Evaluation of WHO's Normative Function

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1. Codex Alimentarius Commission

1. Initiation

The Codex Alimentarius Commission (hereinafter referred to as Codex) is different from the other normative examples included in this evaluation. It is a normative product, but more like a normative organisation or body. It is responsible for the development of a broad range of standards, guidelines and codes of practice applied to food (and the compilation is the Codex Alimentarius), to the extent that Codex, or the food code, has become the global reference point for consumers, food producers and processors, national food control agencies and the international food trade. What is more, Codex food safety texts are a reference in WTO trade agreements and dispute resolution [1].

The Codex Alimentarius Commission was established in 1963 as an intergovernmental body by FAO and WHO. The term Codex is broad and used with multiple meanings, but it is basically a risk management body. Membership is open to all Member States of FAO and WHO, and observers. There are currently 188 members, all of which are WHO Member States with the exception of the European Community, and 240 observer organisations, of which 168 international non-governmental organisations representing producers, industry and civil society, 16 United Nations agencies and programmes and 56 intergovernmental organisations.

The legal basis for the Commission is contained in the ten articles that form the Statutes of the Codex Alimentarius Commission. These were adopted by the FAO Conference and the World Health Assembly enabling it to function as a UN body.

Codex has emerged over time. Food regulators, traders, consumers and experts were looking increasingly to FAO and WHO for leadership in unravelling the complexity of food regulations that were impeding trade and providing mostly inadequate protection for consumers. In 1953, the governing body of WHO, the World Health Assembly, stated that the widening use of chemicals in food presented a new public health problem, leading to the formation of a formal risk assessment body, JECFA.

In October 1960, the first FAO Regional Conference for Europe crystallized a widely held view when it recognized:

"the desirability of international agreement on minimum food standards and related questions (including labelling requirements, methods of analysis, etc.) ... as an important means of protecting the consumer's health, of ensuring quality and of reducing trade barriers, particularly in the rapidly integrating market of Europe".

The Conference also felt that*: "... coordination of the growing number of food standards programmes undertaken by many organizations presented a particular problem".*

Within four months of the regional conference, FAO entered into discussions with WHO, the United Nations Economic Commission for Europe, the Organisation for Economic Co-operation and Development and the Council of the Codex Alimentarius Europaeus with proposals that would lead to the establishment of an international food standards programme.

In November 1961, the Eleventh Session of the FAO Conference passed a resolution to set up the Codex Alimentarius Commission. In May 1963, the Sixteenth World Health Assembly approved

[1] See for example United States - EU trade disputes concerning Meat and Meat Products (Hormones).

the establishment of the Joint FAO/WHO Food Standards Programme and adopted the Statutes of the Codex Alimentarius Commission.

Codex Alimentarius Commission is open to all Member Nations and Associate Members of FAO and WHO. The main decision-making body is the Codex Alimentarius Commission, which meets annually in Rome or Geneva. Between sessions, an Executive Committee acts on behalf of the Commission. The CAC is supported by a permanent joint FAO/WHO secretariat housed at FAO Headquarters in Rome within the Agriculture and Consumer Protection Department.

2. Design and formulation

According to its most recent strategic plan (2014-2019) Codex has four strategic goals:

- Establish international food standards that address current and emerging food issues.
- Ensure the application of risk analysis principles in the development of Codex standards.
- Facilitate the effective participation of all Codex Members.
- Implement effective and efficient work management systems and practices.

The legal basis for the Commission's operations and the procedures it is required to follow are published in the Procedural Manual.

Expert advice and risk analysis

FAO and WHO convened the first joint FAO/WHO Conference on Food Additives in 1955. That Conference led to the creation of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). It has served as a model for many other FAO and WHO expert bodies, and for similar scientific advisory bodies at the national level or where countries have joined together in regional economic groupings.

It could be claimed that the normative aspect in Codex is the risk analysis. To this end, expert scientific advice to inform Codex standard making is provided by established expert committees, financed and administered jointly by FAO and WHO. JECFA (active since 1955) is responsible for food additives, contaminants and veterinary drug residues and JMPR (active since 1963) for pesticide residues. JEMRA is the newest group, and is responsible for microbiological risk assessment.

Codex makes an important distinction between risk assessment and risk management. 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".* The risk assessment activities are independent of and not part of the CAC or the joint FAO/WHO Food Standards Programme. Risk management 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 of consumers and for the promotion of fair trade practices and, if needed, selecting appropriate prevention and control options".* This is the work of the Commission and its subsidiary bodies.

Codex committees and ad hoc task forces are responsible for the preparation of draft standards for submission to the Commission, whether intended for global use or for a region or group of countries. There are two broad types of Codex committees. General subject committees are responsible for establishing standards on general principles of food safety and consumer health protection applicable to all food commodities (e.g. recommending maximum residue limits for pesticide residues). Commodity committees are responsible for establishing standards relevant to specific commodities.

Procedures
Standards are elaborated and adopted by a structured eight-step procedure. In Step 1, taking into account its 'criteria for the establishment of work priorities' the Commission and the Commission's 6-year Strategic Plan, i.e. Member States, decides that a standard should be elaborated and which subsidiary committee or other body should do the work. In Step 2, the secretariat or committee arranges for the preparation of a 'proposed draft standard' taking into account scientific advice from expert committees. In Step 3, the proposed draft is sent out for comment to members and observers and in Step 4 the committee considers the comments and may decide to amend the proposed draft standard. This proposed draft is submitted to the Codex Commission or Executive Committee at Step 5 with a view to its adoption as a draft standard, taking into account comments of members on implications of the proposed draft standard for their economic interests. Steps 6 and 7 repeat Steps 3 and 4 in a second round of consultations and amendments by the committee concerned. If adopted by the Commission at Step 8, the draft becomes a Codex standard. Increasingly a fast-track procedure is being applied, i.e. omission of steps 6 and 7 and adoption of standards at step5/8.

Consensus-based decision making
The Procedural Manual states that *"the Commission shall make every effort to reach agreement on the adoption or amendment of standards by consensus. Decisions to adopt standards are taken by voting only if such efforts to reach consensus have failed".* Though no precise definition of consensus has been adopted, legitimacy is seen to require that the Commission adopts a process of *'active consensus building'* including carrying out further studies to clarify the scientific basis of controversial issues, ensuring thorough discussion at meetings, organizing informal meetings of parties concerned where disagreements arise, redefining the scope of subject matters being considered to cut out issues on which consensus cannot be reached.

The role of science in decision-making
In 1995, the Commission established working principles concerning the role of science in decision-making processes and the role of 'other legitimate factors' that might be taken into account. These principles emphasise that Codex standards, guidelines and recommendations should be based on scientific principles and evidence:

"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."

It is also agreed that 'other legitimate factors' can be taken into account provided these relate to the health protection of consumers and/or promotion of fair trade practices:

"When elaborating and deciding upon food standards, Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade."

There is still no precise agreement on what constitutes an 'other legitimate factor'.

So in summary, the scientific basis for Codex work is that standards are developed/proposed, based on the independent scientific advice provided by expert bodies organized by FAO/WHO, taking other considerations, such as aspects of food security, implications for trade, into account. If accepted, these become global standards, applicable to all countries. Risk analysis is said to be fundamental to the scientific basis of Codex food safety standards.[2] It is for instance due to its

[2] Risk analysis is comprised of three elements: risk assessment, risk management and risk communication. Risk assessment is the independent evaluation of all available scientific information. Risk management is the actual Codex work, elaborating standards and other texts based on the scientific

scientific basis that Codex texts are considered by WTO as the international reference for food safety standards.

3. Quality assurance

From the beginning, the Codex Alimentarius 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 of providing the scientific assessments, has provided a focal point for food-related scientific research and investigation on a global basis, and the CAC itself has become an important international forum for the exchange of scientific-based information about food.

JECFA has been in existence since 1955, to evaluate the safety of food additives. In 1972, contaminants and naturally occurring toxicants were included, and in 1987, veterinary drug residues. It provides scientific advice to the Codex Committee on Food Additives and the Codex Committee on Contaminants in Food and the Codex Committee on Residues of Veterinary Drugs in Food. For veterinary drug residues, it proposes MRLs and for additives and contaminants, acceptable daily intake.

JMPR has been meeting since 1963. It assesses toxicology, dietary intake and residue data to provide scientific advice to the Codex Committee on Pesticide Residues on maximum residue levels (MRLs) in food and feed that are likely to result from legally-permitted uses of pesticides. These estimates are the basis for establishing Codex MRLs.

The Joint Meeting on Microbiological Risk Assessment (JEMRA) examines risks from microbiological hazards in foods. JEMRA's aim is to assist Codex in the development of standards and guidelines and member countries to overcome problems related to microbiological hazards in foods. Codex has requested that JEMRA also become a permanent Committee, but FAO and WHO have not yet implemented the proposal.

FAO and WHO expert meetings are independent of the Commission, although their output contributes to the scientific credibility of the Commission's work. The principle of ensuring the independence of scientific advice from practical realities of risk management has been followed by Codex from the earliest days.

The credibility and acceptability of any conclusions and recommendations in the risk assessments depend to a very large degree on the objectivity, scientific skill and overall competence of the members of the scientific advisory bodies who formulate them. For this reason, great care is taken in the selection of experts invited to participate. Those selected must be pre-eminent in their specialty, have the highest respect of their scientific peers, and be impartial and indisputably objective in their judgement. They are appointed in their own personal right – not as government representatives or as spokespeople for organizations – and their inputs are theirs alone. Experts are invited through a "call for experts". However, the participation of an expert in a FAO/WHO meeting does not imply that they are endorsed or recommended by the two Organizations, nor does it create a binding relationship between the expert and FAO/WHO.

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assessments provided and taking other aspects into account. Risk communication is the responsibility of everybody involved, and entails communication between the risk assessment and management bodies (in this case through the secretariat, i.e. FAO/WHO Secretariats of the scientific advice programme communicate with the Codex Secretariat); but also communication with stakeholders, i.e. national authorities, consumers.

Furthermore, Codex standards and related texts are not a substitute for, or alternative to national legislation[3]. Every country's laws and administrative procedures contain provisions with which it is essential to comply.

Furthermore, the quality of final Codex standards, guidelines and recommendations (as risk management tools) is ensured by the Critical Review of the final draft texts, conducted by the Codex Executive Committee assisted by the Codex Secretariat, prior to final adoption by the Codex Alimentarius Commission.

4. Dissemination and country support

The original Codex texts in the 1960s were hardcopy volumes. With advances in electronic archives, CD-ROMs were adopted in the 90s. Additionally, the booklet "Understanding Codex" was first published in 1999, to foster a wider understanding of the evolving food code and of the activities carried out by the Codex Alimentarius Commission – the body responsible for compiling the standards, codes of practice, guidelines and recommendations that constitute the Codex.

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. Since the first publication there have been many changes to the way in which Codex works. The new 4th edition of "Understanding Codex", currently available only in English (July 2016) has been revised with current data and is now presented with a new format to help all those wishing to learn about international standards for food safety to begin to "Understand Codex". The 3rd edition of "Understanding Codex" is available in French, Spanish, Arabic, Chinese and Russian. Translations of the 4th edition are available since end of 2016.

Codex Trust Fund 1:

The main objective of the first FAO/WHO Project and Fund for Enhanced Participation in Codex (Codex Trust Fund CTF1) was to assist Codex members that are developing countries or have economies in transition, in enhancing their level of effective participation in the development of global food safety and quality standards, including standards for food labelling, by the Codex Alimentarius Commission[4]. When the Trust Fund was launched in 2003, the Codex membership amounted to 169, in 2015 it totalled 188 (187 member countries plus the European Union as a member organization)[5].

The fund ran from 2004-2015, by and large focussing on widening participation in Codex by bringing representatives of developing and transition economy countries to Codex meetings. This, it was claimed, was important, as many developing countries had no, or very limited previous exposure to Codex. Citing WHO/FAO (project) documents, the support of the Codex Trust Fund to physical participation and capacity building for effective participation in Codex is shown to have contributed successfully to improvements in both the quantity and quality of participation in Codex.

Indeed, the final project evaluation of CTF1 highlighted that the CTF had been very successful at fulfilling its primary objective, supporting 2,078 participations from 2004 to December 2013, wherein a clear majority (95-97%) were satisfied to very satisfied with their participation.

[3] The EU has for example adopted Codex guidelines, whereas the United States has not (interview).
[4] 2015 Annual Report and Final Report of the Codex Trust Fund-1 (2004-2015 Codex Trust Fund2-Project Document (December 2015)
[5] Ibid

Further, more developing countries are self-funding their participation than before the start of the CTF6.

Codex Trust Fund 2:
The successor initiative, building on CTF1 was launched in 2016. The new Codex Trust Fund (CTF2), for the period 2016-2027, reportedly "builds on the experience gained over the past 12 years and takes the next step in supporting developing and transition economy countries to help build their capacity to engage fully and effectively in the Codex Alimentarius Commission (where international food safety standards are established)"

To this end, CTF2 will thus shift7 from a primary focus on supporting physical participation in Codex meetings, to helping build strong, solid and sustainable national capacity to engage in Codex. At core of the CTF2 is an application process. Resources are provided to eligible countries/activities aimed at increasing effective engagement in Codex. The increased capacity of countries to engage in Codex, and the sustainability of this engagement will be monitored throughout the entire period of CTF2 8.

5. Relevance and results

There are good reasons to conclude that Codex texts have contributed to the safety and quality of the food we eat – even if it is difficult to know exactly *how* much. The Codex Alimentarius forms a global rule book that everyone in the food chain can follow, and it is at the same time a lifeline to those countries still working to strengthen their own national food safety control systems. The argument goes that the code has had an enormous impact on the thinking of food producers and processors as well as on the awareness of the end users – the consumers. To this end, its influence extends to every continent, and its contribution to the protection of public health and fair practices in the food trade is said to be "immeasurable" (interview).

Survey stakeholders unanimously agree that this is an example where FAO/WHO has provided relevant and strong normative guidance. They assess the relevance and importance of the Codex standards as very high, for instance in terms of "bringing harmonization to member states, enabling international trade whilst ensuring consumer protection". They therefore argue that Codex is "extremely important, both for a consumer protection viewpoint and for facilitating international food trade further, essential for developing countries to form the basis of food regulations and standards". Codex is also actively utilised by over half of the survey stakeholders, and reportedly "accepted" and used in member countries to a large extent as well. To the question *why* Codex has provided relevant and strong normative guidance, the highest rated explanations are "because of its scientific quality/evidence base" and "because of their status as international "law" .

> When asked what is the feedback on Codex in general from networks (internally/externally), survey stakeholders note that Codex is generally renowned (and the work of JMPR and JECFA appears to be well regarded). However, factors such as frequent staff turnover may lead to lack of knowledge and interest in Codex, thus ensuring adequate funding is mentioned as necessary. [9]

The survey asked to what extent Codex has achieved its strategic objectives. Respondents could

[6] Codex Trust Fund2- Project Document (December 2015)
[7] This switch in focus is supported by the findings of the final project evaluation of the Codex Trust Fund which took place in 2014
[8] Codex Trust Fund2- Project Document (December 2015)
[9] WHO secretaries to JECFA and JMPR have been stable for a number of years while WHO Secretary to JEMRA has changed every 3 years. FAO Secretary to JEMRA changed rather frequently while the FAO Secretary to JEMRA has been the same person for a number of years. The Codex Secretariat has been relatively stable for the past decades.

choose from options, wherein "ensuring the application of risk analysis principles in the development of CODEX standards" was achieved to a large extent. Codex has also "established international food standards that address current and emerging food issue" to a large extent.

What emerges from the more qualitative in-depth questions in the questionnaires, is that there are several success stories:

"That Codex standards, guidelines and recommendations are now the bases for setting international food standards, is seen as major success for FAO and WHO, which has been achieved with minimal investment by Member States. Perceived as a flagship programme of both bodies, more publicity should therefore be gained for the excellent work of the Secretariat and advisory bodies".

More specific achievements further include the Codex General Principles of Food Hygiene - HACCP - consensus on risk assessment for GM food. The increased involvement of Russian-speaking countries, including Kazakhstan nominated as next CCEURO chair is also commended (survey response).

Enabling developing countries to strengthen their food control systems may indeed contribute to improving their socio-economic situation. In their own reports, Codex argues that improved food control systems may lead to a safer domestic food supply and hence less of a burden to health care systems, less absenteeism from work and school due to illness and improved nutrition. It also enhances opportunities for those countries to export foods thus increasing their GDP.

The following overall achievements are highlighted in reports:

- Codex is an important international reference point for developments associated with food standards.
- Throughout much of the world, an increasing number of consumers and governments are becoming aware of food quality and safety issues and are realising the need to be selective about the foods being consumed. Codex has helped to put food as an entity on political agendas.
- Codex has been supported in its work by the now universally accepted maxim that people have the right to expect their food to be safe, of good quality and suitable for consumption.

The positive effect of the Commission's work has also been enhanced by the declarations produced by international conferences and meetings. Over the past 20 years, national representatives to the United Nations General Assembly, the FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade, the FAO/WHO International Conferences on Nutrition, the FAO World Food Summit and the WHO World Health Assembly have either encouraged or committed their countries to adopt measures ensuring the safety and quality of foods.

Yet, it is often difficult for many countries to accept Codex standards in the statutory sense. Differing legal formats and administrative systems, financial reasons, varying political systems and sometimes the influence of national attitudes and concepts of sovereign rights may impede the progress of harmonisation and deter the acceptance of Codex standards.

The (first) evaluation of Codex (2002) found that governments agreed that Codex standards had been important for their country. Low- and middle-income countries find them very important in protecting the health of their consumers by ensuring safe food whether produced domestically or imported, and for trade facilitation domestically and internationally. High-income countries, with better-developed domestic food legislation and control systems, place

more emphasis on Codex for export facilitation and ensuring the safety of food imports. Producer and consumer NGOs also rate Codex standards very important in all their functions.
The majority of countries at all stages of development claim to have adopted into their national legislations more than 60% of all types of Codex standards except for those relating to methods of analysis, though for domestic legislation Codex is probably most important to developing countries and the smaller developed countries that do not have the resources to develop all their own standards.

During country visits it was found that exporters and importers, including the major developed countries, find that Codex standards provide a basis for negotiations in trade over quality and safety, a view shared by industry. WFP also uses Codex standards as a reference in specifying contracts for food aid.

Significantly, survey respondents sense the relevance and importance by Codex standards as the ultimate standards, mainly because of their use as benchmark standards at WTO. Codex standards are said to be critical in particular for developing countries that utilize either the standards themselves, or the scientific advice delivered to Codex to shape national legislation. In recent decades, Codex standards may have slightly lost in impact that seems to parallel seemingly the loss in standing of all UN programmes/activities with the rise of other private and multilateral agreements/standards. Yet, it is unique in that it is an institutional framework where public health (WHO) and agriculture/food production (FAO) work intimately together to produce health-protective and trade-inclusive food standards, supporting One Health and multiple SDGs (namely SDGs 2, 3, 8 and 17) in a coordinated and concurrent manner. Relatedly; "codex standards are critically important as benchmark and for developing countries. They are essential for development of nations and to facilitate trade" (survey respondent).

A central critique however, is that Codex is too political, exposed to lobbying and too slow in decision making. This relates to another critique; namely that scientific advice is underfunded and is arguably becoming a limiting factor for the work of Codex (survey respondent).
Codex is also subject to other clear challenges. As summarised by one stakeholder, there are "continuing challenges to ensure effective participation of developing countries and of consensus because of non-science based factors". These challenges are amplified by lack of data/evidence on application of Codex standards at the national level and ensuring sustainable participation of developing and transition economy countries. The more specific challenges mentioned relate to "challenges in interpretation/divergent views of safety of veterinary drugs with endocrine activity" (survey response).

