide some indication that the more scientific- and evidence-based products have a higher effectiveness (level of knowledge, uptake and incorporation) than those with a stronger legal/formal backing and less supportive scientific evidence[22]. There are no direct links between formal status/strength and effectiveness (use and uptake of recommendations). The lists of essential medicines provide secretariat guidance to Member States with a high level of success because of their immediate practical use – not legal status. The two technical guidelines

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[20] The DG sends a Circular Letter to all MS and should no objection be raised then it becomes an INN. Hence, all MS and stakeholders must agree to the INN.

[21] Several programmes argued that it was important to "protect" the technical guidelines from political influence.

[22] See also study by Nasser finding that recommendations with higher level of evidence were associated with greater uptake of recommendations in national guidelines.

in the sample, the INN and essential medicines list are based on WHO´s role as a scientific and evidence-based organisation. Their effectiveness is less founded on formal status than WHO´s legitimacy and scientific authority and the technical quality of the products. The Code on international migration of health personnel is a short and mainly "political" document, however, underpinned by substantial evidence and a long negotiation process. Its effectiveness was found to be mixed, but the second round of reporting evidenced a marked increase in countries reporting on the WHO Global Code. The strategy, roadmap and action plans have evidence-based technical elements, but serve another purpose than the technical guidelines. It has also been difficult to find evidence of their effectiveness.

As discussed in chapter 2.2., the Constitution provides for three legal instruments: (a) Conventions, (b) Regulations and (c) Regulatory recommendations – adopted by the World Health Assembly as recommendations - and non-binding standards such as "Codes" being the most formal manifestation of WHO´s "soft law".

The first two – conventions and regulations - are in principle "international law" agreements intended to be legally binding while regulatory recommendations such as the two codes are only "soft law". A convention should have the most power, creating binding legal obligations, while "soft law" can only build moral obligations (norms). In practice, the difference between "hard" and "soft" may be less important. Some would claim that all international law is "soft". The entire notion of legality is mistaken because the international health system lacks a centralised authority capable of enforcing law[23]. On the other hand, it is argued that legal obligations can exist even if they cannot be enforced. Many rules survive for which there is no or little prospect of judicial enforcement[24]. It is also argued that international norms can be effective in creating compliance (see Raustalia 2004). WHO´s Global Code of Practice on the International Recruitment of Health Personnel has for instance been able to create a relatively high level of compliance to formal rules, but its effectiveness in creating change is more difficult to measure and document.

3.5. Quality and quality assurance

The questions discussed here are about quality assurance and quality of the normative products and to what extent such variables influence effectiveness and results.

Research from 2007 showed that WHO´s recommendations were largely based on expert opinion and rarely used systematic evidence-based methods (Oxman, A. et.al. 2007). In response, WHO established the "Guideline Review Committee" and prepared a Handbook for Guideline Development. A study from 2013 found that *"transparency of WHO guidelines processes has improved and the organisation is making wider use of systematic evidence appraisal"* (Sinclair, D. 2013).

The two technical guidelines have strict quality assurance mechanisms and also Codex Alimentarius Commission – the joint WHO/FAO programme. The same is true for the INN and Essential Medicines Lists. The mechanisms are different for the latter two, but appropriate for what the programmes do. Findings from the case studies are:

"The QA procedures and systems are clearly presented and adhered to when the recommendations were developed. New clinical and operational recommendations were developed in accordance

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[23] "The most basic principle of international law is that states cannot be legally bound except with their own consent" (Chayes&Chayes 1993).

[24] Chayes&Chayes (1998) argues that cases of coercive enforcement are rare and sanctions are too costly and difficult to mobilise to be reliable enforcement tools. They propose instead a "managerial model" of treaty compliance – building on the elaboration and application of international norms in a continuing dialogue between parties – generating pressure to resolve problems of non-compliance.

with procedures outlined by the WHO Guidelines Review Committee and were based on the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) system." (ARV case study)

"There are strict QA systems and procedures. The selection of new INNs necessitates the use of appropriate safeguards to avoid a conflict with established trademarks. When selecting new INNs, the INN Expert Group convened by WHO generally rejects any proposal that could result in a conflict with known trademarks. Selected names are published in a WHO periodical ("WHO Drug Information") as proposed INNs before they are actually adopted as recommended INNs. Interested parties are given a period of four months in which to raise an objection to a proposed INN". (INN case study)

"Most countries require that a pharmaceutical product be approved based on efficacy, safety and quality before it can be prescribed. The medicines on such lists are selected after a study of the medicines used to treat particular conditions, and a comparison of the value they give in relation to their cost. The WHO Model List of Essential Medicines is an example of such a list. WHO provides assurance that solid QA processes are in place and the right experts are used with no conflicts of interest". (Essential Medicines List case study)

"The QA procedures and systems are clearly presented in the document. It shows that systematic evidence-based methods are used in the development of the guidelines following well-defined procedures. Herein, the central role of thorough evaluation of evidence in formulating recommendations is emphasized. Key to the guidelines is thus a set of evidence reviews which inform both the recommendations and plans for supporting implementation in countries. (Indoor air quality guidelines case study)

"From the beginning, the Codex Alimentarius Commission has been a science-based activity. Experts and specialists in a wide range of disciplines have contributed to every aspect of the Codex to ensure that its standards withstand the most rigorous scientific scrutiny. It is fair to say that the work of the Codex Alimentarius Commission, together with that of FAO and WHO in their supportive roles, has provided a focal point for food-related scientific research and investigation, and the Commission itself has become an important international medium for the exchange of scientific information about food". (Codex Alimentarius case study)

On the other hand, there are no explicit QA mechanisms for the strategy and implementation plans beyond stakeholder consultations: The Health Sector HIV/AIDS Strategy, Roadmap for Neglected Tropical Diseases, Maternal, Infant and Young Child Nutrition Plan and Global Mental Health Action Plan. There were no QA mechanisms for developing the Global Code of Practice on the International Recruitment of Health Personnel either – even if those normative products are approved by the World Health Assembly while the technical guidelines were internally approved.

"The HIV/AIDS Department does not consider the strategies as normative products – as compared to their technical guidelines. The strategies are based on scientific evidence, but goals and targets are also influenced by political choices. The strategies provide global and country specific guidance, but are not technical and normative products as such. Hence, they do not follow the rules and procedures followed when technical guidelines are prepared including quality assurance". (HIV/AIDS strategy case study)

"From the report, it is further not clear what QA procedures and systems were used for preparing the document nor how. From the vantage point of WHO informants, the drafting of the plan started with broad country consultations involving more than 100 countries. Additionally, external experts from partner agencies and NGOs provided comments to the draft, and the targets were discussed with the main partners. WHO headquarters also worked closely with regional and country offices

and implementing partners to ensure quality assurance prior to the plan being considered by the Executive Board and before submission and approval by WHA". (Comprehensive Implementation Plan on Maternal, Infant and Young Child Nutrition Case study)

A quality assessment was carried out of all the ten cases (based on a specific format) – focusing on the form and substance of the documents. However, the format was based on standards from the Handbook on Guideline Development and found applicable to only the technical guidelines. The quality was found to be high.

