People's HealthMovement

Background and Commentary on Items before EB148 January 2021

This analysis and commentary on items coming before the WHO Executive Board in Jan 2021 has been prepared by the People's Health Movement as a contribution to WHO Watch, a civil society initiative directed to the democratisation of global health governance (more about WHO Watch).

The Commentary is produced through PHM's team of policy analysts in consultation with a global network of consultants. This version (v2, 21 Jan 2021) includes new comments on Items 6, 13, and 14.4.

This PDF version of the PHM Analysis and Commentary is taken from the PHM Tracker page for EB148. Comment and feedback are welcome; likewise offers of assistance. Write to editor@phmovement.org.

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5. Global Action on Patient Safety

In focus

The Secretariat advises:

> Patient safety is a growing global challenge and is a prerequisite for strengthening health care systems and making progress towards effective universal health coverage under Sustainable Development Goal 3. In response to the request in resolution WHA72.6 (2019), the Director-General will submit a draft global patient safety action plan. The report (EB148/6) will outline the purpose, vision, guiding principles, framework for action with strategic objectives, and the global patient safety targets. The Board will be invited to consider a draft decision recommending that the Seventy-fourth World Health Assembly endorse the global action plan.

Background

Global Patient Safety Action Plan 2021–2030 Towards Eliminating Avoidable Harm in Health Care (2nd draft, Nov 2020)

Previous discussions of patient safety in particular, see PHM comment on Item 12.5 at WHA72.

Notwithstanding the emphasis on the World Alliance on Patient Safety, in the draft action plan there is virtually nothing on the WHO website about who the allies are.

PHM Comment

Patient safety is a critical objective for health systems and the draft Global Patient Safety Action Plan 2021–2030 Towards Eliminating Avoidable Harm in Health Care provides a very polished account of contemporary thinking regarding patient safety.

However, the draft plan completely separates patient safety from wider issues of quality, efficiency and resource allocation. The pursuit of patient safety in the context of health system strengthening cannot be separated from all of the other objectives and functions of patient care, management, planning and governance. The focus on patient safety as something quite separate from quality of care is perplexing.

Globally, the single biggest risk to people who are vulnerable, sick or injured arises from the lack of health system resources, or lack of access to resources because of financial or other barriers.

In resource limited settings it is critically important to use available resources in the most efficient way so that they reach as far as possible.

Maximising the health benefits from health care, particularly in low income settings, depends on action to measure and improve the efficiency with which health care resources are used. Efficiency is inextricably tied to quality (including safety) in that it is quality care which produces those outcomes. Among the various threats to quality and efficiency are:

- Overuse and inappropriate use of medication, including overuse driven by rampant unregulated marketing;
- Lack of access to medicines and vaccines because of prices or failure to invest in research;
- Unregulated and unaccountable private medical practice including private primary care and private hospital practice, including procedural over servicing (and underservicing in low income settings);
- Distributional inefficiencies, eg clustering of private providers in (relatively) wealthy districts;
- Lack of system wide coordination of facilities and resources resulting in chaotic and fragmented care journeys for patients.

The vision proposed for the proposed Global Action Plan makes no reference to quality of care or system wide efficiency.

PHM has no doubt that the accountability of practitioners, managers and planners for rigorously operationalising the principles of patient safety, as set out in the Global Action Plan. However, such systems of accountability and continuous improvement must be integrated in system wide clinical governance frameworks. The draft Action Plan provides an excellent account of the risks of harm and the principles of patient safety but it treats patient safety in isolation rather than presenting it within the context of high quality and efficient health care systems and the health systems strengthening needed to achieve such systems.

WHO's fact sheet on quality of care states that quality health services should be:

- **effective** by providing evidence-based health care services to those who need them;
- **safe** by avoiding harm to the people for whom the care is intended;
- **people-centred** by providing care that responds to individual preferences, needs and values, within health services that are organized around the needs of people;
- **timely** by reducing waiting times and sometimes harmful delays for both those who receive and those who give care;
- **equitable** by providing the same quality of care regardless of age, sex, gender, race, ethnicity, geographic location, religion, socio-economic status, linguistic or political affiliation;
- **integrated** by providing care that is coordinated across levels and providers and makes available the full range of health services throughout the life course; and
- **efficient** by maximizing the benefit of available resources and avoiding waste.

According to this definition, patient safety is but one of seven features which characterise quality health care.

Why is WHO privileging and separating out patient safety and implicitly discounting effectiveness, people-centredness, timeliness, equity, integration and efficiency?