Country Uptake- Example: the use of Codex standards and related texts in the AFRICA region:

As regards country uptake and incorporation, a survey[10] was conducted in October 2016. More specifically, the aim was to analyse the use and relevance of Codex standards and related texts in the African region (23 out of 49 member countries responded to the survey).[11] The main findings suggested that, while 42 percent of the respondents fully adopted Codex Maximum Residue Levels (MRLs) for pesticides in food and feed, 35 percent partially used, but clearly referenced them in national legislation. Only six countries stated they did not make any use of

[10] It was decided to focus on specific standards that would be widely known and representative for their respective categories (i.e. numerical standards, general subject standards and general principles). Based on this assumption the survey covered: 1)The use of Maximum Residue Levels (MRLs) for pesticides in food and feed; 2) The use of three general subject standards General Standard on Food Additives (CODEX STAN 192- 1995), Contaminants and Toxins in Food and Feed (CODEX STAN193-1995), Labelling of Prepackaged Foods (CODEX STAN 1-1985); and 3) The use of General Principles of Food Hygiene (CAC/RCP 1-1969).

[11] Similar surveys have also been carried out in the other regions.

Codex MRLs. In addition, member states were asked about difficulties related to the general use of Codex standards. What emerged is that for many African countries, the most frequent stated difficulty was related to resource investments and capacity building which are needed for adequate testing, monitoring, interpretation and implementation of Codex standards. The survey underscored that many countries also struggle with a lack of awareness of Codex standards and coordination of food safety matters among local authorities [12].

6. Feedback and learning

The first complete evaluation of Codex took place in 2002. The evaluation found that Codex food standards had a very high importance to members. They were seen as a vital component of food control systems designed to protect consumer health and for international trade. Standards were regarded as a fundamental prerequisite in consumer protection. International standards also provide a basis for smaller and lesser-developed countries' own standard setting.

Capacity building in developing countries was found to be essential for countries to protect their own citizens, to benefit from a globalizing market in food and to represent their interests in Codex and WTO negotiations. Codex and FAO and WHO capacity building were found to be continuing to make a substantial contribution internationally and to individual countries.

In improving international food standard setting, it was found particularly important to strengthen the input of independent expert advice into Codex especially for risk assessment. The scientific quality of the advice given at present is rated highly, but backlogs exist and demands are expected to rise in future.

Changes introduced in Codex since the evaluation include annual Commission sessions and a new responsibility for the Executive Committee to conduct a critical review of proposals to undertake work and monitor the progress of standards development. Codex, through the work of the Codex Trust Fund, also works to enhance the skills and knowledge regarding standard setting in developing countries so that national food control systems can be stronger and better prepared.

A more recent global awareness survey on Codex in 2015 underlined the need for Codex to strengthen and target its communications. Codex is now responding to the changing ways people today search for information over the internet and via social media.

Apart from annual reports (which refer to Codex in a broad sense) there is no regular monitoring or follow up carried out by WHO (or others) to what extent member states adopt and use the Codex standards (convert them to national standards), but a survey is carried out every second year through the Codex Regional Coordinating Committees. A recurring challenge nevertheless, seems to be resources, or rather, the lack of the latter.

Yet as paraphrased by one survey respondent, *"successes and challenges are interlinked. The facilitation of participation may illustrate this. Through the Codex Trust Fund Program countries can apply for aid to strengthen their capabilities to participate in Codex. The program worked well in the past, but is currently facing a serious funding challenge. Similar challenges exist for the delivery of scientific advice/risk assessment. National priorities and policies may prevent compromises, here, growth promoters in animal production may serve as an example, where the setting of a maximum limit for residues is challenged due to European Unions refusal to accept*

[12] Joint FAO/WHO Food standards programme/Coordinating Committee for Africa 22nd session Nairobi, Kenya, 16-20 January 2017: Use of Codex standards in the region (October 2016) prepared by the Codex Secretariat

growth promoters as a veterinary medicine. Yet, despite all challenges, Codex continues to be the only forum in which over 120 countries regularly participate to develop standards for food, with the support of FAO and WHO combined, a unique situation".

In this sense, WHO and FAO have an exclusive role. Several stakeholders agree that no other agency possesses the institutional capacity, authority-and de facto ability to cover this vast area of work.

Or as one respondent aptly sums up, "there is no other forum where public health, agriculture, food production and trade are jointly supported by the two pre-eminent UN organization with a mandate in exactly these areas. It is the only global forum where truly independent, science-based, health-protective and trade-inclusive standards can be and are developed. WHO's participation is as critical as is FAO's to support global food safety. If it is not safe, it is not food. WHO's role in the normative work, is essential for global food safety. With food being a basic human need, safe and nutritious food is critical for all human development (social and economic) in all areas. With global food safety standards by Codex (and hence FAO and WHO), there cannot be food security, there cannot not be sustained development for all".

2. Guidelines on the Use of International Nonpropriatory Names for Pharmaceutical Substances (INNs)

1. Initiation

The INN programme represents a core constitutional, but to a large extent invisible WHO normative activity or in the words of the Director General: *"Some activities undertaken by WHO are largely invisible, quietly protecting the health of every person on this planet, every day. By assigning a single international name to drugs. WHO helps to ensure that a prescription filled abroad is what the doctor ordered back home"* (Working for health: An introduction to WHO).

The INN system as it exists today was initiated in 1950 by a World Health Assembly Resolution (WHA 3.11) and began operating in 1953, when the first list of International Nonproprietary Names for pharmaceutical substances was published. The cumulative list of INN now stands at some 7000 names designated since that time, and this number is growing every year by some 250-300 new INNs.

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. It is a communication tool and technical global language ensuring that patients get the same drug all over the world.

As unique names, INNs have to be distinctive in sound and spelling, and should not be liable to confusion with other names in common use. To make INNs universally available, they are formally placed by WHO in the public domain, hence their designation as "nonproprietary". They can be used without any restriction to identify pharmaceutical substances – as such it is a prototype of an international public good.

Another important feature of the INN system is that the names of pharmacologically-related substances demonstrate their relationship by using a common "stem". By use of common stems the medical practitioner, the pharmacist, or anyone dealing with pharmaceutical products can recognize that the substance belongs to a group of substances having similar pharmacological activity.

INNs are available for use by all for the sole purpose of identifying the corresponding pharmaceutical substance. WHO encourages manufacturers to use INNs in conjunction with their corporate name to designate their products. Usually pharmaceutical preparations are also marketed by industry under proprietary names or trademarks. WHO Secretariat interacts with national trademark offices with a view to avoiding problems arising from the registration of trademarks which are similar to or derived from INNs.

INNs are intended for use in pharmacopoeias, labelling, product information, advertising and other promotional material, drug regulation and scientific literature, and as a basis for product names, e.g. for generics. WHO provides only guidance. The INNs are in principle not mandatory, but their use is normally mandatory by national or, as in the case of the European Community, by international legislation. As such, it is an example of a strong normative product – in some cases mandatory by law.

Its wide use and acceptance makes it also more binding and regulatory than other technical guidelines issued by WHO. The names have the legitimacy of WHO endorsement.

It is important to keep in mind that the INN system does not evaluate any drugs – it does not conclude whether a product is good or bad. It gives only a name. However, a global name is important for any product. Most of the pharmaceutical companies recognise and support the INN system – also financially by paying a fee for every new INN name approved. The pharmaceutical companies need an INN for a drug for authorisation and sale in a country. In other words, WHO could in principle give a name to a sub quality product – unless there were requirements for which drugs could apply for an INN.

2. Design and formulation

The selection of a new INN is based on a strict procedure. The names which are given the status of INNs are selected by WHO on the advice of experts from the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations. Only when recommended by WHO it is an INN. Important stages in in the preparation process are:

- A request/application is made by the manufacturer or inventor. After a review of the request a proposed INN is selected and published for comments. After a time-period for objections has lapsed, the name will obtain the status of a recommended INN and will be published as such if no objection has been raised.
- Upon receipt of an INN request form, the WHO Secretariat examines the suggested names for conformity with the general rules, for similarities with published INNs and potential conflicts with existing names, including published INN and trade-marks. A note summarizing the result of these checks is added and the request is subsequently forwarded to the INN experts for comments. Once all experts agree upon one name, the applicant is informed of the selected name.
- Newly selected, proposed INNs are then published in WHO Drug Information, which indicates a deadline for a four-month objection period. This period is allowed for comments and/or objections to the published names to be raised. Users are invited to refrain from using the proposed name until it becomes a recommended INN to avoid confusion should the name be modified. Two lists of proposed INN are published yearly.
- The final stage of the selection process is the recommended INN. Once a name has been published as a recommended INN, it will not normally be modified further and is ready for use in labelling, publications, on drug information. It will serve to identify the active pharmaceutical substance during its life-time worldwide. Since the name is available in the public domain it may be used freely. However, it should not be registered as a trade-mark since this would prevent its use by other parties.
- Recommended INNs are published in the WHO Drug Information following the objection procedure applied to proposed INN. As from 1997, two lists of proposed INN are published yearly and as from list 37 of recommended INN, graphic formulae are also included for better identification of the substances.

The composition of the INN meetings has been characterized by stability. The average number of participants are 20 experts, mostly people with responsible positions in national nomenclature commissions.

This is a typical global headquarter and expert driven programme with no or minimal involvement on WHO regional and country office.

The programme used to be funded by the regular budget (as a constitutional programme), but this was changed and is now fully funded by fees from pharmaceutical companies. The fee for one INN is between 12 and 15 000 USD. Such a practice is still followed despite advice against voiced by auditors due to potential conflict of interests. There is no evidence of conflicts of interest, but it would be more appropriate for WHO to fund at least part of this programme from regular resources – and not as now using INN income also for subsidizing other WHO activities.

3. Quality assurance and quality

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 adopted as recommended INNs. Interested parties are given a period of four months in which to raise an objection to a proposed INN. An objection may be based, for example, on similarity between the proposed INN and a trademark in which the interested party has proprietary rights.

The guidelines are a short document – highly technical and to some extent incomprehensible for non-experts. However, the guidelines and procedures are understood by those involved. The WHO Secretariat provides efficient and effective management of the INN programme and the increasing number of INN applications.

4. Dissemination

INNs are available in all six official languages of WHO (Arabic, Chinese, English, French, Russian and Spanish) and in Latin. They are also translated into many other languages for use at the national level by regulatory authorities, as well as in reference books and in medical literature. There are plans to establish an INN-school.

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 his 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.

5. Relevance and results

The extent of INN utilisation is expanding with the increase in the number of drugs – in particular biological medicines. Its wide application and global recognition are also due to close collaboration in the process of INN selection with national drug nomenclature bodies. The increasing coverage of the drug-name area by INN has led to a situation where most pharmaceutical substances used today in medical practice are designated by an INN. The use of INN is already common in research and clinical documentation, while their importance is growing further due to expanding use of generic names for pharmaceutical products. WHO has a unique undisputed role as the only authoritative source for and coordinator of the INN programme. Even private companies admit that the INN name is often more important than the trade name. INN´s are found useful. It has not been necessary to convince anyone of its usefulness.

"To me, the INN constitutes a common global language for medicines and is extremely important and useful in that respect. They are also useful for pharmacies, prescribing, pharmacovigilance, custom issues and trademark issues" (informant interview).
"Private companies need the INNs so they apply for them. The INNs are beneficial in cross-border transportation and sale" (informant interview).

The INN programme has a global community of 14000 followers and users. There are efforts under way to harmonize the use of INNs in all regulatory bodies.

6. Feedback and learning

There is no regular monitoring of the implementation of the programme. No external evaluations have so far been carried out.

3. WHO Model List of Essential Medicines

1. Initiation

In 1975, the Twenty-Eighth World Health Assembly requested the Director-General to assist Member States by *"advising on the selection and procurement, at reasonable cost, of essential drugs of established quality corresponding to their national health needs"* (Resolution WHA28.66). The first Model List of Essential Drugs was prepared by a WHO Expert Committee in 1977.

In 1978, the Thirty-First World Health Assembly (in resolution WHA31.32) requested the Director-General, *"to continue to identify the drugs and vaccines which, in the light of scientific knowledge, are indispensable for primary health care and control of diseases prevalent in the population, and to update periodically this aspect of the report of the WHO Expert Committee on the Selection of Essential Drugs*" and *"to cooperate with Member States in formulating drug policies and management programmes that are relevant to the health needs of populations and are aimed at ensuring access of the whole population to essential drugs at a cost the country can afford".*

This is not a long and comprehensive WHO technical guideline. The normative product consists basically of two lists. The core list of essential medicines presents the minimum medicine needs for a basic health-care system, listing the most efficacious, safe and cost–effective medicines for priority conditions. Priority conditions are selected based on current and estimated future public health relevance, and potential for safe and cost-effective treatment.

The complementary list presents essential medicines for priority diseases, for which specialised diagnostic or monitoring facilities, and/or specialist medical care, and/or specialist training are needed.

It is emphasised that the presence on the Essential Medicines List carries no assurance as to pharmaceutical quality. It is the responsibility of the relevant national or regional drug regulatory authority to ensure that each product is of appropriate pharmaceutical quality.

The lists are not mandatory. They guide the procurement and supply of medicines in the public sector, schemes that reimburse medicine costs, medicine donations, and local medicine production. Many international organisations, including UNICEF, UNHCR and UNFPA as well as NGOs and international non-profit supply agencies, have adopted the essential medicines concept and base their medicine supply system on the Model Lists.

The list has been regularly updated and included new treatments for serious diseases as illustrated in the next text box:

> "2015 confirmed a significant recent trend in the flagship WHO Model List of Essential Medicines with ground breaking new treatments for hepatitis C and a variety of cancers included in the list despite their high prices. The list also included five new medicines for multidrug resistant tuberculosis. Traditionally considered a tool for developing countries to use as a guide for national medicines selection, the WHO Essential Medicines List is increasingly seen as a tool to increase access globally". (Annual report 2015, p. 3)
>
> "When new effective medicines emerge to safely treat serious and widespread diseases, it is vital to ensure that everyone who needs them can obtain them. Placing them on the WHO Essential Medicine List is a first step in that direction". (WHO DG Margaret Chan in Annual Report 2015).

2. Design and formulation

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. The WHO Expert Committee meets every two years to review the latest scientific evidence on the efficacy, safety and cost effectiveness of medicines to revise and update the WHO Model List of Essential Medicines (EML) and Model List of Essential Medicines for Children (EMLc). 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.

The lists have been updated every second year since 1977 reviewing every time approx. 100 drugs. The 19th WHO Model List of Essential Medicines and 6th WHO Model List of Essential Medicines for Children were recommended by the 20th WHO Expert Committee on Selection and Use which met in April 2015. The lists are subsequently approved by the Director General and then disseminated.

The selection criteria proposed for the new procedure specify that the absolute cost of a medicine will not be a reason to exclude it from the Model List if it meets the stated selection criteria, and cost-effectiveness comparisons be made among alternative medicines within the same therapeutic group. This approach is in line with WHO's practice of including cost considerations in the development of public health recommendation.

3. Quality assurance and quality

Most countries require that a pharmaceutical product be approved based on efficacy, safety and quality before it can be prescribed. In addition, most health care and insurance schemes cover only the costs of medicines on a selected list. 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 that assurance that solid QA processes are in place and the right experts are used with no conflicts of interest.

4. Dissemination

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 e 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 powerful search engine ensures that documents can be identified easily. A facility exists to create sub collections on specific topics that can be exported and duplicated on DVDs or flash drives.

5. Relevance and results

The Lancet Commission highlighted that access to medicines has long been a potent flashpoint in global health, from anti-retroviral to drugs that cure hepatitis C. Much progress has also been made. Key elements for delivering essential medicines have been adopted by countries, e.g. the composition of a limited list to drive procurement and reimbursement, standard treatment guidelines, prescriber training, and regulation of pharmaceutical marketing. The Commission identifies also five areas as crucial to ensure access to medicines for 2030: paying for a basket of essential medicines, making essential medicines affordable, assuring the quality and safety of medicines, and developing missing essential medicines (Lancet November 2016).

"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)

As such, it has not been difficult to argue that a model list is needed. Essential medicines play an important role in improving access to medicines for most the world's population. The concept of a carefully selected list of medicines of assured quality that meet most healthcare needs of a community has proved to be an effective and affordable solution for the treatment of common ailments. The concept gained ground in the 1970s and 1980s and most countries today have a national list of essential medicines based on the model list created by the World Health Organization.

"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 provides a unique normative document, which should form the basis for local (national or sub-national) considerations". (Interview external stakeholder)

It is said that careful selection of a limited range of essential medicines results in a higher quality of care for patients, better management and use of medicines and more cost-effective use of health resources. Clinical guidelines and lists of essential medicines may improve the availability and proper use of medicines within health care systems. Selection of medicines follows market approval of a pharmaceutical product which defines the availability of a medicine in a country.

The Model List is a guide for the development of national and institutional essential medicine lists. It was not designed as a global standard. However, for the past 30 years the Model List has led to a global acceptance of the concept of essential medicines as a powerful means to promote health equity. Most countries have national lists and some have provincial or state lists as well. National lists of essential medicines usually relate closely to national guidelines for clinical health care practice which are used for the training and supervision of health workers.

Numerous studies have documented the impact of clinical guidelines and lists of essential on the availability and proper use of medicines within health care systems. Careful selection of a limited range of essential medicines results in a higher quality of care, better management of medicines (including improved quality of prescribed medicines), and more cost- effective use of health resources.

The Model List is a guide for the development of national and institutional essential medicine lists. It was not designed as a global standard. There is evidence that the lists are found useful and used by developing countries. Developed countries may consult the lists, but don´t use them directly.

"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)

However, over the past 25 years the Model List has led to a global acceptance of the concept of essential medicines as a powerful means to promote health equity. By the end of 1999, 156

Member States had official essential medicines lists, of which 127 had been updated in the previous five years. Most countries have national lists and some have provincial or state lists as well. National lists of essential medicines usually relate closely to national guidelines for clinical health care practice which are used for the training and supervision of health workers. Lists of essential medicines also guide the procurement and supply of medicines in the public sector, schemes that reimburse medicine costs, medicine donations, and local medicine production. Many international organizations, including UNICEF and UNHCR, as well as nongovernmental organizations and international non-profit supply agencies, have adopted the essential medicines concept and base their medicine supply system mainly on the Model List.

"Member states are increasingly seeking WHO´s support and guidance to select, regulate, import, manufacture and wisely use quality essential medicines and health products to ensure universal access" (Kees De Jonchere in Annual report 2015, WHO Essential Medicines and Health Products).

6. Feedback and learning

There have been no independent evaluations, but several relevant issues have been discussed in meetings or in publications.

The cost of medicines has been a specific concern of Member States since the concepts of national drug policies and essential medicines were first introduced in 1975. During the consultation process, some reviewers expressed concerns about aspects of treatment costs. They questioned whether a medicine's high cost could prevent its inclusion even if it satisfied the selection criteria on grounds of need (needed to treat a priority health problem), effectiveness (when compared with other medicines used to treat the same condition) and safety. Reviewers also questioned whether (given the wide cost variations for the same medicine) worldwide comparisons of the cost-effectiveness of different medicines in treating specific conditions would be meaningful.