"Our assessment of quality of the document concludes that it is of high quality in areas of methodology, presentation, substance, innovation and creativity and depth/quality of evidence and recommendations provided. The document (2013) is very long (269 pages), but well structured. It is also easy to navigate and find specific sections of particular interest. An open question is to what extent it is too long and comprehensive for resource poor countries and too general for developed countries with needs for more specialized knowledge and guidance". (ARV case study)

"The evaluation team finds the implementation plan to be of high quality, albeit relatively short. It is concise and entails a list of specific, time-bound objectives, and targets priority actions. The actions are also clearly specified to different target groups, yet not so narrow that they remove flexibility in implementation for countries. Countries should be able to tailor the actions to their own national contexts. In a similar vein, the terminology used throughout the document is understandable for a non-expert, and must be commended for consistency and clarity of presentation (user friendliness)". (Comprehensive Implementation Plan on Maternal, Infant and Young Child Nutrition Case study)

Informants often described WHO publications as "too long, too technical" with a need to be tailored better to different audiences, for example, summaries of technical documents that are written in a more accessible, user-friendly format with a less technical language so they are more concise and clear (Ennis 2016).

Responses in some interviews were also that the strategies are "open" or too "permissive" – to the point where one wonders what the strategic direction really is (Health Sector HIV/AIDS strategy and other plans/roadmaps). The strategies allow almost anything the actors see as desirable to do and are particularly weak on delimitations – what should not be prioritized or not happen at all because of priorities and even more important because of resource constraints (intentions/plans are not linked to resources/budgets).

3.6.   Dissemination

Normative guidance is of limited value if target audiences are not reached, don´t read and use the documents. The case studies discuss to what extent plans for dissemination are included in the normative products, if there is evidence of presentations and introductions, level of technical support provided by WHO as a follow up to the documents and if the normative products are available and used by partners globally and in countries.

The recent evaluation of WHO publications (Ennis 2016) did a much more systematic assessment of reach than this study has done. However, findings are similar – meaning mixed results in terms of the extent to which WHO publications reach their targeted audiences. There is also a lack of basic monitoring information regarding dissemination of WHO publications. When quantitative information on reach does exist, it is limited in both time and scope. *"The general conclusion is that WHO publications are not fully reaching their intended audience, and during planning, all segments of the audience are not fully identified" (Ennis 2016).*

The same evaluation also found room for improvement in planning processes. Before publications are initiated, there should be a more upfront planning on the purpose of the

product, target audience(s), matching of formats and delivery methods to target audience(s), language and translation considerations and monitoring of the reach.

In all the ten cases, there was stronger focus on the preparation, design and formulation of the normative product than on dissemination and follow up. The latter were not ignored, but more time, resources and attention were dedicated to preparing a high-quality product than on dissemination and follow up or at least documentation of the dissemination/follow-up, but perhaps work has been done without being properly documented. There is also limited data and information on the level and effectiveness of dissemination and use. Most of the publications were not based on a "theory of change" – articulating what would be required to initiate change (see chapter 2.3.).

"The document was disseminated as a printed publication and electronically on the WHO web site in the six official United Nations languages. A library of all supporting documentation and evidence was made available on the web site. WHO headquarters worked closely with regional and country offices and implementing partners to ensure their wide dissemination through regional and sub regional meetings. Assistance will be provided to Member States to adapt the guidelines to their national contexts. From August 2013 to May 2014, WHO with partners conducted nine dissemination meetings across six WHO regions serving 100 countries". (ARV case study)

"The guidelines are available in all six UN languages, and an executive summary has been developed. The document was disseminated in accordance with WHO practices; and through press release. Following publication of the guidelines, an official media launch was held in Geneva, convening media/journalists. Regional workshops were conducted and the guidelines were also widely disseminated to bigger networks such as the UN Secretary-General's Sustainable Energy for All initiative, the UN Foundation Global Alliance for Clean Cook stoves and the Climate and Clean Air Coalition. All information related to the guidelines including the full guidelines themselves, the executive summary (translated into Arabic, Chinese, French, Russian and Spanish) and supporting evidence reviews can be found online".

"Following the main feedback from external (survey) stakeholders, the guidelines are also to a large extent available and known in their organization, yet, only to some extent actively utilised (influencing and shaping policies and practices). External stakeholders universally hold that this is an area where WHO has provided relevant and strong normative guidance. While it is still somewhat premature to assess the extent to which the guidelines are being used in countries till date, much progress has been made. There has been a reflection of the importance of this issue globally. According to WHO staff, these guidelines are changing the way prevention of diseases due to air pollution is perceived. The criteria developed by the guidelines are being incorporated, inter alia, into several on-going international initiatives and activities". (Indoor Air Quality case study)

The INN list are published on the Website, in MedNet (=Extranet) which is a community of more then 16.000 users. There is also the INN Global Data Hub (INN are in all the DB of National Trade Mark Departments, WIPO etc.). A mobile application is also being developed.

In the nutrition case study, it was found that a majority of the RO/CO survey respondents (83%) were aware of plans for how the document should be disseminated, and that they have received hard copies that have been circulated to country partners (e.g. 60% note to have circulated 10-51 hard copies). The most often-cited way to disseminate the Plan is through organised meetings and workshops. Most of the respondents suggest that the Plan has reached its target audiences "to some extent". (Comprehensive Implementation Plan on Maternal, Infant and Young Child Nutrition Case study)

The case study on Mental Health provides positive feedback on follow up and dissemination, but the evidence is somewhat anecdotal:

"To paraphrase one stakeholder, "the implementation of the Plan is the responsibility of the entire WHO secretariat, and HQ collaborates very actively with RO´s and relevant CO´s on this. The topic is discussed in each of the annual meetings of the Regional Advisors in Geneva. Some regional offices have developed a regional framework or strategy to implement the Plan". Having regional advisors for Mental Health in place and involvement of RO´s and CO´s in development and dissemination is undoubtedly positive, because it contributes to their buy-in and in turn enhances the likelihood that the Plan will actually be used. The survey questionnaires similarly suggest that the Plan has been actively disseminated and followed up by WHO (HQ, RO, CO), with a majority (75%) answering yes to the question".

While half of the external survey respondents report that the Plan is available and known in their organisation to a large extent, the other half answer "to some extent". Most of the respondents also note that the Plan is actively utilised (50% to a large extent and 37,5% to some extent. In countries, the Plan is less known and used (13% to a large extent, and 50% to some extent). (Mental Health Action Plan case study)

A few of the products have comprehensive plans and budgets for dissemination and follow up, but funds were in one case not provided or later withdrawn. The level of technical support provided to countries by WHO HQ staff seems to be limited, but data were not available – only verbal feedback was provided by WHO staff. Technical support was mostly provided by regional and country offices – in particular when dedicated staff were available in the thematic area.

"A separate implementation plan was developed explaining the roles of Member States, WHO at all levels and other international stakeholders. The plan presented activities for (a) communication and advocacy, (b) development of institutional mechanisms (data collection, information exchange and reporting) and (c) strengthening partnerships. The plan has also a budget for 2010-15 amounting to 24.270 Mill USD. At the regional level, the Secretariat has supported a range of activities and inter-country initiatives promoting the implementation of the Code. The expected budget was not made available to the Secretariat so the implementation was supported by general resources". (Global Code International Recruitment of Health Personnel case study)

Most of the normative products are still available and disseminated as hard copies, but all are accessible electronically (many also as executive summaries). The INN and the Essential Medicines Lists are available electronically and in hard copy through the Technical Report Series. There is an active dissemination of those two, but there is also a demand and requirement that pharmaceutical companies should have drug names approved by WHO.