Who is funding WHO's proposed Global Action Plan on Patient Safety?

It is notorious that WHO's core funding is only just sufficient to keep the lights on. The Programme Budget Portal shows that assessed contributions provide just 14% of the Headquarters cost of Output 1.1 'Improved access to quality essential health services' which presumably includes patient safety) so any extra programmatic activity (such as a Global Patient Safety Action Plan) depends on donor funding.

The bulk of funding for Output 1.1 comes from the US and the Gates Foundation. However, private sector entities are also contributing and have so far (in the present biennium) contributed just under $5m to Headquarters activities under Output 1.1, including contributions from Sanofi-Aventis, Gilead, Novartis, GSK, Merck, Bayer, J&J and BMS.

The fierce opposition of Pharma to many of WHO's programs is well known. Pharma opposed the Essential Medicines List, the rational use of medicines initiative (RUM), resolution WHA41.17 on Ethical Criteria for Medicinal Drug Promotion, and more recently the proposed C-TAP initiative. Perhaps Pharma is more supportive of patient safety, separated out from quality and efficiency.

There are no references in EB148/6 to evidence-based medicine or clinical practice guidelines; indeed the only reference to clinical practice guidelines in the draft Global Plan is in the context of criticising pre-occupation with such guidelines in health professional education as contributing to the neglect of patient safety (page41).

Positioning pharma as patient friendly has been a significant plank in pharma marketing and public relations. Pharma provides significant financial support to IAPO (the International Association of Patients' Organisations) and directly to many of the 'patients' organisations' within the IAPO umbrella.

PHM asks:

Who is funding the proposed global action plan? Has the DG ensured that all significant conflicts of interest have been properly disclosed and managed?

6. Political Declaration of 3rd HLM of UNGA on NCDs

In focus

The Secretariat advises:

> A report will be submitted (EB148/7) in response to the request in decision WHA72(11) (2019) to the Director-General "to consolidate reporting on the progress achieved in the prevention and control of noncommunicable diseases and the promotion of mental health with an annual report …, annexing reports on implementation of relevant resolutions, action plans and strategies, in line with existing reporting mandates and timelines".
>
> The report will also include the biennial report on the implementation of the commitments made in the Rome Declaration on Nutrition, adopted at the Second International Conference on Nutrition (2014). The Board will be invited to note the report and its annexes, adopt the proposed updates to the appendices of WHO's comprehensive mental health action plan 2013–2030, and provide guidance on the continued relevance of WHO's global action plan for the prevention and control of noncommunicable diseases 2013–2020 and the global coordination mechanism on the prevention and control of noncommunicable diseases. In this exercise, the Board will be able to take into account the outcomes of two evaluations, the executive summaries of which will be submitted by the Evaluation Office in separate reports (EB148/7 Add.1 and EB148/7 Add.2.
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> Oral health
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> At the recommendation of the Officers of the Executive Board, the Director-General will submit a report outlining the challenges to global public health posed by oral diseases, recent oral health activities of the Secretariat, and actions towards better oral health by 2030 as part of the work on noncommunicable diseases and universal health coverage. The Board will be invited to note the report (in EB148/8) and provide guidance on the way forward.

Background

Recent governing body discussions of NCDs

Previous reports on implementation of ICN2

Secretariat topic page on NCDs

Secretariat topic page on oral health

PHM Comment

Oral health

PHM appreciates the analysis provided in EB148/8. We look forward to the Global Oral Health Report and we particularly support the inclusion of health taxes or bans on the sale and advertisement of unhealthy products and counteracting the underlying commercial interests that drive key risks. However, PHM is perplexed by the faith being shown in the 'integration strategy' and the common risk factor approach. It is unlikely that somehow oral health will magically benefit from being mentioned whenever NCDs are mentioned. The current approach fails to address the real reasons for neglect and we strongly urge the WHO to highlight the specific policy challenges associated with oral health.

PHM regrets the unproblematic identification of oral health as part of universal health cover, including the references to 'benefit packages' suggesting that a subset of services will be purchased by the State from private providers and families will face user charges for the rest. This reliance on the private sector for oral health services will reproduce dentist-centered health care models, ignore prevention, and exacerbate existing inequalities in access to decent oral health care. PHM urges the Secretariat to rethink this extremely backward policy and instead present a clear positioning of oral health care within a primary health care model, supported by publicly funded and administered specialist services.

PHM regrets the inadequate inclusion of workforce issues in the listing of oral health priorities. The reference in para 12 is weak and there is no emphasis on workforce issues in the listing of WHO priorities in para 22 or policy opportunities in para 23.