It is also an interesting and challenging discussion on the scope of WHO´s involvement – whether focusing on preparing the essential medicines list or to what extent it would be feasible and desirable to develop a more comprehensive approach to country support covering procurement, reimbursement, training, regulation of marketing etc. Interviews brought up other relevant questions to:

"It would be interesting to know whether there are still countries that rely on the WHO Model List without any changes and, if so, what the implications are for local access in those settings. It would also be interesting to consider the need for the two WHO Model Formularies, and whether those have been used as was originally intended, and if not, what the alternatives might be. Within the WHO system, it would be useful to consider what aspects of the GRC-managed policy development process are still not applied by the Expert Committee, and whether these can be addressed (e.g. the reliance on GRADE as a method for assessing quality and relevance of evidence). The effectiveness of the co-ordinating structure between the head office secretariat and regional offices and the various Inter-Agency structures might also be considered". (Interview external stakeholder)

4. WHO Global Code of Practice on the International Recruitment of Health Personnel

1. Initiation

The loss of highly skilled personnel has been a concern of developing countries for the last half century. Despite a call by developing countries, few international initiatives have emerged to manage the gains and losses from the movement of skilled workers. The migration of health workers to middle- and high-income countries is exacerbating existing inequities in the distribution of the global health workforce and further compromising health systems in some of the poorest countries in the world.

On 21 May 2010, the WHO Global Code of Practice on the International Recruitment of Health Personnel was adopted by consensus by WHO Member States in Resolution WHA63.16. The Code establishes and promotes voluntary principles and practices for the ethical international recruitment of health personnel and the strengthening of health systems, including effective health workforce planning, education and retention strategies. This instrument marks the first time in thirty years that WHO Member States have invoked the constitutional authority of the organisation to develop a non-binding global code.

The initiative for the resolution emerged partly outside WHO and WHO was encouraged to take on the work with developing a Code on a politically controversial issue as migration – an unusual normative area for WHO. The initiative has been attributed to the intervention of African ministers of health (Dambisya 2013). At the 2005 WHA, African health ministers tabled a draft resolution that called upon the WHO DG to ensure that such a Code was developed.

The Global Code of Practice on the International Recruitment of Health Personnel was the culmination of efforts by many different actors. The Global Health Workforce Alliance had clearly identified health worker migration as one of the fundamental issues to be addressed for the resolution of the health work crisis. In May 2007, the Alliance convened and facilitated the Health Worker Migration Initiative, which worked with the WHO in support of developing a framework for the Global Code.

The objectives of the Code are:
To establish and promote voluntary principles and practices for the ethical international recruitment of health personnel.
To serve as a reference for member states in establishing or improving legal and institutional framework required for the international recruitment of health personnel.
To provide guidance that may be used when appropriate in the formulation and implementation of bilateral agreements and other international legal instruments.
To facilitate and promote international discussions and advance cooperation.

The preamble and first two articles make especially prominent the Code's focus on supporting health systems, particularly in developing countries, countries with economies in transition, and small island states. The Code's Guiding Principles focus on the need to provide technical and financial assistance for health personnel development; affirm the human right to the highest attainable standard of health; call for a better "managed approach" to the international recruitment of health workers; call for the development of a sustainable health workforce in all countries; and point to the need to protect and fulfill the rights of health workers that do emigrate.

Article 5 discourages active recruitment from countries with critical health workforce shortages, encourages utilisation of Code norms as a guide when entering bilateral, regional, and multilateral arrangements to further international cooperation and coordination.

Although technically non-binding, the Code has certain legal importance. Adopted by consensus as a resolution of the World Health Assembly, it is the expression of the will and the intention of the international community, in its widest possible political forum, to address the global health work force challenges. Since the WHO DG must report on its implementation, it has a certain binding character.

While it was African countries that championed the call for development of the Code, their engagement with implementation of the Code was relatively limited. African stakeholders influenced the development of the Code, but two years after its adoption only four African countries had designated national authorities, and only one had submitted a report to the WHO Secretariat (Dambisya 2013). During the first round of national reporting, 13 African countries designated national authorities and two reported (Information from WHO). The second round of reporting showed significant improvements in both areas.

2. Design and formulation

In May 2007, the Health Worker Migration Policy Initiative (HWMPI) was established to find practical solutions to the worsening problem of health worker migration. It supported WHO in drafting a framework for an International Code of Practice on Health Worker Migration. In September 2008, WHO published the first draft of the Code for comment, incorporating principles from existing bilateral agreements, MoUs and national and regional codes. It was buttressed by views from a web-based multi-stakeholder global dialogue, and the work of the Health Worker Migration Policy Initiative and the global HRH forum in Kampala earlier that year.

A significant actor in the development of the Code was the Health Worker Migration Global Policy Advisory Council, which worked with other partners from February 2008. The Council had many activities that fed into the development of the Code, including journal articles by the chair/co-chair of the Council and inputs into the draft of the Code. A multi-stakeholder meeting was held in preparation for the May 2010 WHA where the Code was ultimately adopted. In between the major activities, the co-chairs of the council – Hon Mary Robinson and Dr Francis Omaswa – wrote to the WHO DG urging adoption of the Code as a matter of urgency and also to the new US President (B.Obama).

There was a long maturation period for the Code. The member states had already in 2004 requested via resolution the DG to develop a code. The process was seriously protracted - partly due to its complexity - 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 first draft was relatively "weak" while the next version was clearer and stricter. This version went through discussions and revisions and lost some of its original muscle.

The Code was negotiated at various levels. Common positions by African health ministers provided the momentum for the Commonwealth Code of Practice for International Recruitment of Health Personnel, a precursor to the 2004 WHA resolution. In the negotiations, some of the wishes of the developing countries, such as compensation and mutuality of benefits, were dropped from the final wording of the Code to keep the support of powerful nations and the Code was made non-binding and voluntary.[13] Earlier positions from African stakeholders had

[13] WHO comments that the Code from its inception was to be non-binding and voluntary. A big achievement was to include a reporting mechanism, with mandatory reporting by the DG, in an otherwise non-binding instrument (US thought it inappropriate for such an instrument to have a reporting mechanism and process. FCTC had for instance not such a process when adopted.

explicitly called for compensation to source countries, which was unacceptable to some countries in the North.
Earlier instruments and position statements from African countries explicitly called for compensation. Some civil society organisations played a stronger role in the development of the Code, including Realising Rights and HWAI, and these organisations also promoted ethical recruitment (Taylor and Dhillon, 2011). Civil society was in favour of some form of compensation. The reluctance by some countries in the North to accept any language that included compensation led to the "watering down" of the Code.

During the negotiations, one of the last clauses to be dropped was one referring to mutuality of benefits. Some countries in the North were also not eager to accept the provisions on reporting on the Code, and only did so as a compromise (after winning the deletion on mutuality of benefits), and in response to sustained pressure from the African countries (Taylor and Dhillon, 2011).

3. Quality assurance and quality
There were no explicit QA procedures for the development of the Code.

4. Dissemination
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 had also a budget for 2010- 15 amounting to 24.270 Mill USD – which was unfunded. At the regional level, the Secretariat has supported a range of activities and inter-country initiatives promoting the implementation of the Code.

The Secretariat has been fostering multi-stakeholder collaboration involving government and academic institutions, and civil society organizations and networks to support the advocacy and analytical work called for by the Code. Particular achievements were: Member States' efforts to make the Code available in their official languages (including Catalan, Dutch, Finnish, German, Indonesian, Italian, Japanese, Polish, Romanian and Thai); the incorporation of the Code's provisions into national legislation (for example, in Germany) and bilateral agreements (specifically in source countries such as the Republic of Moldova and Philippines); and the use of the Code to promote multi-sectoral dialogue on health system sustainability (in El Salvador, Indonesia, Maldives, Philippines and Uganda).

The expected budget was not made available to the Secretariat so the implementation was supported by general resources.

5. Relevance and results
The report of the second Expert Advisory Group cochaired by the representatives from Thailand and Ireland on the relevance and effectiveness of the WHO Global Code concluded that: "Based on available evidence, the EAG unanimously concluded that that the Code remains relevant to the health work force development challenges faced by the Member States. …. Collectively, the global policy drivers and emerging dynamics make the principles and provisions of the Code increasingly essential to health systems strengthening worldwide".

Designated national authorities had been established in 117 countries, which represents a 37% increase since the first round of reporting. Of these authorities, 85% are based in health ministries, 9% are based in public health institutes and 6% are based in other institutions (such as health authorities, health boards or human resources for health observatories).

By March 2016, 94 of the 117 designated national authorities had submitted a complete report using the national reporting instrument for the second round of national reporting. Compared with the first round, this represents an increase for all regions except for the European Region. 74 countries that submitted a report, 49 (66%) indicate that steps have been taken towards the implementation of the Code

The conclusions about results and effectiveness from the second expert group are less clear due to limitations in evidence14: "In the first round of reporting, almost all OECD members designated a national authority and responded to the national reporting instrument. It was also said that countries such as El Salvador, Indonesia, Maldives and the Philippines have demonstrated significant benefits in using the Code to promote multi-sectoral dialogue on health systems sustainability. The South-East Asia region has used the Code as a foundation to underpin a decade of health workforce strengthening".

Given the limitations of the evidence due to the lack of availability of 2nd round reporting, the group was not able to evaluate the success of the Code in comparison with other governance initiatives as requested by the 136th Executive Board. The expert group concluded "there were significant gaps in implementation and dissemination of the Global Code that constrain a clear assessment of the effectiveness of the instrument". The 2nd Round reporting has since evidenced a marked increase in countries reporting on the WHO Global Code; itself pointing to the perceived legitimacy of the Code.

A review of the five-year period following the Code's adoption points to areas of the Code's success and weaknesses. Activity in 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.

Commission on Health Employment and Economic Growth (2016)
In March 2016, the UN Secretary-General announced the appointment of a Commission on Health Employment and Economic Growth, co-chaired by H.E. Mr. François Hollande, President of France, and H.E. Mr Jacob Zuma, President of South Africa.

This report make specific reference to the WHO Code reflecting the continued relevance of the Code: "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.

Lessons can be learned from the Paris Agreement on Climate Change. Its principles of "enhanced transparency framework" and "intended nationally determined contributions" could provide a similar foundation for new dialogues between States on the investments that are inherent within, or arise from, international mobility of health professionals, including resource transfers, migrant remittances and other investments. Resource transfers and investments into health worker education and training are critical to ensure the sustainability of health systems in source countries. As part of the continuing review process for the WHO Global Code, ILO, OECD

[14] Results from the second round of reporting were not available to the expert group.

and WHO should explore and advance the evidence on the resource transfers inherent in health workforce migration. Further, strengthening of the WHO Global Code should align with broader discourse on the global governance of migration, particularly the UN Secretary-General's proposal for a Global Compact for Safe, Regular and Orderly Migration (Commission on Health Employment 2016).

Compliance and effectiveness

There is an interesting distinction and inter-play between the concepts of compliance and effectiveness (Dhillon ??Reference). Compliance seeks to measure to what extent an actor's behavior complies to specific rules or standards, while effectiveness in contrast seeks to identify an observable desired change in behavior. Compliance by a state or regulatory party can be independent of action, while the assessment of effectiveness requires a link to causation. Following is an excerpt from an informant in Malawi that speaks to the above distinction:

"In all honesty, we have not done anything directly related to the Code. But when looking at discussion on support for training, our strategic direction on HR, all those are in
the spirit of the Code. Yes, but not because of the Code perhaps. (Dambisya et al.16)

The same article remarks that the period since Code adoption has generated significant criticism of the Code and its implementation. Commentators have pointed to the Code's voluntary "soft-law" nature; failures in dissemination and the lack of knowledge surrounding the Code; lack of in-country preparedness for implementation; little publicity on the progress of Code implementation; high turnover of key personnel; ambiguity in terms and the need for complementary guidelines; lack of prioritisation and problems of internal coherence; and the lack of sustained resources to support Code implementation. A central challenge identified across the various studies has been the weak leadership by the WHO secretariat and the associated lack of awareness of the Code by key stakeholders.

In light of a normative managerial approach to giving effect to the Code, it was the withdrawal of foundational resources from the WHO secretariat to follow up and support the implementation of the Code that perhaps most negatively impacted Code implementation.

A non-binding code

Voluntary codes of practice or non-binding instruments have been criticized as weak and ineffective in addressing the core challenges of health worker migration and its impact on health systems.[15] Critics have argued, for example, that such non-binding instruments have been largely ineffective in limiting health worker migration from poor countries or protecting the human rights of health workers because they lack meaningful mechanisms to collect data and to monitor national compliance. It was argued that the proposed Code was not legal or could have no impact in state practice because it would be technically non-binding as a matter of international law. The paper then clarifies that it is not the legal or non-legal basis, but the processes that are put in place that is important (see Dhillon undated).

It is admitted that the WHO Global Code is neither a perfect text nor the solution to the challenges associated with health worker migration. The substantive norms advanced by the Code remain relatively general and advanced in a soft manner to Member States. It is emphasised that the WHO Global Code was never intended to be the final answer or encompass the whole solution to the challenges associated with health worker migration. Rather, the goal of the drafters was to establish a global platform that could provide a framework for continuing

[15] WHO comments that there is a growing recognition in the field of international law of the importance of non-binding instruments (Paris agreement with its voluntary system of intended commitments is one prominent example). Through a voluntary instrument we were able to get agreement and regular reporting in manner than is deeper than would have been possible in a binding instrument.

dialogue and cooperation among states on what is a topic of significant complexity and sensitivity.

The legal and institutional arrangements in the WHO Global Code will to some extent ensure that the issue remains on the agenda of the World Health Assembly with reporting by the Director-General mandated every three years.

There is an evolving array of binding and non-binding instruments in global health governance. Consistent with other international legal realms, the pattern that is beginning to emerge is a marked preference for binding global health law instruments, which are also extremely expensive to conclude. There is no alternative to treaties when states want to make credible commitments. However, treaties are not the only source of norms in the international system. It is increasingly recognized that the challenges of global governance demand faster and more flexible approaches to international cooperation than can be provided by traditional and heavily legalized strategies.

Chief amongst the limitations of non-binding instruments is that such voluntary agreements are not subject to the international law of treaties. Many non-binding instruments are purposefully designed as way stations or even permanent detours from hard, binding legal commitments. Consequently, many if not most nonbinding instruments are purely rhetorical and have no impact on state practice16.

However, non-binding instruments have important advantages as mechanisms for international cooperation. The experience negotiating the WHO Global Code evidences some of the key advantages of non-binding instruments, for example their flexibility. Non-binding agreements can facilitate compromise and agreement may be easier to achieve than binding instruments, especially when states jealously guard their sovereignty because non-binding standards do not involve formal legal commitments. In addition, by removing concerns about legal non-compliance, non-binding instruments may, at times, promote deeper commitments with stricter compliance mechanisms than comparable binding instruments.

The Code does provide an ethical standard, has raised global awareness of the ethical considerations in the recruitment of health workers, and brought the issue of health worker migration into mainstream discussions. To the extent that the Code now imposes an ethical standard, the implementation and monitoring process will determine its usefulness, as will the engagement by civil society to ensure accountability in implementation of its provision and intentions. The Code is dynamic in nature; its own evolution (review and revision) given shifting patterns of migration and political priorities could be potentially important.

6. Feedback and learning

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:
The designation of a national authority who could take charge of information regarding the migration of health personnel and implementation of the Code.
In a second step, WHO developed the National Reporting System and the national authority was requested to complete the form.

[16] Same is also true for international treaties. ILO's Convention on Nursing for example only required ratification from two countries to come into force and has been sitting dormant for many years with no reporting process.

The Code encourages information exchange on issues related to health personnel and health systems in the context of migration, and suggests regular reporting every three years on measures taken to implement the Code. The reporting process is an integral component of the effective implementation of the voluntary principles and practices recommended by the Code.

In 2013, the Secretariat presented the Sixty-Sixth World Health Assembly with the first report on progress made in implementing the Code. In 2015, the Sixty-Eighth World Health Assembly reviewed the report of the Expert Advisory Group on the Relevance and Effectiveness of the Code. In 2016 the second report was presented to the WHA

To monitor the progress made in implementing the Code, a national self-assessment tool was created for Member States. The updated national reporting instrument for the second-round reporting was launched in March 2015. To facilitate stakeholders reporting, an additional Independent Stakeholders Reporting instrument was also made available. This additional module facilitates contribution from relevant stakeholders and to enrich knowledge on the Code's implementation.

The Code asks that countries report on progress to the Secretariat, and appoint designated national authorities to oversee implementation of the Code which points to the perceived value and legitimacy of the Code. By September 2012, 81 countries had appointed designated national authorities, and 48 had reported to the Secretariat. Among those, one African country had submitted a report, and only 13 had designated authorities (WHO, 2013). There was increases in the second round of reporting.

Health Workers4All – a European NGO produced a report (2015) with case studies of the implementation of the Code in several European Countries (Poland, UK, Germany, Spain, Italy, Netherlands, Romania)17.

[17] Funded by the European Commission, played an important role in disseminating and pushing for implementation of the Code with domestic policy makers.

5. WHO guidelines for indoor air quality: household fuel combustion

1. Initiation/Background and purpose
Evidence revealing that some 6.5 million people die each year from the joint effects of air pollution (i.e. indoor + outdoor), and 4.3 million deaths are due to household air pollution alone implied a critical need to address the issue. As such, it has not been difficult to argue that measures addressing the health impact of air pollution are needed.

Recognising the extent of this problem, one of the initiatives was the development of WHO indoor air quality guidelines (AQG) for household fuel combustion – (2014) to help address these questions and thereby guide countries in effectively reducing this public health burden (Bruce et al., 2013a). The new guidelines build on existing WHO AQGs for ambient air pollution (WHO, 2006), and the 2010 volume of indoor AQG for selected pollutants (WHO, 2010).

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. Insofar this is not WHO´s traditional area of work, the document arguably represents something new (for WHO), that is, evidence- based guidelines supporting effective interventions – as a global approach to household air pollution. This has not been done previously. Prior to 2009, WHO had not produced guidelines for indoor air quality outside of occupational settings, and no internationally agreed health-based guidance with recommendations for policy was available on how to effectively address the public health impacts of household fuel combustion [18].

The recommendations include general considerations for policy, a set of four specific recommendations, and a best-practice recommendation addressing linked health and climate impacts. Among the general considerations, or overarching advice, is that policies should promote community-wide action, and that the safety of new fuels and technologies must be assessed rather than assumed.

The primary target group for the guidelines is decision-makers developing, implementing and evaluating policy to secure health benefits in the area of household energy [19] as well as specialists working on energy, environmental and other issues related to household air pollution. Although the scope of these guidelines is global, the main focus has been on the health impacts low- and middle-income countries (LMICs), where the burden is by far the greatest, but consideration is also given to higher income countries where biomass is widely used for heating in mainly rural areas.

2. Design and formulation/preparation of the Guidelines
The Guideline development process (individuals and partners involved in the development of these guidelines) is thoroughly described in the report (chapter 3):

The WHO Steering group: (SG) was involved in all stages of planning, review of evidence, the main recommendation drafting meeting (New Delhi, April 2012), and all rounds of consultation on revisions following peer review.

Further, the guideline development group: (GDG) was made up of people with content expertise in all areas covered by these guidelines. The group's members worked to define key questions, priorities and systematic review methods, served as the authors of the systematic reviews, and worked to draft the recommendations, determine the strength of these, and respond to external

[18] WHO guidelines for indoor air quality (2014, 9)
[19] Ibid (2014, 19)

peer review comments. In addition, external reviewers in an External peer-review group (EPRG) were drawn from subject experts, implementing agencies and partners.