"INNs are available in all six official languages of WHO. They are translated into many other languages for use at the national level by regulatory authorities, as well as in reference books and in medical literature. Lists of both proposed and recommended INN are sent by WHO, together with a note verbale, to the Organisation's Member States, to national pharmacopoeia commissions and to other bodies designated by Member States. In a note verbale, the Director-General of the World Health Organization requests that Member States should take such steps as are necessary to prevent the acquisition of proprietary rights on the name, including prohibiting registration of the name as a trade name". (INN case study)

"The lists are made available electronically. The WHO Essential Medicines and Health Products Information Portal supports efforts to improve access to essential medicines and health products by making related, full-text articles available online. The portal receives support from USAID. The Portal contains 5604 medicines and health products related publications from WHO, other UN partners, global NGOs, development agencies and their partners, countries and academics, and is updated monthly. A facility exists to create sub collections on specific topics that can be exported and duplicated on DVDs or flash drives". (Essential medicines list case study)

"The original Codex texts in the 1960s were hardcopy volumes. With advances in electronic archives, CD-ROMs were adopted in the 90s. Today, every Codex standard is created and stored digitally and made publicly available on the Codex website in multiple languages as soon as it is adopted by the Commission. Assistance given to developing countries has included: (a) Establishing and strengthening national food control systems, (b) helping with the establishment and strengthening of food control agencies, countries require an adequate food law, as well as a technical and administrative infrastructure with the capacity to implement it and ensure compliance. (Codex Alimentarius case study)

Many of the normative products are expensive publications, on glossy paper and with several photos, but we have not seen any analysis of the "market" – or in other words needs and demands among various target groups. On the contrary, most of those who have read the publications may be within WHO or close partners who would be satisfied with a simpler presentation and layout. There is clearly no proof that sophisticated layout provides a wider audience and better results.

3.7.   Feedback and learning

The questions are to what extent monitoring and evaluation systems were in place generating data and information on implementation, progress and results – in other words whether preconditions for documenting results exist. There are several findings emerging from the ten case studies:

There is no independent evaluation in any of the cases except for one evaluation of Codex Alimentarius Commission in 2002 and another of Codex Trust Fund and no evaluations in the pipeline either. There have been two expert reviews of the Global Code of Practice on the International Recruitment of Health Personnel, but they were not formal independent evaluations. In other words, reports on progress and results are almost entirely based on self-assessments and internal reviews.

There is a much stronger focus on monitoring than evaluation in all the cases. All the ten normative products have monitoring systems – from the most basic and rudimentary to comprehensive and technically sophisticated systems. In some cases, monitoring is very specific and the use of reviews are systematically implemented to monitor, document and assess progress, while in other instances, monitoring systems are much less sophisticated. The extent and quality of data provided are highly variable, but their reliability and validity have not been systematically assessed.

Presenting figures and changes in global targets is the most common form of monitoring – based on global indicators. There is little monitoring of processes for implementing the normative products. Aggregate data provide useful information on overall trends, but changes in global figures can only exceptionally be attributed to a normative product. The technical guideline on indoor air quality focuses on global targets, but it is difficult to argue that achievement of such targets is influenced by the normative product and if so – how. There is a mismatch in the reporting between the input and expected outputs and outcome[25].

" WHO monitors - on a global scale the use of household energy fuels and rates of household air pollution. The information is compiled and shared periodically in several databases: (a) Population-based household energy surveys, (b) WHO's Household Energy Database, [26] drawing on

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[25] The programme added that within the SDG's, the reporting on Household Energy use is now directly linked to the WHO guidelines on indoor air quality defining 'clean' in the 7.1.2 indicator "primary reliance on *clean* fuels and technologies".

[26] Household energy: http://www.who.int/indoorair/health_impacts/he_database/en/ Household

more than 700 national and international surveys of the main fuels used for cooking to provide the best current nationally-representative information on household air pollution, and (c) Global database of household air pollution measurements ²⁷ from 154 studies, representing data from 37 countries, published between 1968 and 2011". (Indoor air quality case study)

The global nutrition plan includes extensive monitoring of six global targets and to some extent the process and results in implementing the plan.

"The progress towards the six global nutrition targets set out in the implementation plan and the steps being taken to put the plan's constituent actions into effect is systematically monitored:
1. *Data are regularly collected by WHO and its partners and presented in progress reports and nutrition policy reviews. There are several nutrition databases.*
2. *The Global Nutrition Targets Tracking Tool supports countries in the process of adapting the global targets to the national setting. However, 49% of countries do not have enough nutrition data to determine whether they are on course for meeting the global targets.*
3. *The Global database on the Implementation of Nutrition Action launched in 2012, provides detailed country by country results on the implementation of numerous nutrition policies and interventions.*
- *To monitor and evaluate the implementation of policies and programmes, WHO and UNICEF have jointly established a Technical Expert Advisory Group on Nutrition Monitoring to support the implementation of the global nutrition monitoring framework.*
- *The Global Nutrition Policy review makes it possible to identify the presence and implementation of nutrition policies, an updated version with responses from 126 countries is expected published in 2017.*

The Mental Health Action Plan also places an emphasis on providing global information for assessing progress towards global targets:

"Data concerning mental health has been collected and reported through the Global Health Atlas since 2001, as well as more than 80 country profiles based on WHO-AIMS28, as such, some comparisons across time will be possible on global, regional and national levels. The Atlas lays out a clear and comprehensive (yet practical) overview of global information on mental health situation. Specifically, the Atlas has a specific importance as a repository of mental health information in WHO MS, because it is providing much of the baseline data against which progress towards the objectives and targets of the Comprehensive Mental Health Action Plan 2013-2020 is to be measured". (Mental health case study)

The technical guideline on ARV´s provides a unique example of systematic monitoring of the implementation of specific recommendations:

"The guidelines contain fifty new and updated policy recommendations on clinical, operational, programmatic and M&E aspects of HIV treatment and care. WHO reports that within 18 months of publication of the 2013 consolidated ARV guidelines, 100% of the focus countries adopted at least one major recommendation (WHO, Progress Report 2016: Prevent HIV, test and Treat All):
- *60% of focus countries adopted a CD4 count initiation of ≤500.*
- *7% of focus countries recommend treating all at any CD4.*
- *93% of focus countries adopted the use of TDF + 3TC (or FTC) + EFV as preferred first-line therapy.*
- *60-90% of focus countries implementing integration approaches.*

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²⁷ http://www.who.int/indoorair/health_impacts/databases_iap/en/
²⁸ World Health Organization. WHO-AIMS country profiles. Geneva: World Health Organization, 2014. Available at http://www.who.int/mental_health/who_aims_country_reports/en/

A progress report provides a graphical presentation of the implementation of the recommendations in the ARV guidelines. It is commendable that such a comprehensive monitoring system is in place – monitoring both to what extent policies are in place, but also level of policy implementation in countries. Given the specificity of the recommendations, it is likely that country adoption of such recommendations is initiated and influenced by the WHO guidelines". (ARV case study)

The Global Code of Practice on the International Recruitment of Health Personnel has its own approach to monitoring. While the text in the Code is quite "weak" with a set of international guiding principles and ethical standards – being the consensus of political negotiations, the monitoring requirements are demanding and have contributed to enhance compliance.