PHM cautions WHO against the dependence upon digital health technologies for surveillance and service provision under the Global Oral Health Programme (para 22). These technologies remain unfeasible in many parts of the world, and continued reliance on these will exacerbate oral health inequities between and within countries, resulting in worse oral health among marginalized and underserved communities. Instead, PHM urges the Secretariat to support the demonstration of community-based oral health models that depend upon community health workers and integration with existing programs that cover the most vulnerable populations.

Within the realm of oral health, diseases such as fluorosis garner little attention, despite the considerable burden in parts of the world. In addition to sugar consumption, tobacco usage, and poor hygiene, it is worth noting that malnutrition and inadequate access to clean, potable water are significant social determinants of oral health. These determinants provide a valuable avenue for action on multisectoral and systemic action for oral health. PHM urges the Secretariat to explicitly recognise these determinants and direct concerted actions on these fronts.

In para 9, the report speaks of the 'continued low priority accorded to oral health'. In fact, it is not oral health that is neglected; it is low income and marginalized people who are neglected. PHM urges Board members to recognize how the culture and economics of neoliberal globalization are driving increased political and economic inequality and loss of solidarity. We

note the references to social and commercial determinants but these references appear focused solely on behavioral risk factors and their 'underlying social and commercial determinants' (para 6). It is time WHO addressed directly the geopolitical and macroeconomic determinants of political and economic inequality and marginalization, including neoliberal globalization.

1. Oral health services, whatever exist, have been drastically affected during the Covid-19 pandemic due to travel restrictions and lockdowns
2. Note that the general recommendation for availability of dentists is 1:7500, which is a distant dream for practically all of the low and middle income countries, given some concentrations in urban higher-income areas.

Non-communicable Diseases

The data presented in EB148/7 confirm that the disease burden of NCDs is huge. The human cost in terms of morbidity, disability and premature mortality is likewise huge. The economic balance sheet is more complicated. For the industries driving the NCDs epidemic (tobacco, alcohol, junk food, passive transport, etc), the morbidity upon which their profits depend is dismissed as personal choice. However, health care, including the supply industries, provides employment to many and profits to a few. Whether health care expenditure on NCDs is a cost or a market opportunity depends on perspective. PHM takes the view that the human burden and the opportunity costs of the NCD industries (precluding better uses of resources) demand action.

The burden of mal(under)nutrition is likewise huge although for the economic forces whose security depends on widening inequality and deepening poverty and for the industries whose practices drive hunger, the human costs of malnutrition are simply collateral damage.

Important though NCDs are, they need to be seen in context, alongside global warming, biodiversity loss, and the human suffering associated with widening inequality and alienation. Fortunately there are powerful synergies which could be leveraged from strategies directed to addressing these existential challenges facing humanity and also overcoming the drivers of NCDs and malnutrition.

These synergies include:

- transport planning and investment directed to reducing carbon pollution and encouraging active transport and physical activity;
- radical reduction in meat consumption in the rich world and rich classes with impacts on global warming, biodiversity conservation and fresh water conservation as well as impacting on obesity and cardiovascular disease;
- reform of food systems, globally and nationally, to wrest control from the transnational food and supermarket corporations so that farming can move to national and local food sovereignty based on wider spread but smaller scale agroecology - while also reducing the pressures of cheap junk food on people's diets.

These synergies have been recognised in WHO resolutions and in high level political declarations at the UN General Assembly (although there is little in the reports before the Board

which reports action on the synergies). The world needs a much more proactive approach from WHO through vigorous intersectoral advocacy and inspirational leadership. It is exactly such leadership that the donor chokehold is designed to preempt.

It is most unfortunate that WHO has retreated from the radical principles of the original Alma-Ata Declaration on Primary Health Care which highlighted the role of primary health care practitioners in working with their communities to address the structural causes of illness as well as providing health care.

Instead WHO has been forced to adopt the World Bank's model of 'universal health cover' through a mixed service delivery model supported by competitive health insurance markets offering 'benefit packages' for essential services (and out of pocket payment for the rest). This health system model precludes community engagement as part of primary health care and precludes community action around the structural causes of illness.

The tools and guidelines being promoted by WHO (see Table 4 in EB148/7) are important resources for addressing NCDs, prevention and care. However, there is no emphasis in this package on looking for the synergies between the existential challenges (global warming, biodiversity and inequality) and addressing the more immediate commercial, political and economic determinants of health.