The actual formulation and preparation of the guideline was hence in accordance with WHO guideline procedures (and following WHO´s own Handbook for guideline development); through a " WHO Guidelines Review Committee" (GRC)20 set up. GRC is composed of both internal staff and external advisors, tasked with implementing and overseeing internationally recognized standards/quality assurance, and decisions are made by consensus [21].

Additionally, regional workshops and consultations were held, although the main work on guideline was done from HQ (drafting the guideline document itself was the responsibility of WHO staff). During the development of the guidelines, WHO was also working closely with the UN Foundation's Global Alliance for Clean Cookstove's initiative on developing international standards for cook stoves[22].

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 Cookstoves (GACC) and the UK Department for International Development (DFID) (Guidelines introduction). Full funding for follow up of the guidelines has not been secured, however, some funding has been provided for guidelines implementation through the support provided by Norway to implement the WHA 68.8 resolution and it's draft road map, which specifically calls for actions and support to be given to implement the WHO guidelines.

3. Quality assurance and quality

Material and methods:
As described in the (guideline) document, "the guidelines were developed and peer-reviewed by scientists from all over the world and the recommendations were informed "by a rigorous review of all currently available scientific knowledge on this subject" following strict criteria for the evaluation of evidence established by the WHO which are standard for these types of evaluations.

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 (WHO, 2012). 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 23 which inform both the recommendations and plans for supporting implementation in countries. The new guidelines include a wide range of evidence relevant to the scientific and policy issues involved and cover: households fuel use, pollutant emissions, levels of HAP and

[20] Established in 2007 to develop and implement procedures to ensure that WHO guidelines are:
- Consistent with internationally accepted best practices
- Appropriately based on evidence.
- Transparent

Members from headquarters and all 6 regions, 5 external members, Decisions are made by consensus
[21] http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0063715
[22] http://eprints.qut.edu.au/58645/2/58645.pdf
[23] The evidence on which these reviews draw is very diverse, including nationally- representative surveys, laboratory-based testing of stoves, quasi-experimental field studies of the impacts of stoves on HAP and exposure, and a range of epidemiological studies of health risks that include cross sectional studies, analytic observational studies, and a very few randomised trials.
http://eprints.qut.edu.au/58645/2/58645.pdf

exposure, health and safety (i.e. burns, poisoning) risks, intervention impacts, and factors relating to adoption, intervention costs and financing. See table below.

Evidence reviews included in the new WHO indoor air quality Guidelines for household fuel combustion:

Review topic		Main issues addressed
1	Fuel use	Fuels and technologies used for cooking, heating, lighting and other uses, for low and middle-income countries (LMIC), and for high income countries (HIC).
2	Emissions	A systematic review of levels of emissions of health-damaging pollutants from a representative range of fuel and technology options, and the challenges of field testing to capture real-life performance, which is found to differ (sometimes markedly) from laboratory performance.
3	Model	Description and validation of an emissions model, developed to relate emission rates for PM2.5 and CO to WHO air quality guidelines levels for these two pollutants.
4	Population HAP levels	A systematic review of household levels of PM2.5 and CO (kitchen, living area, and the local environment), and of personal exposure to these same pollutants.
5	Health risks from HAP	A summary and synthesis of systematic reviews of health risks from solid fuel use in households for a wide range of health outcomes; summary of available exposure-risk evidence, including newly developed integrated exposure response (IER) functions; (Burnett et al., 2014) summary of evidence (including recent systematic reviews) of health risks with household use of gas and kerosene; summary of specific risks from household coal use, including toxic contaminants; summary of systematic review on impacts of interventions to reduce smoke levels on risk of vector-borne disease (mainly malaria).
6	Safety	A systematic review of the risks of burns, scalds and poisoning from household fuels, and a summary of evidence from intervention studies to prevent these outcomes.
7	Intervention impacts	A systematic review of the impacts of interventions (improved solid fuels stoves and clean fuels) on kitchen PM2.5 and CO, and of personal exposure to these pollutants, when in everyday use.
8	Adoption	A systematic review of quantitative, qualitative and policy studies to identify key enabling and limiting factors for sustained adoption at scale of improved solid fuel stoves and clean fuels.
9	Costs and financing	A narrative review of intervention costs, economic evaluation studies, and financing options including climate finance.

Source: WHO indoor air quality guidelines on household fuel combustion: Strategy implications of new evidence on interventions and exposure-risk functions (2014)

The standard method of assessing quality and strength of evidence for the purposes of WHO guideline recommendations is also known as the scheme called GRADE (Grading of Recommendations Assessment, Development and Evaluation). It is a framework for assessing quality of bodies of evidence, and for the step of moving from evidence to recommendations.

For these guidelines, however, an adaptation of GRADE was used to assess the quality of the evidence supporting the recommendations. The reason for this is that the GRADE methodology would rank all studies for environmental health as 'low' quality. Hence a modification of the methodology, (in close cooperation with Susan Norris), was developed to combine evidence from different steps within the pathway of intervention to health outcome. The revised methodology, called *Grading of Evidence for Public Health Interventions* (GEPHI), can be found in detail in 'Methods used for evidence assessment' available online at: http://www.

who.int/indoor air/guidelines/hhfc

Quality of the normative product:
The document is overall a high-quality guideline, albeit lengthy and dense, it has a well-defined scope and target audience, emphasizing the central role of thorough evaluation of evidence in formulating recommendations. Indeed, the guidelines include a wide range of evidence relevant to the scientific and policy issues involved. At times, the jargon is somewhat technical for a non-expert, yet, the understanding of the relevance, context and substance of the guideline is clear. WHO guideline development methods seem systematic and transparent, as the GRC and quality assurance standards appear to have been functioning well for this specific activity/exercise. Survey respondents (external stakeholders) rate the document highest in terms of presentation and use of evidence, and specificity/utility of recommendations.

4. Dissemination
The release of the document was in 2014. The executive summary is available in all 6 UN languages, while the Guidelines are only in English. The document was disseminated in accordance with WHO practices; and through press release24. 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 at: www.who.int/indoorair/guidelines/hhfc

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 Cookstoves and the Climate and Clean Air Coalition. HQ informants also underscore that they cooperate closely with RO´s and CO´s focal points to ensure that the Guidelines are actively disseminated and followed up by regional/country offices, but resources for proper follow up and facilitation of implementation are often insufficient.

Feedback from external stakeholders suggest that WHO (HQ/RO´s/CO´s) has not actively disseminated and followed up the guidelines. Further, when asked to provide general feedback on the Guidelines from networks (internally/externally), one stakeholder explains as follows:

"*we have heard from our networks that people want more transparency on the modeling. There is also a need to ensure widespread and continued dissemination of guidelines in country - beyond a single regional workshop for MoH nominees - this would obviously require additional resources to implement but would be worthwhile".*

5. Relevance and results
WHO states to work closely with countries to support the implementation of these guidelines including through regional and country offices, more specifically to governments, non-governmental organizations, the private sector and development partners. 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".*

According to another informant, there is an active interest and a desire to validate and use the

[24] http://www.who.int/mediacentre/news/releases/2014/indoor-air-pollution/en/

guidelines as interim targets for research and implementation. Yet others argue that the

guidelines filled a critical gap in guidance specifically for the household sector, for which the health impacts are greater than ambient/outdoor air.

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 however 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 (i.e difficult to establish direct attribution to the guidelines per se), much progress has been made. Above all perhaps, 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. The following are influenced or are directly using the guidelines:

- SDG indicator 11.6: refers explicitly to the definitions given by the guidelines
- 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 and would be measured as the percentage of the population relying primarily on clean fuels and technology. Accordingly, the member states of the Inter-agency Expert Group on the Sustainable Development Goals (IAEG) agreed to use the WHO guidelines to define 'clean' for monitoring this energy access indicator. The SDG´s, unlike the MDG´s also address heating and lighting in addition to cooking.
- Sustainable Energy for All Initiative: Similar to the SDG indicator, the WHO guidelines are being used to track progress towards the universal energy access target set forth by the UN Secretary General's Sustainable Energy for All Initiative. The tiers of performance for cookstoves within the multi-tier tracking system of the Global Tracking Framework directly reference the WHO guidelines, where WHO guidelines values serve as the highest level of performance for indoor emissions.
- Global Alliance for Clean Cookstoves: The Global Alliance for Clean Cookstoves, a public-private partnership, hosted by the UN foundation (gradually shifting their sole focus on cookstoves to household energy solutions) aims to disseminate 100 million clean cookstoves by the year 2020. The Alliance provided some resources for the development and dissemination of the Guidelines. The Alliance is a supporter of the Guidelines and has been an important advocate for their application, particularly in relation to public.
- The International Organization for Standardization (ISO) is currently developing the first-ever global standards for clean cooking solutions. When completed, they are likely to provide a voluntary framework for rating cookstoves against five tiers of performance for a series of indicators, including fuel use, emissions indoor and overall, and safety. these tiers are being informed by the WHO guidelines emissions rate targets and recommendations for pollutant concentrations.
- Global Action Plan for Pneumonia and Diarrheal Disease (GAPPD): An initiative aimed at ending preventable child deaths from pneumonia and diarrhoea by 2025. The finalization of the Guidelines has greatly added to the understanding around indoor air pollution amongst Member States and other actors within GAPPD. The technical guidance of the recommendations has helped provide evidence-based actions that can be implemented.
- Survey Harmonization Process: Reflecting on the recommendations of the Guidelines, and the importance of household surveys and censuses for monitoring household energy access and its impacts on public health, there was a need to enhance and harmonize household survey questions to better reflect the fuel and technology combinations being used by

households for cooking, heating and lighting. WHO has been leading multi-agency survey harmonization process, in cooperation with the Global Alliance for Clean Cookstoves and the World Bank. This process involves stakeholders from national surveying agencies (e.g. DHS, MICS, LSMS), country statistical offices and researchers. The resulting questions are being piloted in 10+ countries and should be finalized in the first quarter of 2017.

6. Feedback and learning/M&E system

WHO Support for implementing guidelines in Monitoring and evaluation:
Although assessments of impact of the guidelines in countries is too premature, 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:

- Population-based household energy surveys are a powerful tool in monitoring the transition to cleaner household energy.
- Global data: WHO's Household Energy Database [25] draws on more than 900 national and international surveys of the main fuels used for cooking to provide the best current nationally-representative information on household air pollution. The database also features an increasing number of surveys that report household lighting and heating fuels.
- Global database of household air pollution measurements [26] from 154 studies, representing data from 37 countries, published between 1968 and 2011.

WHO also provides (technical) support to countries for adaptation and use of guidelines (eg. in air quality and exposure measurement studies, for modelling to estimate population levels, in evaluation of health impacts, advice on methods for evaluating the use, maintenance and replacement of technology and fuel interventions etc). WHO has for example provided technical workshops introducing the guidelines in 3 of the 5 WHO regions. According to one stakeholder, WHO is currently developing a guidance document and a 'toolkit' (i.e. Clean Household Energy Solutions Toolkit (CHEST) to support and provide the technical resources for countries to implement a policy/programme for clean household energy, which aligns with the guidelines. This, it is said, will be accompanied by technical workshops, training of the trainers, etc. for implementing partners in countries.

The findings of these various M&E activities are aimed to contribute in revising the implementation guidance. The guideline is planned reviewed and updated periodically and lessons learned from implementation will inform future revisions of WHO guidelines and tools[27].

No evaluations are however planned yet.

Issues to discuss/significance of the guidelines:
While most stakeholders advocated high standards of the guidelines, the question could be posed as in the guideline handbook; "is this guideline really needed? Is WHO in the best position to issue guidance on this topic? Moreover, does the topic fall within the scope of WHO's remit? Or is another organization better suited to produce this guideline owing to its resources, implementation skills and experience, or its local and regional knowledge?" [28]. The question is certainly valid given that this is not WHO´s traditional area of work. Opinions are somewhat mixed among the external stakeholders. According to one; "*The guidelines fit well into the mandate, and WHO has a clear platform to disseminate, but the timing has been a challenge. More nimbleness is required on development side, and more active collaboration with a wider range of*

[25] Household energy: http://www.who.int/indoorair/health_impacts/he_database/en/ Household
[26] http://www.who.int/indoorair/health_impacts/databases_iap/en/
[27] http://www.who.int/indoorair/guidelines/hhfc/monitor_evaluation/en/
[28] WHO Handbook for guideline development (2014, 15)

stakeholders (beyond MoH) is needed to ensure active implementation".

Another external stakeholder writes that "the effort to develop these has involved a number of organizations and the technical side might be done better by others. WHO's convening, reviewing and disseminating roles however are key". (….) There is also need for better connection between the guidelines and the performance standards.

"*I understand that members of the WHO team are planning a meeting to update the integrated exposure response curves for fine particulate. If that is true, I think this is probably an area that WHO should leave to the academic, foundations and government agencies that have the expertise to do the work. Subsequent review, consideration for policy and dissemination would be in WHO's domain*".

While some areas of concerns are raised, the strong expressions of satisfaction with WHO´s role as convener dampen some of the disappointment with the technical side. Furthermore, in the relevant literature, not much criticism seems to have been levelled at the organization for taking on this work. The interviews with WHO staff suggest that there is overall a strong sense that WHO, (in this area of work) benefits from possessing the needed capacity to undertake evidence-based approaches in the health perspective. The latter strength in fact, to some extent, is a question of competence that is exclusive to the WHO.

In light of the available evidence, there are good arguments on the need for these guidelines. There is both a lack of awareness that indoor air pollution causes health problems, exacerbated by the lack of opportunities to tackle the problem. Thus, the delivery of the guidelines was both timely and appropriate. Importantly, the established guidelines have raised the awareness that this constitutes a multi-sectoral problem. In fact, the WHO indoor air quality guideline provides the first definitive guidance on what counts as "clean" household energy for health. Finally, development of these guidelines has made evident what the health risks are.

Yet, setting guidelines or standards for indoor air also invokes difficult issues in terms of policy and implementation challenges. A pertinent comment has been that the guidelines/recommendations are difficult to achieve, indeed, too ambitious. Extending upon the argument, the guidelines are global standards (and a global response), but the adaptation in countries may work out differently, moreover, expected changes are potentially complex.

While this is not a surprising finding in itself (given that efforts have been initiated relatively recent), experience thus far has yielded important lessons. Implementation thus requires a degree of flexibility and adaptation and further support and greater resourcing are required. Notwithstanding, when questioned, the informants would not have done things differently, if writing the guidelines today.

6. Comprehensive Implementation Plan on Maternal, Infant and Young Child Nutrition

1. Initiation/Background and purpose

Recognizing that accelerated global action is needed to address the pervasive and corrosive problem of the double burden of malnutrition, the World Health Assembly Resolution 65.6 in May 2012, endorsed a "Comprehensive implementation plan on maternal, infant and young child nutrition" (hereinafter referred to as the "Plan").

At the request from member states (MS), WHO, with the broad participation of many stakeholders developed the plan based on previous experiences, more systematically through the first global policy nutrition review (2009-2010) – in which gaps were identified.

The plan adopts a multidimensional approach to global nutrition challenges, and the objective of the plan was to provide detailed and dove-tailed implementation strategies to address key global targets for reducing maternal, infant, and young child malnutrition. The implementation plan consists of six global targets to be achieved by 2025 and five priority action areas, as recommended by WHO:

Global targets:

- Stunting: 40% reduction of the global number of children under five who are stunted
- Anemia: 50% reduction of anemia in women of reproductive age
- Low birth weight: 30% reduction of low birth weight
- Overweight: no increase in childhood overweight
- Breastfeeding: increase the rate of exclusive breastfeeding in the first six months up to at least 50%
- Wasting: reduce and maintain childhood wasting to less than 5%

Additionally, the plan outlines five accompanying "actions" to help achieve the global nutrition targets. These include specific activities for the primary target groups; MS, the Secretariat, and international (and national) partners. The five actions orientate around:

- A supportive environment for the implementation of nutrition policies
- The inclusion of all nutrition-related health interventions in national nutrition plans
- Integration of nutrition with development policies and programmes outside the health sector
- Provision of sufficient human and financial resources
- Monitoring and evaluation of policies and programmes

It recommends countries to apply this implementation plan to improve maternal, infant and young child nutrition. It further suggests that the five actions should be adapted to specific (country) contexts and jointly implemented by national and international stakeholders.

The importance of the *targets* should, however, be emphasized, the latter envisaging something new, as, for the first time, consolidated global targets were agreed upon and adopted in the global nutrition community. Informants cite the value added by the targets by noting that the six nutrition targets can be considered as a key product/the concrete part, and WHO has been promoting the inclusion of the relevant target indicators in countries, while the comprehensive implementation plan is more overall. According to informants, it is further important to recognize the distinction between the implementation of targets and the implementation of the plan.

While the document is not a clear normative product as such, it contains normative elements. In this sense, the (global) plan is similar to a guide or a map that helps MS identify actions. Albeit voluntary, it is a commitment to nutrition, arguably therefore, provides a platform on which to build political commitment and accountability. One interviewee suggests that the plan in fact includes much more than a technical guideline, - as the challenge in a global plan is to find the right balance between developing a product that is appealing for all, while simultaneously capturing the specificity of country needs (HQ interview).

2. Design and formulation

Stakeholders in development and review:

Although the rationale for the establishment of targets and implementation plan is clear, the actual process for preparing the plan is not thoroughly described in the report itself, nor are the stakeholders involved in the process of formulation, review and quality control. As described in the document, the background against which the plan was developed was a review and policy analysis of MS carried out in 2009–201029 indicating that most countries have a range of policies and programmes on nutrition, but the latter are often inadequate.

In January 2011, the 128th Executive Board noted the preparatory work on a plan, making several suggestions on its content. Interviewees confirm that, upon MS requests, the document came about through a comprehensive process of negotiations; discussed in five regional consultations (in 2011) to obtain feedback and inputs from MS and concerned stakeholders including UN and bilateral agencies (e.g. FAO and Unicef), regional development communities, World Bank and NGOs on the proposed outline of the comprehensive implementation plan. The development of global targets was requested by a number of MS during these consultations[30].

For the purpose of this study, a short questionnaire has been sent to selected respondents from RO´s/CO´s. The latter indicate that demand for the plan was also expressed from RO´s and Governments, moreover, confirm that RO´s took part in the preparation of the Plan.

It was reportedly a complex, but relatively smooth process. In January 2012, the 130th Executive Board considered the report on "Maternal, infant and young child nutrition: draft comprehensive implementation plan". The 2- year preparation period culminated in the plan (developed by the Secretariat/written by HQ) being endorsed by WHA in 2012.

Funding

Funding to support the work with the plan came from external resources. As paraphrased by one WHO stakeholder; *"we could not have done the plan on our own initiative"* (HQ interview).

A costing of the implementation was done by World Bank, summarizing the analysis of the costs, impacts and investments needed to achieve the targets (thus far 4 of the 6 targets considered) and how governments, donors, the private sector, foundations, and others can come together to finance these at scale. The key message is that reaching 4 of the 6 targets costed 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[31].

3. Quality assurance and quality

From the vantage point of WHO informants (and as described above), 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

[29] www.who.int/nutrition/publications/policies/global_nut_policyreview/en

[30] http://www.who.int/nutrition/events/2012_proposed_globaltargets_backgroundpaper.pdf?ua=1

[31] http://documents.worldbank.org/curated/en/963161467989517289/pdf/104865-REVISED-Investing-in-Nutrition-FINAL.pdf

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.