"Article 9 in the Code specifies that Member States should periodically report the measures taken, results achieved, difficulties encountered and lessons learnt. The World Health Assembly should periodically review the relevance and effectiveness of the Code. Two elements were central in monitoring the implementation of the Code:
(a) The designation of a national authority who could take charge of information regarding the migration of health personnel and implementation of the Code.
(b) In a second step, WHO developed the National Reporting System and the national authority was requested to complete the form.

To monitor the progress made in implementing the Code, a national self-assessment tool was created for Member States. To facilitate stakeholders reporting, an additional Independent Stakeholders Reporting instrument was also made available. This additional module facilitates contribution from relevant stakeholders and enriches knowledge on the Code's implementation". (Global Code on International Recruitment of Health personnel case study)

Several indicators in WHO´s work plan measure only policy compliance – not effectiveness. The indicator for the global mental health action plan is for instance: *"number of countries with a national policy that is in line with the global mental health action plan".* For the guideline on indoor air quality the indicator is: *"number of countries that have developed new or revised policies or national standards based on WHO guidelines for environmental and occupational health risks".*[29] In other words, the indicator is if a plan or policy is in place – not to what extent the plan has been implemented and created results. The indicator for the health sector HIV/AIDS strategy includes *"no of countries implementing national HIV/AIDS strategies in line with the global strategy".* This sounds as a relevant promising indicator, but it is in practice an awkward indicator. There is no simple measure for successful national implementation of an entire strategy. The cost of monitoring of such a process would also be exorbitant – so the indicator is unrealistic.

3.8.   Relevance and results
Relevance
All ten normative products were found relevant based on feedback from interviews, surveys among stakeholders and available documentation. The findings in the nutrition case study is illustrative:

"Interviewees at HQ generally note a broad uptake and incorporation among countries, while half of the RO/CO´s asked, claim that the Plan has been used "to a large extent" in their respective country/region. In assessing its role, one RO advisor emphasises that "it has directed policy actions, promoted scaling up of nutrition interventions and helped countries in setting targets based on the

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[29] The Programme commented that this indicator predates the publication of these indoor guidelines and refers to other environmental health guidelines. A new indicator was developed in the following PB to replace this one.

Global targets". Another stakeholder refers to it as a "background document to help governments understand their obligations and to advocate for adoption of the global targets in national Plans ". What also emerges from the questionnaires is that most of the RO/CO staff have supported the work through technical guidance and support. Furthermore, there is a unanimous view that the Plan has contributed to improved health outcomes in the respective country/region "to some extent".* (Comprehensive Implementation Plan on Maternal, Infant and Young Child Nutrition case study)

The same is true for the Global Mental Health Action Plan:
"Among the external (survey) stakeholders. there is an unanimous view that the Plan is an important guidance document. According to the feedback, it is comprehensive, yet, focused on key strategically driven priorities and related actions. It is said to be critical for providing and legitimizing a coherent vision for the global mental health community to work towards, and setting the framework for MS to develop and implement policies in line with international evidence and best practice. That said, the majority of external stakeholders agree that the plan is an example where WHO has provided relevant and strong normative guidance. Furthermore, WHO is seen as the only organisation with institutional capacity and de facto ability to take on this type of initiative". (Global Mental Health Action Plan case study)

It is as such a positive sign that the guidelines are considered as relevant and important among the external (survey) stakeholders. The guidelines received praise for the timeliness of development, publication and update; ease of interpretation of guidelines; practical application and demonstrated use in priority countries. As one stakeholder puts it: "I think they are quite important and provide the first international targets for the research and implementer communities. Ultimately, they will need to be validated and probably adapted with a growing body of information, but this is a very important effort". (WHO Guidelines for indoor air quality case study)

Indeed, it is not difficult to argue that most the products reviewed are both timely and appropriate, feeding into the needs of the users. The need for the products was well explained in the documents – often stronger than level of demand was described. Four of the normative products were requested by Member States, but the majority were initiated internally by WHO itself. The demand for and relevance of technical guidelines are often stronger than for the broader global strategies and plans. However, the Expert Advisory Group reviewing the WHO Global Code's relevance and effectiveness, identified a strong finding of relevance.

It is difficult within this evaluation to assess level of relevance for (a) WHO internally, (b) global partners and (c) Member States. It would also be variable – depending on which target group. The specific recommendations in the ARV guidelines were found highly relevant to country needs while the health sector HIV/AIDS strategy has a different more global purpose – providing overall guidance on the health sector response to HIV/AIDS. Global partners such as UNAIDS, the Global Fund to Fight HIV/AIDS, TB and Malaria, UNICEF, PEPFAR, the World Bank are recipients and users of WHO´s normative guidance. People interviewed found the normative products useful, relevant and of high quality, but feedback from partners was limited in scope.

The recent more extensive evaluation of WHO´s publications concluded:
"WHO produces a number of high quality, high impact publications. There is no doubt that WHO is a credible organization and that health professionals throughout the world look to it for science-based guidance and advice. However, opportunities for improvement do exist. WHO must strive to maximize the reach and impact it can have with the significant investment it is making in publications". (Ennis 2016)

However, the positive conclusion about high quality and relevance comes with a caveat:

"WHO publications are perceived as being very useful. WHO is, however, facing an increasingly complex global health agenda which implies more needs, more stakeholders and more actors, without necessarily more resources. The frequent comments regarding WHO publications being either too long or too technical is an indication that there are important audiences whose needs are not being addressed by technical documents alone, and that derivative products for other target audiences should be planned upfront and produced". (Ennis 2016)

It is also noteworthy that four of the products have innovative qualities: (a) nutrition by introducing new elements in the global nutrition targets and indicators, (b) mental health action plan and the accompanying resolution — a first in the history of WHO representing a formal recognition of the importance of mental health and (c) neglected tropical diseases, consolidating 17 very different diseases as a "brand" in global health and (d) WHO indoor air quality guideline, providing the first guidance on what counts as "clean" household energy for health.

Long-term impact
It is difficult to measure the long-term impact of normative products for a broad range of methodological reasons. Several of the normative products were prepared in the last 4-5 years so it is premature to expect long-term impact. The effects of a normative product are also often catalytic, indirect and long-term. An evaluation of discrete normative products faces challenges in trying to judge to what extent the outcomes and impact can be attributed to a specific product, when a range of other external factors are likely to have made a difference – and more important difference. Changes and improvements have also been supported by several other initiatives and cannot be attributed to the normative product and WHO alone. Further, the often general nature of these documents hampers the ability to capture and monitor achievements and progress.

Hence, it is puzzling when WHO departments in their reporting to the World Health Assembly claims that global epidemiological changes are results of WHO normative products, such as for the health sector HIV/AIDS strategy. The targets (and baselines) from the Programme budget 2014-2015 were not used as far as we could see. Annual reports present a much more nuanced picture and maybe the inflated reporting can be explained by limitations in WHA reporting:

"It was reported to the World Health Assembly in April 2016 that "The global health sector strategy on HIV/AIDS, 2011–2015 played a key role in the achievement of global HIV targets outlined in the Millennium Development Goals. At the end of 2015, over 15 million people were on antiretroviral therapy. Since 2000, it has been estimated that as many as 7.8 million HIV-related deaths and 30 million new HIV infections have been averted".

The strategy for 2016-2012 states in its introduction that *"the Global health sector strategy on HIV/AIDS 2011–2015 has galvanized global and country action that has helped halt and reverse the AIDS epidemic. During that period, HIV treatment coverage was expanded rapidly with well over 15 million people living with HIV on antiretroviral therapy by the end of 2015; new HIV infections and deaths declined; dozens of countries moved towards the elimination of mother-to-child transmission of HIV; and HIV responses have been embedded in broader health and development programmes".* (HIV/AIDS health sector strategy case study)

It should also be noted that there are "results" that can be attributed to the normative products, but which are broader and beyond achievement of specific targets. The formulation of strategies or guidelines have other indirect benefits as illustrated in the Nutrition case study:

- *The Plan represents a combination of summarizing an emerging consensus – while the targets and indicators are new elements.*
- *Enabled a common understanding – wherein WHO produced the rationale to why the targets were needed.*

- *Provided the opportunity to define what nutrition is in the world; (how we think and work in nutrition).*
- *Two out of the six WHA nutrition targets now included in the SDG´s reflects growing consensus and political support (maternal nutrition also included in SDG´s)*
- *The "nutrition movement" is now referring to the targets.*
- *Increased profile politically, the plan played an important role in how the UN harmonizes – a work in partnership, the document also elevated discussions in e.g. UNGA*
- *The Plan and defined global targets have worked well as an advocacy tool.* (Mental Health case study)

Evidence of results: Complex, complicated or simple change

The summary of findings from the cases (Annex 1) show that all ten normative products provide evidence of results, but results are exceptionally varied. With few independent evaluations, the documentation of results depends on internal reviews and self-reporting. The lack of structured and systematic monitoring and evaluation can also mean that more work may actually have been done and results achieved than what is documented.

The question is what kind of change is expected to follow from the normative product: "significant" and "complex" change involving transformations in global and national health policies and practices or more "simple" and "incremental" reforms[30]. Most of the products are somewhere in the middle on that continuum. The level of complexity and comprehensiveness of change will influence expected and actual results.

The most simple and straightforward is the INN which is basically to agree on a name to identify a pharmaceutical substance. This involves a complicated and vigorous process, but it is not a complex undertaking. The result chain is simple in the sense that results follow from the implementation of the activity. There is also evidence that WHO has successfully established a global programme – accepted and respected by all stakeholders. There are of course short- and long-term benefits of having an international nomenclature for pharmaceutical substances and those benefits can be documented.

"Since its inception, the aim of the INN system has been to provide health professionals with a unique and universally available designated name to identify each pharmaceutical substance. The existence of an international nomenclature for pharmaceutical substances, in the form of INN, is important for the identification, safe prescription and dispensing of medicines to patients, and for communication and exchange of information among health professionals and scientists worldwide". (INN case study)

The Global Code of Practice on the International Recruitment of Health Personnel is on the other side of the continuum. It is not only about a disease or the health sector, but about the politically sensitive issue of international migration – a multi-sectoral issue that goes beyond the health sector in which even small changes can mean big results.

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[30] **Simple problems** are when the destination is known, the path to reach it is known, and it is simple to follow the plan. Simple problems are predictable and the outcome is known.
Complicated problems refer to interventions in which multiple components are required to produce the intended result. Such problems may require additional measurement effort, such as the use of multiple tools to triangulate data to arrive at conclusions.
Complex problems refer to interventions where the causal pathway is adaptive or emergent: Interventions where it is not possible to set out in advance the details of what will be done. The intervention may not have pre-identified outcomes, but rather a broad, goal-level description of the desired end-result without a clear pathway of how to get there (Patton 2016).

"The initiative for the resolution emerged partly outside WHO and WHO was to some extent encouraged to take on the work with developing a Code on a politically controversial issue as migration – an unusual normative area for WHO". (Global Code case study)

There has been as mentioned systematic monitoring of the implementation of the Code and despite significant visibility in some areas, the second expert group could not draw any firm conclusions on effectiveness:

"The Expert Advisory Group determined that the success of the Code in comparison with other governance initiatives and instruments in global health would be better assessed once further evidence is available from national reporting. Evidence of the effectiveness of the Code is emerging in some countries. The group concluded that there were still gaps in implementation and dissemination of the Global Code that constrain a clear assessment of the effectiveness of the instrument. A review of the five-year period following the Code's adoption points to areas of the Code's success and weaknesses. The WHO EURO region evidences that, with associated resources, a systematic process towards Code implementation, as well as meaningful action in the area, is possible. However, evidence of the Code's implementation outside the European Region is patchy, with knowledge of the Code and efforts towards its implementation often dependent upon personality (and presence during Code negotiations) rather than systematic. (Global Code case study)

The HIV/AIDS strategy and the other roadmaps/implementation plans have a global scope and potential reach. The Mental Health Action Plan has six global targets, raising the question about realism. The basic problem is that setting a prefixed and global target may be motivating, but inappropriate because there is no reason to assume that the goal will be attainable with the available means. WHO resolutions request Member States to provide financial support, but no commitments are made. As such, the strategies become intentions without funding and if figures are mentioned funds are not necessarily available.

"The Plan proposes a global vision[31], and such an activity begs a further question, namely; is it "too global, or even, too ambitious"? Or does it lay out practical, deliverable expectations? The plan suggests that (global targets), by 2020, WHO intends that 80 percent of countries will have updated their mental health policies and 50 percent will have updated their laws in line with international human rights". (Mental health case study)

"In a similar vein, it could be claimed that "global documents" easily can end up being classified in two camps: either as an articulation of what WHO wants to do, or a document that is used to create a new direction and a way of making changes. According to interviewees, however, the plan represents both dimensions, including a third, because the commitment and agreement from MS gives credibility – along with targets that can measure progress in implementation of the Plan. Relatedly, an action plan may therefore have great potential to change the direction of mental health in countries around the world. Indeed, it is said that if the plan's principles are adopted and

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[31] The vision of the Plan is ambitious: a world in which mental health is valued and promoted, mental disorders are prevented and in which persons affected by these disorders are able to access high quality, culturally appropriate health and social care in a timely way to promote recovery and exercise the full range of human rights to attain the highest possible level of health and participate fully in society free from stigma and discrimination. World Psychiatry. (2014) Jun; 13(2): 107–109 WHO's Mental Health Action Plan 2013-2020: what can psychiatrists do to facilitate its implementation"
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4102273/

implemented they will result in a difference for mental health service users, and their families, globally [32]". (Mental health case study)

The technical guideline on indoor air pollution is an interesting case. The document is clearly a formal technical guideline issued by WHO´s Secretariat in consultation with regional and country offices, country partners and technical experts. It represents a new normative product for WHO, that is, evidence-based guidelines supporting effective interventions – as a global approach to household air pollution. This has not been done previously. The recommendations include general considerations for policy, a set of four specific recommendations, and a best-practice recommendation addressing linked health and climate impacts. The case study concludes that it is too early to find country level effects. The major results so far were to create awareness and influence global partners and initiatives:

"While it is still somewhat premature to assess the extent to which the guidelines are being used in countries, much progress has been made. Above all, there has been a reflection on the importance of this issue globally. According to WHO staff, these guidelines are changing the way prevention of diseases due to air pollution is perceived. The criteria developed by the guidelines are being incorporated, inter alia, into several on-going international initiatives and activities. The following are influenced by or are directly using the guidelines: (a) SDG indicator 11.6, refers explicitly to the definitions given by the guidelines, (b) SDG indicator 7.1.2: One of the three main goals for SDG 7 seeks to "ensure access to affordable, reliable, sustainable and modern energy for all" by 2030, (c) Sustainable Energy for All Initiative. (c) Global Alliance for Clean Cook stoves, (d) The International Organization for Standardization (ISO) is currently developing the first-ever global standards for clean cooking solutions. (Indoor air quality case study)

Regarding use, there is evidence that some WHO publications are used by countries as authoritative sources for decision making and policy making. That is especially true of technical guidelines. The recent evaluation of WHO publications concludes that there is room for improvement to maximize the return on investment of publications. Better publication planning around target audiences and dissemination, more active dissemination and communication, and translation were some of the common themes that were identified as means to improve the use and maximize the impact of WHO publications (Ennis 2016).