Quality of the document

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). RO/CO (survey) respondents assess the overall quality of the Plan most positively as regards relevance of country needs and utility of recommendations.

4. Dissemination

The document was disseminated as a printed publication and electronically on the WHO web site translated in 6 official United Nations languages. A library of related documentation and evidence was made available on the web site. There is no information on how many people have read the plan, yet one can see how many have downloaded it. Stakeholders however underscore that the Plan has been communicated and presented in a range of fora and meetings, and the global nutrition targets as a component of the plan even more so. "*The Plan has been constantly referred to in ICN2 documents and follow-ups, WHA reports, policy briefs on the targets and the 2013 Lancet series on nutrition, etc. The latter have quite a large audience*" (HQ Informant).

In addition, the e-Library of Evidence for Nutrition Actions (eLENA) 32 (WHO 2016) provides information on approximately 117 evidence-informed diet- and nutrition- related interventions addressing all forms of malnutrition. It acts as a single point of reference for the latest nutrition guidelines, recommendations and related information[33]. Content is also available in the six WHO official languages. Currently, the online library contains details of 100 nutrition interventions and the website has been viewed by more than 1 million users since its launch in 2011 [34]. Moreover, the new eLENA mobile phone application allows access through smartphones in settings without reliable Internet access [35].

A majority of the RO/CO survey respondents (83%) report that they are 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".

5. Relevance and Results

Uptake and incorporation

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 also helped countries in setting targets based on the 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/support. Furthermore, there is an unanimous

[32] http://www.who.int/elena

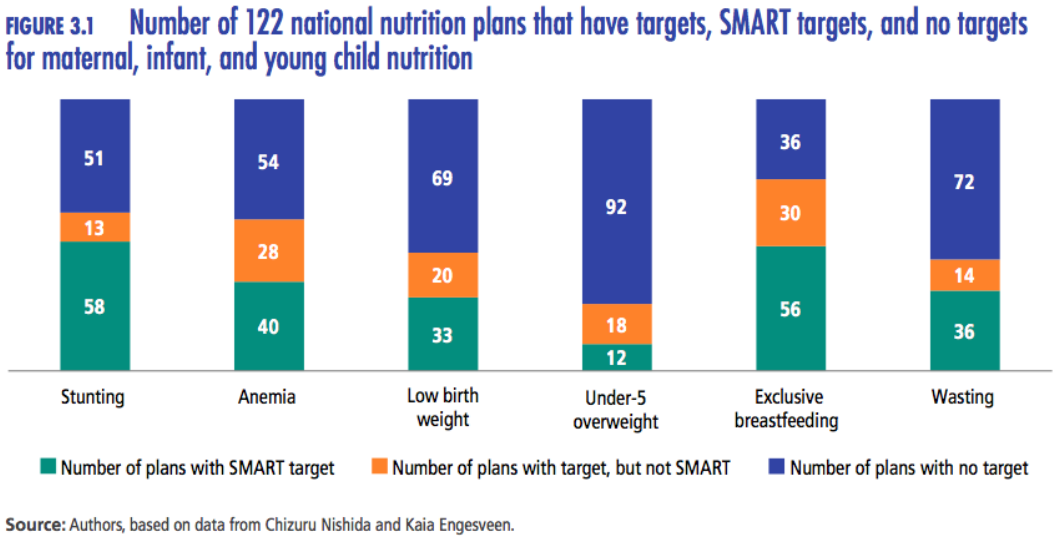
[33] Meeting Report:Bi-regional meeting on Scaling-up Nutrition/Colombo regional consultation document

[34] Progress report 29 April 2016

[35] Global Nutrition report 2016, 26

view that the Plan has contributed to improved health outcomes in the respective country/region "to some extent".

One way to track countries progress is to apply the global targets to a national level. Uptake and incorporation among MS is tracked by WHO in the Global Nutrition Policy Reviews and through the Global database on the Implementation of Nutrition Action (GINA), which identifies whether countries have nutrition policies and programmes, how they are being implemented, what the implementation coverage is, who the stakeholders are etc. (Implementation is here understood as having a programme in place). According to one informant, the plan is clearly relevant to country needs and prioritities. This is corroborated by the frequent use by countries to revise their own plans (HQ informant interview). The below figure shows an analysis done by WHO regarding the number of national nutrition plans with national policy targets related to the Global Nutrition Targets:



Source: Global Nutrition Report 2016

WHA report (A 69/7, 29 April 2016) lists several other specific steps taken in carrying out the comprehensive plan, such as:

- Above all, nutrition is now a contributor to the seventeen Sustainable Development Goals adopted by United Nations General Assembly in 2015. It is a direct contributor to Goal 2 ("End hunger, achieve food security and improved nutrition, and promote sustainable agriculture") and a decisive enabler to Goal 3 ("Ensure healthy lives and promote well-being for all at all ages"). Nutrition was also reflected in the MDGs (underweight) but in an unsatisfactory way as the indicator is less specific. To this end, the SDGs incorporate nutrition in much better way, by actually referring directly to the Global Nutrition Targets
- The Global Nutrition Targets were adopted into the Second International Conference on Nutrition (ICN2) outcome documents
- Progress towards the global targets: In 55 countries, there is evidence that stunting, wasting and anaemia are being tackled through WHO's recommended approach (including guidelines). In a number of countries, effective nutrition programmes are starting to be factored into the achievement of universal health coverage, with the active support of WHO and above all, guided by WHO evidence-informed guidelines.
- Several WHO regions have developed regional nutrition strategies that are aligned with the comprehensive implementation plan, for example: the PAHO Plan of action for the prevention of obesity in children and adolescents (2014–2019); the European food and

nutrition action plan (2015–2020); and the Action plan to reduce the double burden of malnutrition in the Western Pacific Region (2015–2020).

- WHO (the Secretariat) provides technical support to MS for reviewing policies (national food and nutrition action plans) and establishing or expanding the coverage of programmes
- Nearly 60 countries have been reviewing their national food and nutrition action plans in 2014–2015 with WHO's support, with reference to the comprehensive implementation plan and the outcomes of the Second International Conference on Nutrition (11 in the African Region; three in the Region of the Americas; seven in the South-East Asia Region; 22 in the European Region; nine in the Eastern Mediterranean Region; and six in the Western Pacific Region)

6. Feedback and learning / M&E system

The establishment of an agreed indicators' framework and the refinement of data collection methodologies, supported by several donors and multilateral agencies, is reportedly rapidly improving the quality of surveillance systems[36]. A recurring challenge across several countries however, seems to be a lack of data. Still, the establishment of global targets appears to intensify the efforts of MS in strengthening their surveillance systems. The majority of RO/CO staff in the survey (83%) claim to be actively monitoring implementation of the Plan. No evaluation has however been done yet.

According to a recent report by the Secretariat (29 April 2016), the progress towards the 6 global nutrition targets set out in the implementation plan and the steps being taken to put the plan's constituent actions into effect is also systematically monitored:

1. Data in this area 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 (WHO 2016) supports countries in the process of adapting the global targets to the national setting. The tool displays a country's updated, comparable data on five of the six global nutrition target indicators. The tool was developed jointly by WHO, UNICEF and the European Commission to help countries set their national targets and monitor progress [37]. Overall, however, 49% of countries do not have enough nutrition data to determine whether they are on course for meeting the global targets.
3. In addition, The Global database on the Implementation of Nutrition Action (GINA) launched in 2012, provides detailed country by country results on the implementation of numerous nutrition policies and interventions. (i.e. what are the commitments made and who is doing what, where, when, why and how (including lessons learnt). http://www.who.int/nutrition/gina_guidance.pdf?ua=1 (summaries of policies and action by countries- GINA action data can be uploaded by those involved in nutrition interventions, e.g. programme planners, government officials, NGO staff, research- teams or other stakeholders).

- 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 as approved by the Sixty-seventh and Sixty-Eighth World Health Assemblies.
- As mentioned above, the Global Nutrition Policy Review, which provides information about the adoption, makes it possible to identify the presence and implementation of nutrition policies (which countries have updated policies based on the plan). An updated version with responses from more than 150 countries is expected published in 2017.

[36] Summary of main issues and raised WHO responses (4h April 2012)
[37] See http://www.who.int/nutrition/trackingtool/

- Since 2014, the Global nutrition report has brought together various stakeholders to describe progress in combating malnutrition and to identify gaps and propose ways of filling them[38] .
- The comprehensive implementation plan has a 13- year timeframe, and reporting is done biannually until 2022 [39] .
- The two indicators of PAN- Programme Area Network 40 are related to the monitoring of the uptake of the plan and its implementation:
    - Countries enabled to develop, implement and monitor action plans based on the maternal, infant and young child nutrition comprehensive implementation plan, which takes into consideration the double burden of malnutrition (Value for 2015 : 58/194).
    - Norms and standards and policy options for promoting population dietary als and cost effective interventions to address the double burden of malnutrition, and their adoption by countries in developing national guidelines and legislation supporting effective nutrition actions. (Value for 2016 : 68/147).

Conclusions/Significance of the plan

It seems then, that over the years (and significantly since the 1992 ICN), important nutrition commitments have been taken, but that there has been an increase in the past couple of years. It is said that the definition of the six global targets have been taken up broadly by the nutrition community, allowing the alignment/conceptualization of harmonized (global) nutrition targets, to the extent that donor strategies and global reports refer to the latter. Yet, one could argue, had the plan not been developed, what would have been missing? Extending upon the argument, was it worth the effort? Overall, informants generally expressed broad satisfaction with what the plan has achieved up till date. Relatedly, not much criticism or debate has been found concerning the Plan in the relevant literature.

The most significant results (that can be attributed to the plan) are, inter alia;

- 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).
- 3 out of the 6 WHA nutrition targets are now included in the indicator framework of SDG2, reflecting growing consensus and political support (maternal nutrition also included in SDG´s and the weight-for- height is used for wasting and overweight)
- 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.

[38] Progress report 29 April 2016

[39] Comprehensive Implementation Plan on maternal, infant and young child nutrition, WHO (2014, 6)

[40] Established to strengthen the coordination across three levels to work coherently on each of the technical areas

7. Global Mental Health Action Plan

1. Initiation/Background and purpose
The World Health Organization (WHO) defines Mental Health as:

"a state of well-being in which the individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community"[41]

Including mental health as an integral part of development is however relatively new to the United Nations and its development partners. While there has been progress in recent years on awareness and acceptance for the importance of putting mental health on the health and development agenda, stigma, discrimination and human rights violations persists against people with mental disorders and psychosocial disabilities.

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 [42].

Against this backdrop then, 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 States (MS). This being the first formal Action Plan dedicated to mental health in the entire history of WHO, can therefore be considered as representing a new (normative product), or as some hold, a landmark[43]. It focuses international attention on a long-neglected problem. It is also a commitment by all MS to take specified actions to improve mental health and to contribute to the attainment of a set of agreed global targets.

More specifically, the four major objectives of the action plan are to:
- Strengthen effective leadership and governance for mental health.
- Provide comprehensive, integrated and responsive mental health and social care services in community-based settings.
- Implement strategies for promotion and prevention in mental health.
- Strengthen information systems, evidence and research for mental health.

Each objective is accompanied by one or two specific targets, which provide the basis for measurable collective action and achievement by the target groups MS, for international and national partners, and for the WHO Secretariat. The action plan thus builds upon, but does not duplicate, the work of WHO's mental health gap action programme (mhGAP)[44].

2. Design and formulation
Development of the plan and stakeholders involved in review:
The actual process for preparing the plan is not thoroughly described in the report itself, nor the stakeholders involved in the process of formulation, review and quality control. Background documents describe that the process was initiated with a proposal by a number of Member

[41] Promoting mental health: concepts, emerging evidence, practice. WHO, 2004
[42] "WHO's Mental Health Action Plan 2013-2020: what can psychiatrists do to facilitate its implementation? World Psychiatry (2014) Jun; 13(2): 107–109
[43] Ibid
[44] WHA66.8 Agenda item 13.3, 27 May 2013; "Comprehensive mental health action plan 2013–2020" http://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_R8-en.pdf

States (MS) (Switzerland, India and USA in particular) to include an agenda item on mental health at the Executive Board meeting of the WHO in January 2012. This was accepted and led to a Resolution, first at the Executive Board and subsequently at the World Health Assembly (WHA) of that year, on the global burden of mental disorders and the need for a comprehensive, coordinated response from health and social sectors at the country level. The WHA resolution requested the Director-General, inter alia, in consultation with MS, to develop a comprehensive mental health action plan, covering services, policies, legislation, plans, strategies and programmes.

Hence began an iterative but intensive and wide-ranging consultation and drafting period to develop the action plan. The consultative process involved WHO Member States but also nongovernmental 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 [45]. What is more, for the first time, specific and measurable global targets and indicators were agreed upon as a way to monitor implementation, progress, and impact.

To conclude the work, the WHO Secretariat submitted a final draft through the Executive Board, for consideration by MS. 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.

The plan was developed within the existing (and very limited) resources of the Department. Yet as one stakeholder formulates it "although the Resolution was passed unanimously by all MS, the budget allocated for its implementation across the Organisation and its MS was exactly zero".

3. Quality assurance and quality

A noteworthy and extensive stakeholder consultation has helped ensure that the action plan corresponds well with the health and development community. Quality assurance of the "zero draft" (prepared by the WHO Secretariat), was done through a consultative (and seemingly transparent) process. More specifically, regional technical consultations were conducted on the draft action plan (including SEARO, EMRO, AFRO, PAHO). A web consultation with all stakeholders – was then held (27th August to 19th October 2012), following discussion in Regional Committees. Subsequently, face to face consultations with all stakeholders took place in Geneva on World Mental Health Day (10th October 2012). Lastly, the WHO Secretariat convened consultations on the "zero draft" with MS and UN agencies (2 November 2012).

During the informal consultation, a summary of comments was received from MS and UN agencies, as well as the views from relevant global NGOs and selected private sector entities[46].

Informants underscore that 4-5 staff were working full time on the plan and RO´s and CO´s also assisted in writing the draft and arranging for regional consultations. The Global Mental Health Action plan was approved through the Executive Board, for consideration by MS, before submission to WHA on November the 9th 2012.

Quality of the document: The document is relatively short (48 pages) and easily read also for a non-expert. It articulates practical, measurable indicators by which MS can track progress. The Plan has an overall approach aiming to mainstream mental health services across various sectors. It provides a clear framework and proposed actions targeted to different audiences; to which MS, the Secretariat, international and national partners can mutually align. Following one

[45] "Comprehensive mental health action plan 2013–2020" Eastern Mediterranean Health Journal, Vol. 21 No. 7 (2015)

[46] For detailed feedback from stakeholders on the structure of the plan see: http://www.who.int/mental_health/mhgap/2_11_2012_Funk.pdf?ua=1

commentator, the alignment of MS and the wider development community may prove an interesting model for subsequent WHO Action Plans seeking to turn aspiration into action[47].
Survey respondents (external stakeholders) rate the document high in terms of presentation and use of evidence, and specificity/utility of recommendations.

4. Dissemination
The document is made available electronically on WHO´s website in English; French; Italian; Japanese and Spanish.

A formal launch (event) of the Mental Health Action Plan with civil society participation- (linking the action plan to the Mental Health gap guidelines) - took place on 7. October, 2013. At what is called the mhGAP Forum, which is convened by WHO every October in Geneva, MS, intergovernmental and nongovernmental organizations, including UN agencies, international development agencies, philanthropic foundations, research institutes, universities, and WHO Collaborating Centres[48] participated. During the opening session of this Forum, Dr Margaret Chan launched the plan. The vision, goal, objectives, and targets of the Plan were presented, along with the actions that all stakeholders need to undertake to implement it in the six WHO regions[49].

To the question whether there is a mechanism to ensure that RO´s/CO´s actively disseminate/use guidance documents issued from HQ, stakeholders point to the existence of Regional advisors for Mental Health in each region. RO interviews confirm that a few hard copies of the document were received, and that circulation to country partners is predominantly done electronically. Informants also note the advantage of WHA documents, being seen as more prominent, are also more prioritized.

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).

5. Relevance and results
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

[47] https://www.csis.org/blogs/smart-global-health/global-mental-health-comes-age
[48] mhGAP Forum's participants included 48 Member States comprising 14 Ambassadors, 58 partner organizations including UN agencies, philanthropic foundations, NGOs, academic and research institutions, and WHO Collaborating Centres. Planned actions for implementation of the Plan were then presented by different groups: WHO Secretariat and Member States, Civil Society and WHO Collaborating Centres. http://www.globalcampaignagainstepilepsy.org/who-director-general-launches-the-mental-health-action-plan-2013-2020/
[49] http://www.who.int/nmh/events/2013/mhGAP_forum_2013.pdf?ua=1

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. Yet, following one respondent, "within NGO/CBO networks it is also felt that the plan is very targeted at governments and policymakers and that the role of NGO´s/CBO´s (especially in lower resource settings) is not very strongly represented or emphasized (e.g sections on NGOs is very short and not representing the full scope of their role)".

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.

While the plan has a global outreach, countries are expected to develop their own national targets to contribute to the achievement of the global targets. Indeed, the plan seems to be designed with flexibility, adaptable to countries and regions with different needs (has options for implementation). That there are recognized, effective strategies to address the global burden of mental disorders is undoubtedly a vital step towards improving mental health system access, quality and outcomes globally. Still, the Plan proposes a global vision50, 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.

Given that the emergent concept of"Global Mental health"is still in its infancy[51] much progress has been made/several steps have been made in carrying out the plan, and among the most significant results are:

- The Plan represents a formal recognition of the importance of mental health for WHO's 194 MS, i.e more importance to mental health.
- Plan demands commitment by all member states to take specified actions to improve mental health and to contribute to the attainment of a set of agreed global targets.
- Mental health is now a contributor to the SDG´s - goal 3 after being ignored in the MDG´s (but difficult to verify if change is plausibly attributable to the plan). Certainly important that there was an already endorsed WHA resolution.
- Mental health becoming a part of basic health package, which is not always there. (eg. inclusion of mental health drugs in essential medicines lists).
- MS are increasingly seeking WHO technical support and guidance to implement the plan/align with national/regional plans.

[50] 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/

[51] Rob Whitley, 2015 Global Mental Health: concepts, conflicts and controversies Epidemiology and Psychiatric Sciences (2015), 24, 285–291.

- Adaptation to country/local circumstances facilitated by WHO through the development of regional action plans and implementation frameworks, which has enabled groupings of countries with shared cultural values to better reflect their own needs and preferences. Thus in the Eastern Mediterranean Region, the initial consultation held at the drafting stage of development has been followed by a technical inter-country meeting at which regionally-focused objectives, implementation strategies and performance indicators could be reviewed, discussed and approved by national counterparts[52].
- Other regions have developed own regional strategy frameworks based on the plan. Ethiopia has developed national health strategy influenced by the plan, South Africa and Sri Lanka, Canada, United Kingdom and India have also done good work in this area
- The Plan has worked well as an advocacy tool – created awareness on a neglected issue .

6. Feedback and learning/M&E system

Monitoring and implementation of the Plan:
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-AIMS53, 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.

Through periodical surveys progress in MS is monitored through indicators that MS report against (self rating). Informants underscore that the survey is sent to focal points in MS (baseline data collection in 2013) and the most recent survey (2016) shows that 179 out of 190 MS responded.