A study of 158 recommendations included in HIV and TB guidelines issued by WHO from 2009 to 2013 has been carried out (Nasser undated). The study found that 76% of all recommendations had been taken up in national guidelines. Strong recommendations – based on high evidence were adopted 82% of the time, whereas conditional recommendations only 61%. Higher level of quality of evidence were as such associated with increased uptake in national guidelines. The country level uptake of recommendations could be explained by other factors, but the study believes there is a correlation. However, no inference can be drawn from the level of implementation of these guidelines.

The evaluation of publications (Ennis 2016) also found that WHO programmes are often not clear on who their target audience is, with a "traditional" view of WHO being an international standard- and norm-setting organization on the one hand, and others viewing its role as much more operational, focusing on institutional strengthening at the country level. It is clear that at the operational level training of health care officials may be required to support the implementation of new policies, or information disseminated to that audience in a specific way relevant to their context. There are different target audiences along the causal chain and the

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32 Gabriel Ivbijaro. The case for change: The Global Mental Health Action Plan 2013–2020.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3622905/

evaluation found that there is no consensus or clarity on WHO target audiences for their publications, derivative products and possible implementation support.

However, our global desk-based evaluation could not track country level use and outcomes. Direct attribution of a single publication to a health outcome is as mentioned difficult to prove at any level be it global, regional or national, given the complexity in the causal chain and number of factors that influence outcomes. To better understand the causal linkages in achieving health outcomes and role of publications, a more calibrated approach would be required to assess programme impact versus impact from any one publication.

On the continuum from complex to simple the ten normative products could be placed as follows:

Table 4: Scope of change

Scope of change		
Complex	**Complicated**	**Simple**
Global Code of Practice on the International Recruitment of Health Personnel. Indoor air quality	HIV/AIDS strategy International food standards developed and adopted by the Codex Alimentarius Commission Roadmap for neglected tropical diseases Mental Health Action Plan Nutrition implementation plan	International Nonproprietary Names Essential Medicines List ARV guidelines

CHAPTER 4: CONCLUSIONS AND RECOMMENDATIONS

4.1. Conclusions

The following chapter draws conclusions from chapter 3 on the two overall evaluation questions: (a) How to define WHO´s normative function? and (b) What factors determine strength and effectiveness of normative products?

WHO´s normative function

WHO claims to be a normative UN agency, but the term is often used not because of its clarity, but because of its attractive ambiguity. There was no consensus either in the ten case studies on how to define normative products. The understanding of WHO´s normative role among people interviewed varied immensely. Flexibility in use of concepts supports pragmatism, but the downside is weak strategic direction. It is important to emphasise that this is more than a semantic issue. The understanding of normative goes to the core of WHO´s mandate with important implications for how to set priorities and allocate resources. It is ultimately about organisational identity.

The evaluation has presented a broad variety of normative products of high technical quality reflecting the international norm- and standard-setting role of WHO. Some of the programmes are small and not always well known either within or outside the organisation, but represent and reflect core WHO functions and deserve higher visibility and recognition.

The multiple and at times conflicting meanings of normative are understandable. "Normative" is a complex concept. Most of the definitions are legitimate and can be justified. The underlying challenge is that the understanding of normative depends on the theoretical (explicit or implicit) perspective – from which normative is defined. To reach one universally "correct" definition is unlikely. On the other hand, it is possible to come to an agreement on how normative work should be defined – in other words how terms should be understood and used within WHO – acknowledging that alternative definitions exist.

WHO´s activities are often placed in two categories: normative and technical cooperation. Normative activities have to do with ideas, values, setting goals, standards and advocacy, and are seen to have salience for all Member States of WHO. Technical cooperation activities are on the other hand said to be operational, and to be assisting countries plan and implement their own health systems. They are relevant for a smaller number of Member States and are assumed finally to be relevant at country level.

In such an approach, normative becomes global activities that are thought to be distinctly different from technical cooperation. In reality, technical cooperation has both normative and operational aspects, with activities at global, regional and country levels. Normative work builds on an iterative dynamic process between all levels of the organisation – countries, regions and global. Furthermore, the balance between the two often changes over time and within programmes, as does the mix of sources of funds (Cooperation for Health Development 1995).

How is normative understood in the ten case studies? What are the underlying theoretical perspectives or categories shaping the understanding?

(a) A constitutional perspective

The first option is a legal constitutional perspective. The Constitution specifies three types of legal instruments which can contribute to the achievement of the overall objective: conventions and agreements; regulations; and recommendations. All such products endorsed by the World Health Assembly are "normative" based on the legitimacy of their status and approval.

Consequently, there would only be three truly normative products among the ten cases: Codex Alimentarius, the Global Code of Practice on the International Recruitment of Health Personnel and the Global Health Sector Strategy on HIV/AIDS. They are regulatory recommendations adopted by the World Health Assembly as formal manifestations of WHO´s "soft law".

In an extended version of the same option, the Roadmap for Neglected Tropical Diseases, Global Mental Health Action Plan and Maternal, Infant and Young Child Nutrition Comprehensive Implementation Plan could be included since they are also submitted to and approved by the World Health Assembly even if they are "roadmaps" and "implementation plans" – broad operational plans with strategic normative elements.

The legal or formal perspective – defining all products endorsed by WHA as WHO´s normative work is as such an option – and a simple one. The normative character of a product does not follow from form and substance of the products, but their legal basis. All conventions and agreements, regulations, and recommendations are per definition normative. The question is to what extent this is sufficient when it comes to understanding WHO´s scientific and broader normative function?

(b) A scientific evidence-based perspective

The Twelfth General Programme of Work of WHO (2014) specifies that, in its normative and standard-setting work, WHO is a science- and evidence-based organisation with a focus on public health. WHO´s legitimacy and technical authority lies in its rigorous adherence to the systematic use of evidence as the basis for all policies. Normative products are only those based on scientific principles and empirical evidence. In this option, there would be five normative products in the sample: Guidelines for Indoor Air Quality, Guidelines on the Use of ARVs, Codex Alimentarius, International Nonproprietary Names and the Essential Medicines List.

The first two are clear examples. They strictly follow procedures outlined in the Handbook for Guideline Development and have also been screened by the Guidelines Review Committee (GRC).[33] The role of science is also emphasised by Codex Alimentarius Commission:

"The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply."(Codex case study)

The INN and essential medicines lists have a different format than the technical guidelines. They are lists of drugs – the first with names and the second specifying essential drug requirements. However, both programmes follow scientific rules and expert committees for selecting names and drugs. From that perspective, the Global Code of Practice on the International Recruitment of Health Personnel would not qualify as a normative product since it serves a different purpose providing ethical norms and standards. The strategies and action plans come in a middle category. They are based on available scientific evidence, but also on political priorities and choices.

The Codex Alimentarius Commission makes a useful distinction between risk assessment and risk management – applicable in most other cases too. Broadly speaking, risk assessment is conducted by the expert committees and consultations that give scientific advice to Codex and is described as *"a scientifically-based process".* Risk management on the other hand is defined as *"the process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection*

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[33] It has been mentioned that the GRC is supposed to ensure that the guidelines are developed based on proper evidence and review processes, but does not review or endorse their actual content.

of consumers and for the promotion of fair trade practices and, if needed, selecting appropriate prevention and control options". (Codex Alimentarius Commission case study)

The scientific evidence approach is a clear and relatively simple option for defining WHO´s normative function, but is excluding what is often considered as normative action and processes.

(c) A global public goods perspective

Public goods are understood as goods and services that are "non-rival" and "non-excludable". In other words, no one can be excluded from their benefits. Their consumption by one person or country does not diminish consumption by another. Such goods are provided by non-market mechanisms such as the UN – since the benefits are available to everyone. [34] There is also an increasing demand for international public goods.

Public goods become global when the benefits flow to more than one country and no country can effectively be denied access to those benefits[35]. Global public health goods can be divided in two categories:

- Final public goods – e.g. eradication of polio.
- Intermediate public goods such as:
  - International norms and standards.
  - Control of infectious disease – to avoid cross-border risk.
  - Information and knowledge.

It is important to emphasise what constitutes global public health goods. It is not their legal status or scientific character, but their benefit to all countries. They include the "traditional" normative products, but also research, evaluations, descriptive global health trends assessment, such as the annual World Health Statistics, Global Burden of Disease, Risk and Injury, World Malaria Report, Maternal Mortality, Countdown 2015, etc.

Within such a perspective, normative means global products and functions of salience to all Member States regardless of the state of health development in the country, combining regulation, coordination, policy identification and formulation, research information and advocacy. This is an inclusive delineation of WHO´s normative function and all the ten cases will qualify as normative products.

Technical cooperation represents on the other hand those activities aimed at assisting countries with special needs, responding to their requests for support to develop and implement their own health services. They cover both normative and operational activities, which specifically serve those countries with development needs.

(d) A policy process perspective

This perspective is even broader and defines normative as part of all phases in a policy process. It includes the normative product, but also the broader normative process in which it is placed and operates. All the ten cases will in principle qualify as normative products, but it is their implementation and follow up that determine their ultimate normative value. The case studies

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[34] The normative instruments acknowledge the transnational nature of health threats. Through these instruments, countries gain collective defence against shared threats (The Future of Financing for WHO 2010).

[35] "Global functions can be distinguished from national or sub-national functions in that they are beyond individual states´ capacity and entail such categories as norms and standards, global action, professional management, financial resource transfer, scientific research capacity, and leadership. Global health functions can also be distinguished as actions taken to promote global public health goods" (Ruger and Yach 2008).

have tried to place and explain each product within the process from initiation, formulation and design, dissemination, adaptation and incorporation to monitoring, evaluation and learning.

The previous chapter explained that the focus and attention in most of the cases have been on the design and formulation of a high quality normative product. Aspects of dissemination, follow up and use are not absent, but they (arguably) do not get as much attention as the product itself (or aspects of dissemination are simply not systematically documented). There are examples of normative products making constructive contributions as advocacy tools to broader normative processes, but good examples were difficult to find.

"At the global level, the WHO Global Code and the ILO Conventions and Recommendations on migrant workers are key instruments for the global governance of health worker migration. The 2015 review of the WHO Global Code found that it is maturing and gaining in legitimacy. In 2016, there was a significant increase in the number of countries participating in national reporting to WHO. However, many countries with critical health workforce shortages still need support to implement the WHO Global Code and its national reporting processes. These instruments could be made more effective by an updated broader international agreement on the health workforce, including provisions to maximize mutuality of benefit from socially responsible health worker migration". (Global Code case study)

Needs and demands for policy formulation and support for the implementation of policies come from Member States, the organisation itself, other international organisations, pressure groups, aid agencies and the wider scientific community. These pressures stimulate a process of problem identification and policy formulation. Policy development makes policies operational through a process of research, consensus building and meetings of experts, whose outputs are norms and standards, plans and guidelines, which can then be used by countries.

Although many activities occur at the global level, their development requires a constant exchange of information and experience with those countries where the problems manifest themselves. Regions and countries are supported in putting new policies into practice by such activities as the provision of plans and guidelines, training programmes, draft regulations, supply of new technologies and procurement of supplies.

In this perspective – normative are aspects in the identification, formulation and implementation of a framework, recommendation or guideline. The strength of such an approach is the focus on normative functions – on how WHO is practising its normative mandate and using normative products. WHO´s role is to present recommendations on the worth and merit of health policies and practices – to guide countries on questions about what to do and how to do it while leaving out implementation.

Effectiveness of normative products

The ten normative products cover vast thematic areas and are heterogeneous both in terms of form and substance. There is no surprise that effectiveness varies between the ten products. The discussion about effectiveness is crucial. WHO should prepare high-quality normative products, but quality without or with only sub-optimal results is insufficient. A stronger focus is required on measuring and evaluating results, but also on a more systematic reflection on what constitutes and fosters strong and effective normative products.

Chapter 3 discusses the importance of eight different variables or contributing factors to effectiveness. The list is not exhaustive, but had to be limited for practical reasons. What makes a normative product effective varies considerably between the products. There is not one decisive variable – in most cases there is a mix. The following findings and trends emerged from the ten case studies:

Who initiated the normative process (extent and source of demand) was found to be important, but not in all cases. For at least two normative products, relevance and effectiveness were the results of perceived usefulness (INN and EML) rather than strong partner and/or country demand. The best example is the INN Programme. Since its inception, the aim has been to provide health professionals with a unique and universally-available designated name to identify pharmaceutical substance. It originates from WHO´s core constitutional mandate and is a headquarters and expert-driven normative activity – producing an international "public good" in which WHO´s mandate is not contested. The concept of a carefully selected list of medicines of assured quality that meets the majority of health care needs of a community has also proved to be an effective and affordable solution for the treatment of common ailments. The list is used because it is found useful and intuitively relevant.

A lesson from the theory of strategic planning is that the process whereby a strategic plan is constructed is of utmost importance. This was not true in all cases. The strategy, technical guidelines and roadmaps/implementation plans were all the result of extensive internal and external consultations with stakeholders. It was not possible to quantify volume of consultations, but the case studies illustrate serious intent and commendable practice in requesting feedback and involving stakeholders in consultative processes. However, it is striking that the International Nonproprietary Names and Essential Medicines lists are headquarters and expert-driven programmes – without broad consultations with and involvement of external stakeholders. For those three normative products, there is no correlation between level of consultation and participation in design and their importance and impact.

The ten case studies indicate that the more scientific- and evidence-based products have a higher direct/immediate effectiveness (level of knowledge, uptake and incorporation) than those with a stronger legal/formal backing and less supportive scientific evidence. Content matters more than legal status. Higher level of quality of evidence were as such associated with increased uptake in national guidelines. The lists of essential medicines provide secretariat guidance to Member States with a high level of success because of their immediate practical use. The two technical guidelines, the INN and essential medicines list are based in WHO´s role as a scientific and evidence-based organisation. Their effectiveness is not founded on formal status, but WHO´s legitimacy and scientific authority and the technical quality of the products. The Global Code of Practice on the International Recruitment of Health Personnel is mainly a legal and "political" document and its effectiveness mixed, but underpinned by a substantial body of evidence. The strategy, roadmap and action plans have evidence-based technical elements, but serve another purpose than the technical guidelines.