Baseline data collection for the indicators has been undertaken via a revised version of the 2014 Atlas. The latter show that the percentage of countries fulfilling the condition of these targets is already quite substantial. In terms of global reporting on core mental health indicators, the 2014 Global Atlas key findings suggest that:

- 171 out of WHO's 194 Member States (88%) at least partially completed the Atlas questionnaire; the submission rate exceeded 80% in all WHO Regions;
- 60% of Member States were able to report on a set of five core indicators that covered mental health policy and law, promotion and prevention programmes, service availability and mental health workforce;
- 33% of Member States regularly compile mental health service activity data covering at least the public sector.

Relatedly, in mental health governance:

- 68% of WHO Member States have a stand-alone policy or plan for mental health; 51% have a stand- alone mental health law. In many countries, however, policies and laws are not fully in line with human rights instruments, implementation is weak and persons with mental disorders and family members are only partially involved.

[52] Eastern Mediterranean Health Journal Vol. 21 No. 7 (2015) "Comprehensive mental health action plan 2013–2020"
[53] 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/

Mental Health Action Plan 2013-2030: Baseline values for global targets:

Action Plan Objective	Action Plan Target	Baseline value for 2013
OBJECTIVE 1: **To strengthen effective leadership and governance for mental health**	**Target 1.1:** 80% of countries will have developed or updated their policies or plans for mental health in line with international and regional human rights instruments (by the year 2020).	88 countries, equivalent to 56% of those countries who responded, or 45% of all WHO Member States. Value is based on a self-rating checklist (see Section 2.1 of report).
	Target 1.2: 50% of countries will have developed or updated their law for mental health in line with international and regional human rights instruments (by the year 2020).	65 countries, equivalent to 42% of those countries who responded, or 34% of all WHO Member States. Value is based on a self-rating checklist (see Section 2.2 of report).
OBJECTIVE 2: **To provide comprehensive, integrated and responsive mental health and social care services in community-based settings**	**Target 2:** Service coverage for severe mental disorders will have increased by 20% (by the year 2020).	Not computable from Atlas 2014 data, but expected to be less than 25%, based on treatment gap and service uptake studies.
OBJECTIVE 3: **To implement strategies for promotion and prevention in mental health**	**Target 3.1:** 80% of countries will have at least two functioning national, multisectoral mental health promotion and prevention programmes (by the year 2020)	80 countries, equivalent to 48% of those countries who responded, or 41% of all WHO Member States. Value is based on a self- completed inventory of current programmes (see Section 4 of report).
	Target 3.2: The rate of suicide in countries will be reduced by 10% (by the year 2020).	11.4 per 100,000 population. Value is based on age-standardized global estimate (see WHO report on suicide, 2014).
OBJECTIVE 4: **To strengthen information systems, evidence and research for mental health**	**Target 4:** 80% of countries will be routinely collecting and reporting at least a core set of mental health indicators every two years through their national health and social information systems (by the year 2020).	64 countries, equivalent to 42% of those countries who responded, or 33% of all WHO Member States. Value is based on a self-rated ability to regularly compile mental health specific data that covers at least the public sector (see Section 1 of report).

Source: Mental Health Atlas (2014)
http://apps.who.int/iris/bitstream/10665/178879/1/9789241565011_eng.pdf?ua=1&ua=1

Issues to discuss/Significance of the Plan:

It seems then, that mental health has been greatly neglected by the global community, but that in recent years, a critical mass of scientists and stakeholders have driven initiatives to promote mental health at a global level. However, WHO is the only agency that has systematically been working on this issue in all regions worldwide (WHO informant).

Given that, between 76% and 85% of people with severe mental disorders receive no treatment for their condition in low income and middle-income countries[54], the development of the action plan was both extremely timely and appropriate, to the extent that some (external survey) stakeholders refer to it as "a key reference document for mental health at all levels" (…) regularly referred to in a wide range of forums, from the World Bank to government liaison meetings, to local NGO programmes (survey respondent). Indeed, among external stakeholders (survey) the preponderance of feedback is overwhelmingly positive – one respondent concludes by noting that "the Plan is one of the most important priorities adopted by WHO in the past century. The programs being developed and implemented are an excellent example of the role WHO can play".

Yet, criticism has also been voiced around the invocation of the word "global" [55]. The latter argument often goes that the "global" (in a top down manner) may ignore adaptation to prevailing local circumstances, standards and priorities, and attention to bottom up notions.

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 (also as an advocacy tool/via lobbying) in countries around the world. Indeed, it is said that if the plans principles are adopted and implemented, they will definitely result in a difference for mental health service users, and their families, globally [56].

Notwithstanding that the significance of the plan is contingent on the countries uptake (and funds to implement the plan is, following several stakeholders, extremely insufficient), the fact that this is the first time WHO's MS formally recognize and endorse the importance of mental health, in itself indicates a shift in the political conversation around mental health. For this reason it is not difficult to argue that developing an action plan that is actually ripe for action, is needed.

[54] World Health Organisation (2013)"Mental Health Action Plan 2013-2020"

[55] See for example Rob Whitley editorial"Global Mental Health: concepts, conflicts and controversies" in epidemiology and Psychiatric Sciences (2015), 24, 285–291

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

8. Accelerating work to overcome the global impact of neglected tropical diseases- a Roadmap for Implementation

1. Initiation

Neglected tropical diseases (NTD´s)57 have traditionally not been the highest priority on national and international health agendas. Indeed, a need to address this area in an integrated approach and raise the awareness of NTD´s seems to have triggered the preparation of this document.

Efforts to recognize the fact that many tropical, poverty-related diseases or conditions remain overlooked reached a peak in 2007, when WHO convened the first meeting of global partners. Important steps were made, as the meeting culminated in a shared commitment to support WHO strategies and goals by working together. The results have been streamlined and integrated approaches [58]. Then, on 14th of October, 2010, WHO´s Director General, Dr. Margareth Chan, launched the first WHO report on NTD´s, to demonstrate the progress achieved since 2007 and the challenges ahead.

This also set the scene for defining interventions to tackle NTD´s and consolidate them in a roadmap with targets. Against this backdrop,"Accelerating work to overcome the global impact of neglected tropical diseases- a Roadmap for Implementation"(hereinafter the "Roadmap") was formulated in 2011 by WHO, approved by its Strategic and Technical Advisory Group for Neglected Tropical Diseases in 2011, and endorsed in 2012 by signatories to the London Declaration on neglected tropical diseases (hereinafter the "London Declaration") committed to facilitating its implementation.

In Margaret Chan´s words, "the roadmap for implementation represents the next step forward in relieving and, in many cases, finally ending the vast misery caused by these ancient diseases of poverty". Informants underscore that the document was requested by senior WHO management, and that Chan was instrumental in creating more priority to NTD issues.

More specifically, the stated purpose of the roadmap is:

- To implement policies and strategies set out in the Global Plan to Combat Neglected Tropical Diseases 2008-2015 (WHO, 2007) and developed in the First WHO Report on Neglected Tropical Diseases (WHO, 2010) - documents which underline the impacts and complexity of challenges related to NTD´s.
- To provide guidance and technical insight to policy makers and programme managers in countries
- To encourage the community of partners, including donors, pharmaceutical companies, agencies, NGOs, philanthropists and universities, to maintain and expand their commitments to overcoming NTDs

In order to achieve this, the roadmap contains milestones for 17 NTDs to be reached between 2015 and 2020, which specifies targets for eradication, elimination, and intensified control of

[57] Neglected tropical diseases (NTDs) are a diverse group of communicable diseases that prevail in tropical and subtropical conditions in 149 countries and affect more than one billion people, costing developing economies billions of dollars every year. They mainly affect populations living in poverty, without adequate sanitation and in close contact with infectious vectors and domestic animals and livestock (http://www.who.int/neglected_diseases/diseases/en/)

[58] NTD Roadmap, 2012, 1

the different NTDs59. Some of the elimination targets are global, some are regional and some are country-specific.

The roadmap further outlines the five main interventions required to achieve those targets; preventive chemotherapy (PC), case detection and management, vector control, veterinary public health, and water, sanitation and hygiene.

The targets are supported by the first Resolution on NTD´s (WHA 66.12), adopted in 2013, which amongst others urges Member States (MS) to achieve and maintain universal access to interventions and reach the targets of the roadmap[60].

The purpose of the roadmap hence seems very clear, in a context wherein NTDs have gathered significant momentum over recent years. This was arguably made possible due to the establishment of NTDs as a "brand" in global health, where the roadmap seems to have played a central role.

Given that the roadmap is a comprehensive implementation plan with shared targets (identifying the areas of need with clearly defined objectives), it is not a clear normative product as such, but contains normative elements. Albeit endorsed by MS, it is not mandatory, and implementation plans must be tailored to national needs. Nevertheless, it reportedly represents an important document for its target groups: MS, and as guidance to policymakers, and programme managers in governments, in terms of where to prioritize their efforts. It is also an encouragement to the community of partners, including donors NGO´s, pharmaceutical companies etc. to increase commitments to overcoming NTD´s.

What is more, the roadmap inspired the London Declaration on NTDs—(which reaffirms a commitment by the multinational pharmaceutical companies to continue donating essential NTD medicines and invest more seriously in research and development for new tools)—and the 2013 WHA resolution. In short, a declaration combined with practical information on how to do it makes an enormous difference, to paraphrase one informant.

2. Design and formulation

The roadmap gives a relatively good description of the needs and demands to develop an approach to NTD´s and the process leading up to the preparation of the document. The latter explains the context in which a pardigm shift took place (background and purpose) but is less detailed with regards to the design, formulation and stakeholders involved in preparation of the Roadmap. Survey respondents (HQ stakeholders) report that there was a great demand for the roadmap, in particular expressed from Governments.

Through interviews we learn that the document itself was a collective effort, primarily involving people at HQ (but with inputs from RO´s and CO´s). Following one stakeholder, it served to bring together all major actors, committing themselves to contribute in different ways and also to monitor their contribution and the progress jointly (HQ survey). Targets and milestones for elimination were established in consultation with Member States, WHO regional and country offices, national programme managers and various partners. The targets are based on recommendations made by MS in several WHA resolutions[61]. As articulated by one informant, the document is not inventing something new per se, but is based on WHO resolutions (HQ

[59] The WHO Roadmap targets the eradication, elimination of transmission or elimination as a public health problem, at regional or global level, of Chagas disease, human African trypanosomiasis, human dog-mediated rabies, leprosy, lymphatic filariasis, onchocerciasis, schistosomiasis, trachoma, visceral leishmaniasis and yaws by 2020.

[60] http://www.who.int/neglected_diseases/WHA_66_seventh_day_resolution_adopted/en/

[61] NTD Roadmap 2012, 2

informant). The roadmap was further discussed by the WHO NTD Strategic and Technical Advisory Group (STAG) in April 2011 and finalized thereafter. https://www.google.no/search?client=safari&rls=en&q=technical+language+for+a+non+practitioner&spell=1&sa=X&ved=0ahUKEwjehfvA_v_QAhUKI8AKHU_wBSsQvwUIGSgA

Overall, funding to control of NTD´s relies crucially on external assistance from donors such as; Bill and Melinda Gates foundation, United States Agency for International Development (USaid), United Kingdom Department for International Development (Dfid), and Geneva Global to mention but a few.

Funding to develop the roadmap was met from WHO budgets. Given the comprehensive, coordinated action it seems that the resources have been used efficiently and effectively. Accurate evidence-based costings of implementing the interventions to meet the targets in the roadmap is important to address, but no comprehensive analysis is given for estimating the cost of global NTD control in the document.

3. Quality assurance and quality

The actual process of formulation, review and quality control in preparing the roadmap is not thoroughly described in the document itself. It is stated that regional directors and members of their staff provided support and advice to the development of the Roadmap, while inputs in the form of contributions, peer reviews and suggestions were received by members of the Strategic and Technical Advisory Group for Neglected Tropical Diseases.

In terms of overall Q&A on the work of WHO on NTD`s, it is guided by international experts who serve on the STAG-NTD, which was set up in 2007. The group's mandate is to advise WHO on overall global policies and strategies, ranging from epidemiology, monitoring implementation and research development to delivery of interventions and their linkages with other health interventions.

More specifically, and as mentioned in the roadmap, the STAG-NTD advises WHO's Director-General on the following areas[62]:

- Adequacy of progress towards the achievement of the goals of the Global Plan;
- Major issues and challenges to be addressed with respect to achieving the goals of the Global Plan;
- WHO's response to current public-health priorities with regard to NTDs;
- Major general policies, goals and targets related to NTDs;
- Adequacy of WHO's strategic plan and priority activities for controlling NTDs, to achieve the goals consistent with its mandate and considering the comparative advantages and the respective roles of partner organizations;
- Intersectoral activities and initiatives related to the control of NTDs, and strategies and linkages with other health interventions;
- WHO's relations with partnerships in the control of NTDs;
- Role of WHO in promoting integration of NTD interventions in national health systems

Quality of document:

The roadmap is comprehensive albeit not too lengthy (38 pages). Although the language and terminology is somewhat technical (for a non- practitioner), the reader can arrive at an understanding of the rationale and purpose for setting the targets as well as the ultimate destination of the Roadmap. Survey respondents (HQ stakeholders) rate the document highest in terms of presentation of evidence, reader friendliness and utility of recommendations, while the overall assessment of the quality and relevance of the Roadmap is considered very good.

[62] Roadmap 2012, 5

4. Dissemination

The roadmap was disseminated as a printed publication and is available electronically on the WHO web site in English, Arabic, Chinese and French. An executive summary (15 pages) has also been produced.

The preponderance of feedback suggests that the roadmap has reached its target audiences and is used; "the road map has been used as a guiding document in the all regions and most of the countries" (survey response) and has received wide publicity (also among global partners) and in the press. It is said to have given renewed impetus for collaboration between NTD actors in that international organisations, academics, donors, practitioners. Indeed, WHO/NTD is referred to as "a leading advocate for bringing the NTD agenda to the affluent developed world"[63].

Survey stakeholders (HQ) report that they are aware of plans for how the document should be disseminated, further, they have received hard copies (between 10-51 copies) for circulation to country partners. As noted by one "as part of the NTD department, my unit also participated in the country dissemination. However, additional ways were used, like disease specific workshops, and congresses to disseminate the road map targets". The survey indicates that HQ to a large extent has been involved in the introduction and adaptation of the Roadmap to countries, for instance through technical guidance/support.[64]

5. Results and relevance

General progress achieved to date include, inter alia:

- NTDs have attracted increased attention and investment - policy momentum has been generated through continued bilateral, philanthropic, and non-governmental development organisation (NGDO) support, and donations of drugs from pharmaceutical companies
- The research agenda has defined the need for affordable products (diagnostics, drugs and insecticides)
- The roadmap seems relevant to country needs and prioritities, corroborated by high country commitment. For example are more than 74 countries worldwide ready to implement national NTD master plans – crucial to reaching the Roadmaps targets [65]
- A key element is also country investments. Several countries are showing great initiative on domestic financing for NTD programs. Some have already taken on primary responsibility for financing their NTD program: E.g. Bangladesh and the Philippines pay for 85% and 94% of their NTD programs, respectively, and Honduras recently became the first Latin American country to launch a national NTD program fully supported by the government[66]
- More than 1 billion people in 88 countries have benefited from preventive chemotherapy in 2014 (a significant advance from 2011 when 729 million people were covered) [67]
- Inclusion in SDGs: SDGs include a target of ending the epidemic of NTDs by 2030 as part of SDG 3 ("ensure healthy lives and promote well-being for all at all ages")
- Availability of drugs is no longer a barrier to achievement of universal health coverage for most NTDs, yet they remain a chronic pandemic in the poorest sectors of society in endemic countries who now have access to donated drugs (Lancet article)

- The roadmap has helped to mobilize resources and political commitment (HQ survey respondent)

[63] Roadmap, 2012, 4

[64] However, the response rate to the survey was very low.

[65] Investing to overcome the Global Impact of NTD´s, Third WHO report on NTD´s (2015)

[66] http://unitingtocombatntds.org/report/third-report-country-leadership-and-collaboration-ntds

[67] Neglected tropical diseases: progress towards addressing the chronic pandemic (2016) David H Molyneux, Lorenzo Savioli, Dirk Engels, Lancet 2017; 389: 312–25

For the progress on specific NTD´s and the associated global burden, targets, partnerships, endemic countries, treatment progress, and research needs please see the following table:

http://www.thelancet.com/action/showFullTableImage?tableId=tbl1&pii=S0140673616301710

The list above shows that significant steps have been made. However, progress towards achievement of the 2020 WHO Roadmap targets has been uneven. According to Molyneux et al., the resources allocated to NTDs are not yet adequate to address the totality of the problem.
The argument goes that the estimated requirements to achieve Roadmap goals are double the current $300 million annual funding provided (however if vector control is included the estimated amount required would be ten times that amount)[68].

6. Feedback and learning/M&E systems
Monitoring and implementation of the Roadmap:

As shown above, progress towards the NTD roadmap is already being measured and reported to WHO as disease specific indicators[69]. More specifically, the roadmap provides operational definitions and indicators for eradication targets and elimination targets. The definitions of elimination as a public health problem, elimination of transmission and eradication of disease, as well as the indicators used to assess their achievement, are specific to each disease and were established through a consultative process by WHO and partners.

Survey respondents (HQ) claim to be actively monitoring the implementation of the Roadmap. WHO has led the development of an integrated NTD data management system/database. The latter has been designed to strengthen the capacity of national NTD programs to store, manage, analyze, and report their M&E data:
http://www.who.int/neglected_diseases/data/ntddatabase/en/

Other NTD databases are:

PCT Databank:
http://www.who.int/neglected_diseases/preventive_chemotherapy/databank/en/
Global Health Observatory: http://www.who.int/gho/neglected_diseases/en/

So in summary, the number of people requiring treatment against NTDs is thus measured by existing country systems, and through common systems of reporting (requests of medicines, logistics etc.) which in practice functions as a monitoring tool for the roadmap. There are arguably good incentives to report, as countries receive free medicines. Currently, 98% of the data is complete (self reporting from MS annually showing progress) from 120 countries (HQ interview). No evaluations have however been carried out yet.

While attribution of plausible results is not straightforward, the value-added by the roadmap seems to be clear following one informant. This is arguably because of compilation of the most accurate statistics of the status of NTDs in each country.

Issues to discuss/Significance of the Roadmap:
The stakeholders (HQ interviewees and survey respondents) overall provided positive feedback on the significance of developing a roadmap: what emerges from them is that over the last decade, NTDs have received increased recognition. This was made possible due to the

[68] Neglected tropical diseases: progress towards addressing the chronic pandemic (2016) David H Molyneux, Lorenzo Savioli, Dirk Engels, Lancet 2017; 389: 312–25
[69] Leaving no one behind: a neglected tropical disease indicator and tracers for the Sustainable Development Goals International Health (2016) Mar; 8 Suppl 1:i15-8 Fitzpatrick C, Engels, D.

establishment of 17 very different NTDs as a "brand" in global health, which in turn was critical to rally action and visibility/resources at international level. To this end, the roadmap marked a major strategic advance, providing countries with consolidated recommendations and targets, or as one informant articulates it; "the roadmap provides countries with a relatively easy view on what the solutions are".

According to Molyneux, the change of paradigm to the concept of an "NTD" brand based on integrated control or elimination was a crucial decision. This was communicated through strong and visionary leadership by WHO, and through the establishment of a WHO NTD Department [70].

Yet others have criticised pharmaceutical companies' drug donations, the latter has been a key platform for the expansion of NTD programmes. Critical voices such as Médecins Sans Frontières (also known as Doctors Without Borders) have said that challenges in the area were being "glossed over" in the roadmap. In this view, the emphasis on donations from pharmaceutical companies could mean that strategies are influenced by what products are made available rather than what is actually required for good public health[71].

Still, the fact that affected countries now place NTDs higher on their agenda and develop national NTD plans[72], stands as evidence to the growing commitment of MS and public (and private) partners in reaching targets outlined in the 2012 WHO roadmap. This development should be welcomed. If following Bernhard Liese's work, "only 0.6% of overseas development assistance for health is allocated to neglected tropical diseases, despite such diseases affecting at least 1 billion people" [73], then, the allocation of health ODA does not reflect the diseases' respective health burdens. It is therefore not difficult to argue that a roadmap that targets the worlds poorest individuals is both timely and cogent.

[70] Molyneux, David "The 'Neglected Tropical Diseases': now a brand identity; responsibilities, context and promise" in Parasit Vectors. 2012; 5: 23

[71] http://www.nature.com/news/road-map-unveiled-to-tackle-neglected-diseases-1.9938

[72] See for example: Lancet Editorial (2014) Neglected tropical diseases: becoming less neglected, and Molyneux DH (2014) Neglected tropical diseases: now more than just 'other diseases' – the post-2015 agenda, in International Health

[73] Official development assistance for health-how neglected are neglected tropical diseases? An analysis of health financing, Liese BH, Shubert. L in International Health. 2009 Dec;1(2):141-7

9. Consolidated Guidelines on the Use of Antiretroviral Drugs. Recommendations for a Public Health Approach

1. Initiation

WHO has developed four consolidated guidelines to support fast-track action in countries:

- Consolidated guidelines on HIV testing services.
- Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection.
- Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations.
- Consolidated strategic information guidelines.

The focus is here being on the second guideline completed in 2013 with a new version in 2016. With this publication, WHO issued its first consolidated guidelines for the use of antiretroviral drugs to treat and prevent HIV infection.

WHO published guidelines on the use of ART for HIV infection among adults and adolescents in 2002 and on the use of ARV drugs for PMTCT in 2001 and 2004. These publications and their updates, have provided guidance to countries that have scaled up national ARV programmes during the past decade. In 2013, WHO for the first time revised and combined these and other ARV-related guidance documents into one set of consolidated guidelines addressing the use of ARV drugs for HIV treatment and prevention across all age groups and populations.

The objectives of the consolidated guidelines are to:

- Provide updated, evidence-based clinical recommendations outlining a public health approach to providing ARV drugs for HIV treatment and prevention in the context of the continuum of HIV care.
- Provide guidance on key operational and service delivery issues that need to be addressed to increase access to HIV services, strengthen the continuum of HIV care and further integrate the provision of ARV drugs into health systems.
- Provide programmatic guidance for decision-makers and planners at the national level on adapting, setting priorities for and implementing the clinical and operational recommendations and monitoring their implementation and impact.

The primary target group for the guidelines is national HIV programme managers, especially in low- and middle-income countries. The guidelines are anticipated to guide country policy decisions and planning the scaling up of ART. They will also be a resource for clinicians and informing the priorities of development agencies, international organisations, non-governmental organisations and other implementing partners.

The guidelines compile new recommendations, existing recommendations and other guidance across the continuum of HIV care including guidance on HIV diagnosis, general HIV care and the strategic use of ARV drugs for treating and preventing HIV infection.

The document is clearly a technical guideline issued by WHO´s Secretariat following extensive consultations with regional and country offices, country partners and technical experts.

2. Design and formulation

Stakeholders in development and review

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. The composition of the Groups included HIV experts, researchers, programme managers, guideline methodologists, epidemiologists, human rights experts, development agencies, UN partners, civil society representatives and representatives from networks of people living with HIV. Community group members were selected following an open call for nominations. A full draft of the guidelines was circulated for comment to members of the Guideline Development Groups and the external Peer Review Group.

Four Guideline Development Group meetings were held in Geneva between November 2012 and January 2013. The Guideline Development Groups discussed both the proposed wording of the recommendations and the rating of its strength (strong or conditional). All decisions were reached by discussion and consensus on the recommendations, including their strength and, where appropriate, the conditions to be attached to the recommendations. Disagreements were resolved through e-mail discussions, teleconferences and redrafting recommendations and rationale. Early drafts of sections of the guidelines were circulated to Guideline Development Group members, and a full draft of the guidelines was circulated to Guideline Development Group members and peer reviewers for comment.

Sources of information

The following sources of information were used in developing new recommendations.

- Systematic reviews commissioned on 41 topics using Population, Intervention, Comparison and Outcome (PICO) format by the WHO Guideline Steering Group. Systematic reviews were outsourced to researchers who developed search protocols and conducted reviews of the available scientific evidence.
- Community consultations on values and preferences in priority areas for the guidelines were conducted through an online e-survey and moderated e-forum discussions with civil society networks and coordinated by the International HIV/ AIDS Alliance and the Global Network of People Living with HIV (GNP+). Focus group discussions were also held in Uganda and Malawi on the experiences of pregnant women with lifelong ART, and on PMTCT and pediatric ART.
- Two global community and civil society consultations on service delivery across the continuum of care in generalized and concentrated epidemic settings.
- Consultations with health workers working with adults and with children on the values and preferences related to priority areas in the guidelines were conducted through an e-survey.
- Mathematical modeling on the impact and cost–effectiveness of earlier ART in various populations and settings, based on data from countries with both generalized and concentrated epidemics.

Funding

Funding to support the work came from the US Centers for Disease Control and Prevention, Bill & Melinda Gates Foundation, Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ), UNAIDS Unified Budget, Results and Accountability Framework, United States Agency for International Development and specific funds through WHO staff time. The comprehensive document represents an indication that resources have been used efficiently and effectively.

3. Quality assurance and quality

The Grade system

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 with procedures outlined by the WHO Guidelines Review Committee

and were based on the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) system. The system classifies the quality of evidence as high, moderate, low and very low. The strength of a recommendation reflects the extent to which the Guideline Development Group was confident that the desirable effects of following a recommendation outweigh the potential undesirable effects.

The GRADE system classifies the strength of a recommendation in two ways: "strong" and "conditional". A strong recommendation is one for which the Guideline Development Group was confident that the desirable effects of adhering to the recommendation outweigh the undesirable effects. A conditional recommendation is one for which the Guideline Development Group concluded that the desirable effects of adhering to the recommendation probably outweigh the undesirable effects.

Our assessment of the quality of the document (attached) concludes that the document 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.

4. Dissemination

The document was disseminated as a printed publication and electronically on the WHO web site in the six official United Nations languages. A short version summarised key new and existing recommendations for easy reference. 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.

An evaluation of how users have implemented the guidelines has been developed to assess the uptake of the recommendations and the barriers to effective implementation. A review of the guidelines was planned for 2015. Interim technical and programmatic updates may be developed if important new evidence becomes available.

From August 21013 to May 2014 WHO with partners conducted nine dissemination meetings across six WHO regions serving 100 countries.

5. Relevance and results

With the 2013 guidelines WHO brought together more than fifty new or updated recommendations across the continuum of treatment and care. WHO supported countries to more rapidly adopt and implement new policies and the Department concludes that *"full implementation of these recommendations creates the foundation towards achieving the 90/90/90 target"* (Presentation 2015).

In the Progress Report to the World Health Assembly from 2014, it was noted that:

"In June 2013, WHO issued its consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection, which included new recommendations on community-based HIV testing and counselling; earlier initiation of antiretroviral therapy; treatment of all children under five years of age and all pregnant and breastfeeding women; harmonization of antiretroviral regimens across different populations; use of simpler and safer regimens; improved patient monitoring and task shifting; decentralization of treatment and care; and service integration and linkage. The guidelines placed emphasis on improving the quality of interventions and services

across the continuum of HIV care, including expanding HIV testing and counselling; linking people diagnosed with HIV infection to care and treatment; maximizing adherence to antiretroviral treatment; retaining people in care; and preventing and managing major comorbidities. WHO has conducted workshops in all regions to facilitate the rapid adoption and adaptation of the guidelines and is monitoring their impact on national policies and practices related to the use of antiretroviral medicines".

The report from 2014 describes mainly what the guideline consists of and that WHO has conducted follow up workshops in all region - not progress in implementation and preliminary achievements. However, such data and information are available in the comprehensive annual progress reports.

Uptake and incorporation

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 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.

Data in the following table – based on WHO´s own reporting system indicates a high uptake in countries of the recommendations in the consolidated guidelines on testing. The progress report confirms also that a high number of countries are providing lifelong ART to pregnant and breastfeeding women living with HIV. The same report provides a graphical presentation of the implementation of the recommendations in the ARV guidelines. It is interesting 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.

Table: Countries adapting HIV testing policies and practices in accordance with WHO guidance

	Have recommendations from WHO's 2015 consolidated guidelines on HIV testing services been adapted in a national process on testing guidelines:	Do the current HIV testing service guidelines address:		Do the national HIV testing policies recommend provider-initiated testing and counselling for:	Do the national HIV testing policies support:				
		Children	Key populations	All people attending health facilities	The use of community-based HIV testing services	The use of diagnostic tests to be performed by lay providers	The use of rapid diagnostic tests for HIV self- testing	Couples or partner testing in programmes for eliminating the mother-to-child transmission of HIV	Assisted partner noti cation services
Yes	97	117	130	69	99	65	23	119	69
No	28	25	12	72	41	73	112	20	57
Don't know	1	0	1	1	3	3	0	4	1
Reporting countries	126	142	143	142	143	141	135	143	127

Source: Global AIDS Response Progress Reporting (WHO/UNICEF/UNAIDS).

6. Feedback and learning

The monitoring system is explained above. Data were collected from dissemination meetings, annual e-surveys with national MoH HIV programme managers, peer reviewed literature and national strategic plans.

No external evaluation of the technical guidelines has so far been conducted.

Annex: Assessing aspects of quality

Basic information about the normative product[74]

Title:	Consolidated Guidelines on the Use of Antiretroviral Drugs
What is the normative product called (guideline/ strategy/ roadmap/ plan etc.?	Guideline
What kind of normative product?	( ) Convention ( ) Regulation ( ) Regulatory recommendations (x) Secretariat Guideline
Thematic area (from WHO Programme budget)	(x) Communicable diseases ( ) Non communicable diseases ( ) Promoting health through the life-course ( ) Health systems ( ) Preparedness, surveillance and response
When was the normative product published?	2013
No of pages main report	228
No of pages incl. annexes	269
Steering group verified/listed[75]	Yes
Development group verified/listed	Yes
Systematic review team verified/listed	Yes
Was a peer review of the draft report completed?	Yes
Does the report explain if, how and by whom the report was approved?	No (?)

[74] All questions are not relevant for all normative products.
[75] This terminology refers to WHO´s Handbook for Guideline Development and may not be relevant for all normative products.

3. Structure and presentation

	1*	2	3	4	5	6	ND*	NR
Does the title of the report reflect the contents and is it well chosen?					**X**			
Is there a clear and adequate presentation of foreword and executive summary?					**X**			
Is there a clear and logical structure to the chapters of the report and to the report as a whole?					**X**			
Is there a sufficient level of subtitles to facilitate reading and understanding?								
Are the titles accurate and reflect the content?					**X**			
Are illustrations and figures used to facilitate reading and understanding?					**X**			
Are tables, boxes and models well designed, clear and accurate?					**X**			
Does the report make use of references and is it appropriately referenced?					**X**			
Are annexes well structured and readable?					**X**			
Is the language of the report precise, varied and interesting, free from technical jargon?				**X**				
Is the report frank, does it address issues squarely and straight on?					**X**			
Is the report written impartially and does it apply different perspectives to issues treated?				**X**				
Have the authors developed the report in creative and innovative ways?						**X**		

Key to the rating of quality indicators:
6 – Yes excellent, very well done
5 – Yes, quite good
4 – Yes, it can pass
3 – Not quite adequate
2 – No, significant problems
1 – No, very poorly done
ND stands for not done at all, that is, cannot be assessed,
NR stands for not relevant – meaning that the question is meaningless in the context of this report.
A slash means that we cannot answer the question.

Formulation and approval

	1	2	3	4	5	6	ND	NR
Was the process for preparing the normative product explained in the report?					X			
Were relevant country authorities consulted?					X			
Were any WHO regional/country offices consulted?					X			
Was data and information gathered data from end-users or target audience?					X			
Does the report refer to relevant literature?					X			
Does the report refer to previous or other relevant normative products?					X			

Description of the problem/rationale

	1	2	3	4	5	6	ND	NR
Are the questions clear and focused?					X			
Does the report interpret and focus the task as defined in the terms of reference?					X			
Is what triggered the preparation of the normative product explained? (Why it was needed.)					X			
Can the informed reader arrive at an understanding of the basic question/rationale for the normative product?					X			

Description of methods

	1	2	3	4	5	6	ND	NR
Is there a section that describes the methodological choices?					**X**			
Is there a discussion of threats to reliability and validity?				**X**				
Can the reader make an independent assessment of the evidence and conclusions?				**X**				
Is there a clear statement of limitations to the conclusions and recommendations?				**X**				

Purpose, audiences and use

	1	2	3	4	5	6	ND	NR
Are the main audiences for the normative product clearly defined?						**X**		
Are the normative product targeted to different audiences?						**X**		
Have the purpose and objectives of the normative product been clearly defined? (What should be achieved).						**X**		
Is the process of developing the normative product made explicit and transparent: can the user see how and why a recommendation was developed, by whom and on what basis?						**X**		
Is the process for developing the normative product explained?						**X**		

Analysis and assessment

	1	2	3	4	5	6	ND	NR
Does the report present empirical material?					**X**			
Is the analysis relating to the questions exhaustive and complete?				**X**				
Are findings and conclusions supported by the data?					**X**			
Are there any clear success indicators and targets?					**X**			

Evidence, recommendations and use

	1	2	3	4	5	6	ND	NR
Does the report respond to the questions?					**X**			
Are the conclusions clear and consistent?					**X**			
Were systematic reviews of evidence carried out for each key question?					**X**			
Was the quality of evidence evaluated for each outcome (using GRADE when appropriate)?						**X**		
Do the recommendations follow from the analysis and conclusions?					**X**			
Are the recommendations practical, can they be translated into decisions?						**X**		
Are there recommendations for clearly specified groups of actors?						**X**		

Does the recommendation help the user to make informed decisions?						**X**		
Does the normative product present choices among different interventions?					**X**			
Does the recommendation help the user to select and prioritise across a range of potential interventions?					**X**			
Are the recommendations realistic/achievable within the relevant programme´s work area and budget?					**X**			
Is a process for disseminating and implementing the normative product explained in the report?					**X**			

Holistic assessment of the normative product

	1	2	3	4	5	6
Methodology					**X**	
Presentation					**X**	
Understanding of the need, context and substance of the normative product					**X**	
Innovation and creativity in the process of preparing the normative product						**X**
Depth and quality of the evidence and recommendations provided					**X**	

10. Global Health Sector Strategy on HIV/AIDS

1. Initiation

In May 2011, the Sixty-Fourth World Health Assembly endorsed the global health sector strategy on HIV/AIDS, 2011–2015. The strategy aimed to guide the health sector's response to HIV, including recommended actions at country and global levels, as well as contributions to be made by WHO. Resolution WHA64.14 requested the Director-General to monitor and evaluate progress in implementing that global strategy, and to report on that progress, aligned with the reporting of other United Nations agencies, through the Executive Board, to the Sixty-fifth, Sixty-seventh and Sixty-Ninth World Health Assemblies.

The two overarching goals of the strategy were:

- To achieve universal access to comprehensive HIV prevention, treatment and care.
- To contribute to achieving MDG 6 and other health related goals.

The four targets for 2015 were:

- Reduce new infections: reduce by 50% the percentage of young people aged 15-24 who are infected (compared with a 2009 baseline).
- Eliminate new HIV infections in children: reduce new HIV infections in children by 90% (compared with a 2009 baseline).
- Reduce HIV related mortality: reduce HIV related deaths by 25% (compared to 2009 baseline).
- Reduce tuberculosis related mortality: reduce tuberculosis deaths by 50% (compared with a 2004 baseline).

Strategic directions were defined as:

- Optimize HIV prevention, diagnosis, treatment and outcomes.
- Leverage broader health outcomes through HIV responses.
- Build strong and sustainable systems.
- Reduce vulnerability and remove structural barriers to accessing services.

For each of the strategic directions it is defined what is expected to be done by countries and WHO respectively.

In September 2014, the Secretariat initiated a process to develop a draft global health sector strategy on HIV for the period 2016–2021, in combination with the development of the draft global health sector strategies on viral hepatitis and on sexually transmitted infections, respectively. A reason for preparing a new strategy was a need to broaden the strategy – emphasising the movement towards universal access and need for an integrated HIV response within the health sector and to align with the agenda for sustainable development and universal health coverage.

The goal of the strategy on HIV is "to end the AIDS epidemic" as a public health threat by 2030, within the context of ensuring healthy lives and promoting well-being for all at all ages. The strategy provides a framework for WHO and Member States for joint action at the global, regional and country levels. It is based on existing good practices and available evidence on the effectiveness of HIV-related approaches and interventions in the health sector. The strategy (a) reaffirms global goals and targets for the health sector response to HIV, (b) identifies four strategic directions to guide national responses, (c) outlines recommended country actions and WHO's contributions within each strategic direction.

There are five strategic directions:

- Information for focused action (know your epidemic and response).
- Interventions for impact (covering the range of services needed).
- Delivering for equity (covering the populations in need of services).
- Financing for sustainability (covering the financial costs of services).
- Innovation of acceleration (looking towards the future).

The strategy was elaborated to define the health sector's contribution to the broader, multi-sectoral response to HIV outlined in the UNAIDS strategy for 2011-2015.2 Implementation of the WHO strategy will be supported by the WHO Secretariat, in collaboration with UNAIDS and other UNAIDS cosponsors.

2. Design and formulation

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, nongovernmental 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.

The process of developing the draft global health sector strategy on HIV, 2016–2021 was managed together with two other draft health sector strategies for the same period. The universal health coverage framework provided a common structure for the three draft strategies. For the draft strategy on HIV, substantial input was provided by the Secretariat, in particular from areas with involvement in HIV-related activities, and from all regional offices and some country offices. The process was enhanced by input from the WHO civil society reference group on HIV and the WHO Scientific and Technical Advisory Committee on HIV.

Ensuring alignment and coordination with the UNAIDS strategy for 2011-2015, Getting to Zero, was underscored in WHO's strategy. The UNAIDS strategy provides the multisectoral framework for the response of the ten cosponsors and secretariat to the HIV pandemic. In addition to setting the agenda for HIV programmes, the WHO strategy aims to maximize the synergies between HIV and other health programmes to achieve the health-related Millennium Development Goals.

3. Quality assurance and quality

The HIV/AIDS Department does not consider the strategies as normative products – setting norms and standards for the HIV/AIDS response such as in 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.

4. Dissemination

There is a section in the strategy explaining how the WHO Secretariat will organise itself to support implementation of the strategy. It also outlines how the health sector response dovetails with other sectoral responses and partners, and how the implementation of the strategy will be

monitored and reported. The survey response from stakeholders and partners was limited, but it appears that the strategies are not well known beyond WHO´s HIV/Aids Department[76].

The strategies and in particular the most recent (2016 – 2021) are informative and well written documents providing a broad overview of the epidemic and guidelines, directions and targets for the health sector response to HIV/AIDS. However, people interviewed commented that the target groups for the strategies are not clear. It appears primarly as a WHO strategy – an effort to articulate what WHO want to achieve more than a strategy for guiding countries´ response to HIV/AIDS. The objectives and strategic directions are broad (with few if any delimitations) and of limited relevance to health sector planning.