In terms of formal status, the two most "powerful" products in the sample are the Codes – Codex Alimentarius and the Global Code of Practice on the International Recruitment of Health Personnel. They are examples of constitutional "soft laws". The Global Code is an international resolution approved by the World Health Assembly. The "strongest" and in practice most binding normative products are the International Nonproprietary Names (INN) and the food quality norms and standards defined by Codex Alimentarius Commission. The INNs and the food safety and quality norms and standards are advisory and approved internally by the DG (INNs), but when used and adopted they often become mandatory in national or, as in the case of the European Community, international legislation.

WHO has few and weak instruments for supporting implementation of norms and standards. There are no "sticks" whereby WHO can order implementation and ensure compliance. There are seldom any "carrots" either, where there are incentives (and additional resources) for actors in the system to design interventions according to the strategies or guidelines. There are mostly "sermons" where external partners are motivated to act according to the guidance as a result of WHO´s credibility, awareness raising and through information sharing.

In all the ten cases, there was a much stronger focus on the preparation, design and formulation of the normative product than on dissemination and follow up – having a negative impact on effectiveness. Dissemination and follow up were not ignored, but more time, resources and attention were dedicated to preparing a high-quality product than on the former. There is also limited data and information available on the actual level and effectiveness of dissemination and use. Most of the publications were based on a "theory of change" – articulating what was required to initiate change - and consequently there were no systematic and comprehensive plans for promoting change and reform.

All ten normative products provide evidence of results, but results are exceptionally varied. With few independent evaluations available, the documentation of results depends also on internal reviews and self-reporting. Given the lack of structured and systematic monitoring and independent evaluation of implementation more results may actually have been achieved than those documented.

There is a major difference in effectiveness between normative products requiring "significant" and "complex" change involving transformations in global and national health policies and practices and those promoting "simple" technical changes and "incremental" reforms. Those with a high level of complexity have obviously the greatest difficulty to document effectiveness. The most straightforward is the INN which is basically to agree on a name to identify a pharmaceutical substance. This is often a difficult practice and involves a complicated and vigorous process, but it is not a complex undertaking – the result follows from the implementation of the activity. The concrete and evidence-based recommendations in the ARV guidelines can also document a high level of implementation and incorporation in country policies.

The Global Code of Practice on the International Recruitment of Health Personnel is on the other side of the continuum. It is not only about a disease or the health sector, but about the politically sensitive issue of international migration – a multi-sectoral issue that goes beyond the health sector and, as such, long-term results are much more difficult to measure. On the other hand, the Global Code has in place a system for monitoring intermediate outcomes.

In other words, there is no single and simple answer to what guarantees determines strong and effective normative products. There are lessons to learn and share, but each case requires its own "theory of change" and a strong implementation plan. It should also be emphasized that other explanatory factors could have been included in the analysis, such as for instance type and level of managerial support to normative processes and products. Several of the people interviewed referred to the lack of recognition, low visibility and weak senior-level support to WHO´s normative function as constraining factors.

There is also another issue influencing effectiveness – which has not been directly discussed – the weak or missing link between plans and resources. Several WHO resolutions – recommendations and guidelines are presented every year including political and moral commitments to global objectives and targets, but there are no or weak links between intentions and budgets. In the literature on aid effectiveness, the differences between planners and searchers are discussed and WHO belongs among the planners (Easterley 2006). In foreign aid, planners announce good intentions – grandiose global plans, but don't have the resources to carry them out. Searchers on the other hand find projects that work and reap the rewards. Planners raise expectations, but take no responsibility for meeting them. Searchers accept responsibility for their actions. Planners determine what to supply while searchers find out what is in demand. Planners apply global blueprints. Searchers adapt to local conditions. Planners at the top lack knowledge of the bottom while searchers find out what the reality is at the bottom.

The basic problem is to what extent it is irrational to set a prefixed and grandiose goal because there is no reason to assume that the goal is attainable at a reasonable cost with the available means. Most WHA resolutions seem to come in this category. Hence, as you cannot do what you want, want what you can do. The searchers argue for small, incremental reform as opposed to "utopian" social engineering. They argue that the solution is to have fewer objectives. Donors will perform better when they have tangible measurable goals with a clear link between efforts and results.

4.2.   Recommendations

The following strategic and more operational recommendations are suggested:

1. WHO should prepare a policy paper defining its normative instruments (normative products and functions). It should also prioritize and prepare stronger and more effective normative instruments. This could mean fewer publications but, even more importantly should include an active deliberation of how to ensure their normative strength and effectiveness.

2. Normative instruments could be defined as follows:
    - **Core normative products** are international public goods. Such products are per definition global, but the regional and country levels play important roles in their preparation, validation and application. There are several categories of normative products, each with its own characteristics:
        o *Constitutional normative products* – conventions/regulations/regulatory recommendations approved by the World Health Assembly or by an equivalent body (e.g. Codex Alimentarius Commission). Such products vary in form and substance. They are sometimes binding legal instruments. WHO adopts the normative products via its constitutional authority.
        o *Scientific and technical normative products* – norms and standards set by the Secretariat for a broad range of thematic areas, based on scientific evidence and advice from leading technical experts.
        o *Health trend assessments* such as the annual World Health Statistics, Global Burden of Disease, Risk and Injury, World Malaria Report, Maternal Mortality, Countdown 2015, etc. (international public goods).

    - **Supportive normative functions** – defined as the normative elements of WHO core functions.

3. WHO should also prepare a plan for the development of normative products based on an assessment of demands and needs and in line with WHO´s corporate priorities for achieving a higher level of coherence between the normative products.

4. Guiding principles and agreed quality assurance procedures should be established for the design, formulation and dissemination/follow-up of all normative products. It would be appropriate if all normative products, including strategies, roadmaps and global action plans, were based on agreed standards and reviewed independently, as is the case for technical guidelines. The GRADE approach to assessing quality of evidence for recommendations could, with adjustments, be used for all normative documents – not only technical guidelines.

5. WHO should give equal attention to products and process and shift attention and resources from preparation of normative products to the entire normative processes, encompassing assessment of needs, initiation, design and preparation, dissemination and use, adaptation and incorporation in health policy and practices, feedback and learning. They should also be appropriately and adequately budgeted.

6. Normative functions in WHO should be funded through sustainable funding and not only through voluntary and more unpredictable funding. Funding of normative products exclusively through voluntary funding, including from the private sector, should be avoided.

7. Systems and plans for monitoring and evaluation should be more standardised and streamlined. There is a need to shift focus from assessing quality of normative products and their recommendations to documenting effects. High quality monitoring should be combined with independent evaluations.

8. There should be a follow up to this evaluation: (i) assessing WHO´s normative functions from a country perspective, in order to better understand how and to what extent WHO´s normative work is relevant and makes a difference in countries; (ii), assessing the global scope of WHO´s normative work in terms of size and number of normative programmes, activities and funds utilised; and (iii) assessing and analysing the actual and changing profile of what WHO does as a normative Organisation.