5. Relevance and results

According to the requirements, 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".*

The report was supposed to be on the implementation of the global health sector strategy on HIV/AIDS, but includes mainly information on declining infections and deaths, expanded coverage of services etc., based on the assumption that such changes can be attributed to the global strategy. It is relevant to report on trends in the global pandemic, but it could have been more relevant to also include progress and achievements for more operational indicators – more directly linked to WHO performance and efforts.

However, the brief report to WHA is based on annual comprehensive annual report on the global health sector response to HIV providing detailed global and country specific information on the various parts of the strategy.

Accountability

The WHA Resolution 64.14 has the following formulations (referring to the 2011-15 strategy):

- Endorses the global health sector strategy on HIV/AIDS,
- welcomes the alignment of the global health sector strategy on HIV/AIDS with other strategies,
- urges the Member States to adopt and implement the strategy, and
- requests the Director General to give adequate support for the implementation of the strategy and report on the progress to the newt WHAs.

There are as such no formal accountability mechanisms for the implementation of the strategy. However, a strategy can set global targets which member states commit themselves to – which in principle is a commitment to a set of shared goals. The follow up and reporting would also have information on to what extent countries have met the goals. However, the reporting is not used deliberately to rate and compare ("name and shame") individual countries. When the

[76] Except for staff interviewed in UNAIDS.

strategy is adopted by the World Health Assembly it has potentially more authority as it represents an unanimous support by member states.

6. Feedback and learning

The strategy explains that the implementation of the strategy will be monitored using existing mechanisms (2011-2015 strategy):

(a) At the global level, regular reviews are planned to assess progress on the commitments and targets established in the United Nations Declaration of Commitment on HIV/AIDS, Political Declaration on HIV/AIDS and Millennium Development Goals. These reviews will build on the data received from countries through the reporting framework set by the United Nations General Assembly Special Session on HIV/AIDS and other monitoring and evaluation mechanisms.

(b) Monitoring and evaluating the response at country level. Progress in implementing the health-sector response to HIV should be assessed with indicators on availability, coverage outcome and impact, taking into consideration recommendations by the United Nations General Assembly for monitoring implementation in its Declaration of Commitment on HIV/AIDS. Progress towards the HIV-related Millennium Development Goals will be tracked and reported. Numerous indicators are available to support country-level monitoring and reporting in the HIV Indicator Registry.

UNAIDS – Joint Programme Monitoring System

The progress reports: Global Health Sector response to HIV, 2000-2015 and Prevent HIV, test and treat all (2016) are high quality reports providing an overview of "Fifteen years of progress in the global HIV response" including both global and country level data and information

The reports are said to depend on data and information from UNAIDS. "The Joint Programme Monitoring System" (JPMS) is the tool to collect reporting on implementation by UNAIDS, and is based on the indicators in UBRAF. The JPMS is the vehicle to allow the Joint Programme to report together in a structured and transparent way.

Within the JPMS, there are four levels of reporting: each individual country, region, organisation (from HQ) or thematic group (globally), which works with their own template to list results. Each template has multiple forms to list different aspects of implementation, for example by different UBRAF outputs, related indicators or outcomes. The focal point for each template is responsible for ensuring that it is completed and that there is consensus on the reporting.

Focal points are as follows:

- Country: UNAIDS Country Director/Coordinator or their designate.
- Region: Designate of UNAIDS Regional Director.
- Global organization (HQ): Global Coordinator or designated Focal Point.
- Thematic group: Coordinator(s)/ Convenor(s) of group.

The reporting should be – and to some extent is – validated through multi-stakeholder reviews at country, regional and global level. The key objective is to demonstrate as clearly as possible how UNAIDS has contributed to responding to the AIDS epidemic and made a difference.

So far, however, the JPMS is basically a self-reporting tool for UNAIDS – how UNAIDS staff and stakeholders assess aspects of performance. There is a review of data quality, but no systematic and critical validation of data. UNAIDS recognises that this approach is "inherently subjective, but represents the Joint Programme´s best efforts to capture credible and high quality data" (PCB Report July 2014). The indicators are not the only data source for reporting. They are meant to be combined with other sources such as narrative and financial reporting and more in depth assessments and evaluations. (Kruse (2014). Review of UBRAF. UNAIDS Unified Budget, Results and Accountability Framework.)

ANNEX 2: PEOPLE MET AND/OR INTERVIEWED

(Link to case in parenthesis)
Adair-Rohani, Department of Public Health, Environmental and Social Determinants of Health, WHO) (Indoor air guideline)
Ainali, Aikaterini, Programme Officer, Nutrition for Health and Development (Nutrition)
Ball, Andrew, Senior Advisor, WHO´s HIV/AIDS Department (HIV/AIDS)
Balocco, Rafaella, Group Lead, International Nonproprietary Names (INN)
Borghi, Elaine, Statistician, Growth assessment and surveillance
Branca, Francesco, Director, Nutrition for Health and Development (Nutrition)
Campbell, Jim, Director of Health Workforce Department (Global Code)
Chisholm, Daniel, Health Systems Adviser in the Department of Mental Health and Substance Abuse (Mental health)
Chamla, Dick, UNICEF New York
Dhillon, Ibadat, Health Workforce, WHO, Geneva (Global Code)
Doherty, Meg, Coordinator, HIV Treatment and Care Unit, Department of HIV/AIDS (HIV/AIDS)
Dora, Carlos, Interventions for Health Environments
Engels, Dirk , Director, Control of Neglected Tropical Diseases (NTDs)
Engesveen, Kaia, Technical Officer, Nutrition Policy and Scientific Advice (Nutrition)
Gray, Andy, Senior Lecturer, University of Kwa Zulu Natal, South Africa (Essential Medicine List)
Granziera, Egle, Legal Adviser, WHO
Holland, Patience, Operations Manager, British Pharmacopoeia and Laboratory Services. (INN)
Kawar, Rania T. – Health Workforce, WHO, Geneva (Global Code)
Kazuaki Miyagishima, Department of Food Safety and Zonooses (Codex)
Kestel, Dévora, Unit Chief, Mental Health and Substance Use Pan American Health Organization (PAHO/WHO) (Mental health)
Kiragu, Gikonyo Karusa, Senior Maternal and Child Health Advisor, UNAIDS
Kunjumen, Teena, Health Workforce, WHO, Geneva (Global Code)
Lachat, Antoinette, Sr Trademark Specialist I&D, Novartis Pharma AG (INN)
Lasseur, Sophie, Technologies Standards and Norms, WHO (INN)
Low-Beer, Daniel, Coordinator Strategic Information and Planning, Department of HIV/AIDS
Magrini, Nicola, Scientist, Essential Medicines and Health Products (Essential medicine list)
Miyagishima, Kazuaki, Director, Department of Food Safety and Zonooses (Codex)
Møgedal, Sigrun, previous MFA Norway (Global Code)
Mulholland, Catherine, Administrator, Codex Trust Fund
Neira, Maria, Director, Public Health, Environmental and Social Determinants
Nishida, Chizuru, Coordinator, Nutrition Policy and Scientific Advice(Nutrition)
Passarelli, Carlos, Senior Expert Treatment, UNAIDS
Raffaella G. Balocco Matavelli, Group Lead, Department of Essential Medicines and Health Products
Saxena, Shekhar, Director of the Department of Mental Health and Substance Abuse (Mental health)
Tangcharoensathien, Viroj, Ministry of Health, Thailand (Global Code)
Tritscher, Angelika, Coordinator, Department of Food Safety and Zonooses (Codex)
Vaidyanathan, Ramakrishnan, Neglected Tropical Diseases (NTDs)
Verger, Philippe, Scientist, Food Safety and Zonooses (Codex)

Survey questionnaires sent to:
Stakeholders related to "Comprehensive Implementation Plan on Maternal, Infant and Young Child Nutrition":
Al-Jawaldeh, Ayoub (EMRO)
Bekele, Hana (Zimbabwe AFRO)
Da Silva Gomes, Fabio (AMRO)
Diaz, Adrian (Ecuador – AMRO)

De Silva, Padmini Angela (SEARO)
Dominguez, Elisa (Burkina Faso AFRO)
Engelhardt, Katrin (WPRO)
Irianto, Sugeng Eko (Indonesia – SEARO)
Onyango, Adelhid (AFRO)
Rodrigues da Silva Breda Joao (EURO)
Snowdon, Wendy (Fiji and French Polynesia – WPRO):

Stakeholders related to "WHO Guidelines for Indoor Air Quality: Household Fuel Combustion":
Balakrishnan, Kalpana, Professor & Director, WHO Collaborating Center for Occupational and
Bruce, Nigel, Professor of epidemiology, University of Liverpool
Environmental Health, SRU-ICMR Center
Chiang, Raynee, Director of Standards, Technologies and Fuels
Global Alliance for Clean Cookstoves, Chairperson for the ISO cookstove standard development
Foster, Vivien, Leading the Global Tracking Framework for Sustainable Energy for All Initiative
Global Lead (Energy Economics, Markets & Institutions) and Practice Manager, Energy &
Extractives, World Bank
Johnson, Michael, Berkeley Air Monitoring
Mehta, Sumi, Senior Director for Research and Evaluation, The Global Alliance for Clean
Cookstoves
Rosenthal, Joshua, Senior Scientist,Division of Epidemiology and Population Studies
Fogarty International Center, National Institutes of Health
Smith, Kirk, Professor of Public Health, University of California, Berkeley
Vera, Ivan UN Energy, UN DESA

Stakeholders related to "Global Mental Health Action Plan 2013-2020":
Ayuso-Mateos, Jose-Luis Universidad Autonoma de Madrid, Spain (WHO Collaborating Centre)
Eaton, Julian CBM (iNGO)
El Chammay, Rabi Ministry of Public Health, Lebanon
Freeman Melvyn, Ministry of Health, S Africa
Giorgis, Tedla, Ministry of Health, Ethiopia
Herrman, Helen World Psychiatric Association
Ivbijaro, Gabriel, World Federation for Mental Health (WFMH)
Morgan Ellen, Grand Challenges Canada (Donor)
Ndyanabangi, Sheila Ministry of Health, Uganda
Patel, Vikram Public Health Foundation of India
Ritchie, Pierre International Union of Psychological Science
Thornicroft, Graham King's College London
Weissbecker, Inka, International Medical Corps (iNGO)

WHO staff requested for Skype interview, but no response:
Dr Khalid Saeed, regional advisor, EMRO

Stakeholders related to "Codex Alimentarius":
Boobis, Alan, JECFA and JMPR expert (served as chair several times)
Delen, Marie-Ange, Donor representative to the Advisory Group of the Codex Trust Fund
Fazil, Aamir, JEMRA expert
Heilandt, Tom, Codex Secretary
Kruse, Hilde, Former WHO Food Safety Advisor at EURO and member of the Codex Trust Fund
Coordinating Group
Lipp, Markus, FAO senior officer for scientific advice
Ochieng-Pernet, Awilo, Elected Codex Chairperson (2014-2017) and former Vice Chairperson
(2011-2014), former chair of CCNMW

Reilly, Alan, former WHO staff member, former CEO of Food Safety Authority of Ireland
Tsujiyama, Yayoi, Senior Counsellor and secretary to the WTO SPS Committee (since 2015)

Stakeholders related to "Accelerating work to overcome the global impact of neglected tropical diseases- a Roadmap for implementation":

HQ Coordinators/Team leaders and NTD focal points in Regional offices:
Abela-Ridder, Bernadette
Abeyasinghe, Rabindra Romauld
Atta, Hoda Youssef
Biswas, Gautam
Castellanos, Luis G
Dagne, Daniel Argaw
Robalo Correia E Silva, Magda
Sarkar, Swarup Kumar

External stakeholders requested for Skype interview - but no response:
Pooley, Thoko, Uniting to Combat NTDs
Jacobson, Julie, Gates Foundation

Stakeholders related to HIV Guidelines and Strategy:
Birx, Deborah, U.S. Global AIDS Coordinator, Office of the Global AIDS Coordinator (PEPFAR)
Bloem, Martin, Nutrition Advisor, WFP
Cayir, Mae, International Civial Servant, UNODC
Castle, Christopher, Chief, Section of Health and Education, UNESCO
Dhaliwal, Mandeep, Director- HIV, Health, and Development, UNDP
Deperthes, Bidia, Senior HIV Technical Advisor, UNFPA
Garcia, Antonio, Programme Analyst, UNDP
Kasonde, Lombe, Health Specialist, World Bank
Kreshchuk, Nadia, Executive Associate, UN Women
Lipponen, Marianna, Programme Officer, Europeaid, European Commission
Martholm Fried, Katarina, Counsellor, Permanent Mission of Sweden to the United Nations Office
Martin, Julia, Chief Operating Officer, PEPFAR
McNeil, Malcolm, Senior Health Adviser, Department for International Development
Milkowski Andrea, Senior Adviser, GIZ
Oduwole, Modupe, Strategic Intervention Adviser, UNAIDS
Petrachkov, Alexandre, Senior Administrator, ILO
Spiegel, Paul, Deputy Director, UNHCR
Stahmer, Ariana, Focal Point for HIV and AIDS, UNESCO
Weidle, Pau, Teamleader, Centers for Disease Control & Prevention
and other International Organizations at Geneva

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ANNEX 4: OVERVIEW OF CASES

	HIV/AIDS strategy	ARV guidelines	Neglected tropical diseases	Mental health	Nutrition	Indoor air quality	Health personnel	Essential medicines	INN	Codex
Initiation										
Reasons/background for normative product?	Mainly internal Changing context	Internal, but revision required	Internal, request from senior management- Need to address the area in an integrated approach	Proposal by MS. Plan developed as a direct consequence of a discussion by WHA	Request from MS	Internal. Perceived need to address the issue	Partly external – later internally driven (MS resolution)	Internal/ external	Internal /extern al	
What kind of normative product?(new/revised /consolidation)	Revised	Consolidation/ new	Based on consolidation of existing material	The action plan builds upon the work of WHO´s mental health gap action programme	Based on previous experience (consolidati on), yet introduces new global targets	New guideline in an area which is not WHO´s traditiona l area of work	New	Continuously updated	Con-tinuous	Continuous
Who proposed? (HQ, member states, RO/CO offices, others)	HQ	HQ	HQ	Member States	Member States	HQ	African MS and others	HQ	Exter-nal	
Needs and demands assessed? (yes/no – systematically/weakly)	No	No	N/A	N/A	Yes, gaps identified in first global policy nutrition review (2009-2010)	N/A	No		No	
Level of demand? (Strong, medium/weak)	Weak	Medium	Strong	Strong	Medium	Strong	Strong	Medium	Strong	Strong
Type of normative instrument?	Strategy	Technical guideline	Roadmap	Action Plan	Implement ation Plan	Technical guideline	Code	Guideline (list)	Guide-line	Code
Approved by	WHA		WHA	WHA	WHA	DG	WHA	DG	DG	Internal

	HIV/AIDS strategy	ARV guidelines	Neglected tropical diseases	Mental health	Nutrition	Indoor air quality	Health personnel	Essential medicines	INN	Codex
Design and formulation			Collective effort, HQ with inputs from RO´s, CO´s	Internal and external wide ranging consultations/ negotiations	Internal& external consul-tation (MS/extern al experts from partner agencies	Internal (HQ) in consul-tation with RO´s/ CO`s&tec hnical experts				
Who led the process? (internal/external team)	Internal	Internal	Mainly internal	Collective effort (internal and external teams)	Mainly internal	Mainly internal	Internal		Internal	
Supportive groups in place? (steering/ development group/external review)	An external steering group that advised on the strategy development and consultation process and on drafts.	Yes	Peer reviews, advice from Strategic and Technical advisory group/working groups for NTD´s	Regional consultations, web consultations, MS and UN agency consultations	Country consultatio ns, external review	Yes, steering group, guideline developm ent group, external review	Yes	Yes	Yes	Yes
Scope of change envisaged	High	Medium	High	High	Medium	Yes	High/complex	Medium	Low	Medium
Level of participation by RO&COs? (high/ medium/ low/none	Medium	High	Medium	High	High	Medium	Low	Low	None	Low

	HIV/AIDS strategy	ARV guidelines	Neglected tropical diseases	Mental health	Nutrition	Indoor air quality	Health personnel	Essential medicines	INN	Codex
Process of developing normative product made explicit and transparent? (yes/no/partially)	Partly	Yes	Not in the actual document (in background documents)	Yes, but not in document itself (in background documents)	Yes, but not in document itself (in background documents)	Yes	Yes	Yes	Yes	Yes
Cost of product available? (yes/no)	No	No	No	No	No	No	No	No	Yes	No
Source of funding available? (only internal/ external/ combination)	No	Yes	Funding to develop the roadmap was met from WHO budgets	"The plan was developed within the existing (and very limited) resources of the Department	N/A	Yes, external funding	Yes	Internal	Yes	Yes - core funding plus voluntary contributions
Quality assurance and quality										
QA procedures and systems in place? (yes/no/partially)	No	Yes	Partially	Yes	Yes	Yes	No	Yes	Yes	Yes
Quality of format/design? (very good/good/medium/poor)	Good	Very good	Good	Good	Good	Good	Poor	Not applicable	Not applicable	Good
Quality of reader/user friendliness? (very good/good/medium/poor)	Good	Very good	Good	Very Good	Very good	Good	Poor	Not applicable	Not applicable	Good
Solidity of scientific evidence presented? (very good/good/medium/poor)	Good/medium	Very good	Good	Good	Good	Very good	Good	High	High	High
Dissemination										
Plans for dissemination and use in place? (yes/no/partially)	Partly	Yes	Yes	Yes	Yes	Partially	Yes	Yes	Yes	Yes
Evidence of presentations/introductions? (yes/no/to some extent)	To some extent	Yes	Yes	Yes	Yes	Yes	Yes		Yes	

	HIV/AIDS strategy	ARV guidelines	Neglected tropical diseases	Mental health	Nutrition	Indoor air quality	Health personnel	Essential medicines	INN	Codex
Level of technical assistance provided from WHO? (high/medium/low/none)	Low	Medium	Medium	High/medium	High/medium	High/medium	Medium	Low	None	Medium
How disseminated? (printed/electronically/both)	All	All	Both	Both	Both	Both	All	All	All	Both
Evidence that product is available and known in countries (yes/no/to some extent)?	To some extent	Yes	Yes	To some extent	To some extent	To some extent	Yes	Yes	Yes	Yes
Involvement of RO and COs in dissemination (yes/no/limited)?		High	N/A	Yes	Yes	Yes, regional(technical workshops	Mixed RO very much, high level 2nd round reporting	No	No	Low
Relevance and results										
Evidence of relevance to country needs (yes/no/to some extent)?	To some extent	High	Yes	Yes	Yes	Yes	High	High	High	High
Evidence of adjustment and adaptation to country contexts (yes/no/to some extent)?	No	To some extent	Yes	Yes	Yes	To some extent	Yes	Not relevant	Not relevant	Yes
Evidence of results (incorporation in health policy&practices)? (yes/no/to some extent)	To some extent	Yes	Yes	Yes	Yes	To some extent	Yes	Yes	Yes	Yes
Feedback and learning										
Data/information from monitoring implementation and results available.	No from implementation	Yes	Yes	Yes	Yes	Yes, but less on country level thus far	Yes	No	No	Yes
Evaluations carried out (yes/no)?	No	No	No	No	No	No	Yes (Expert Adsvisory Group)	No	No	Yes