Even so the number of WHO staff, in particular in country offices and working on NCDs, is far too few to have the impact which is needed. The gross underfunding of WHO is a major constraint on global aspirations to reduce the burdens of NCDs (see EB148/7 Add.1). Perhaps this is also intentional.

Further, para 34 of EB148/7 advises that,

> *Bilateral donors have not shown increased appetite for funding activities specifically earmarked as addressing NCDs to establish even the minimal critical capacity, mechanisms and mandates needed in low- and middle-income countries to pursue change. In the absence of such funding, groups with economic, market and commercial interests stepped up their efforts to lobby against implementation of interventions by WHO, discrediting WHO's scientific knowledge, available evidence and reviews of international experience, and bringing legal challenges against countries to oppose progress.*

Building stronger community engagement around NCDs and the existential synergies noted above is critical to achieve both and comprehensive PHC is a critical step towards this. Stronger community engagement also has the potential to increase the political pressure on governments and donors to properly fund WHO (adequate in total, lift the freeze on ACs, untie donor funds) so it can do its job.

PHM appreciates the work done through the Inter Agency Taskforce on multisectoral action but it needs to be matched by community engagement directed to building a political constituency to drive such reforms.

The individual behaviourist focus of the ‘concrete guidance to strengthen health literacy’ provided in Annex 6 is a lost opportunity. As argued above, any such initiatives must ensure that literacy regarding individual risk and behaviour is matched with literacy regarding the structural reforms needed to address the commercial, political and economic determination of health.

PHM appreciates the recognition in Annex 7 (to EB148/7) of the need for multisectoral action for the prevention and control of NCDs. However, the commitment to analyse possible approaches is now over ten years old and still has not been fulfilled; owing, we are told in para 2 to lack of resources. This is truly an indictment of the donor chokehold.

7. Access to effective treatments for cancers and rare and orphan diseases and market transparency

In focus

The Secretariat advises:

> At the recommendation of the Officers of the Executive Board in 2019, and pursuant to the following resolutions, the Director-General has prepared EB148/9 which reports (Part A) on progress in implementing WHA70.12 (2017) regarding access to health products for rare and orphan diseases, and (Part B) on implementing the market transparency resolution WHA72.8 (2019).
>
> The Board is invited to note the progress made and to provide further guidance on optimizing access to cell- and gene-based therapeutics and other health products for rare and orphan diseases.

Background

See the commentary by Thiru on KEI OnLine (21 Dec 2020) here for the background into Part A of EB148/9. Thiru notes the absence from EB148/9 of any response to the 2019 request by South Africa for WHO to "discuss the role of the public sector and charities in funding research for new cell and gene therapies, and measures to promote more transparency of the licensing of intellectual property rights from public sector research, and concrete measures in licenses to address the objective of universal access."

Thiru notes that EB148/9 does not fully address the issues raised by Peru in relation to the availability and affordability of medicines for rare and orphan diseases.

Recent GB discussions of medicines, including access

Secretariat topic page for Medicines

For more on cell and gene based therapies see

- Dunbar et al (2018) Gene therapy comes of age;
- Shah et al (2018) Multi-targeted CAR-T Cell Therapies for B-Cell Malignancies
- Jin et al (2019) Stem cell therapies for acute spinal cord injury in humans: a review

PHM Comment

Part A. Access to safe, effective, quality-assured and affordable health products for cancer and rare and orphan diseases

The paper sets out the problem clearly: *'Despite recent advances, access to safe, appropriate, effective and quality-assured health products remains a global concern'*. The paper mentions a range of barriers to access, focusing largely on domestic health system issues (but not mentioning intellectual property barriers).

The paper then elaborates on some particular challenges including vaccines (hepatitis B and HPV), rare diseases with and without treatments, particularly expensive therapies (including cell therapies, gene therapies and cell-based gene therapies), medical devices, diagnostics and assistive products.

The paper then describes what the WHO Secretariat is doing in a range of related fields. The paper does not provide a comprehensive analysis of the barriers to access nor the range of structural reforms which might be needed to address these barriers. The focus is on what the Secretariat is doing. Even under the heading, 'The way forward', the focus remains on what the Secretariat will do.

The exception is para 22 which calls for *'more collaborative work … to shape research, innovation and development with a view to encouraging the development of affordable solutions for low- and middle-income primary health care settings for the management of cancer, other noncommunicable diseases such as diabetes, and rare and orphan diseases'*.

The field which this paper addresses is vast; a wide variety of technologies including vaccines, medicines, medical devices, in vitro diagnostics and assistive products all with complex value chains from conception to utlisation. Assuring affordable equitable access requires policy interventions and structural reforms at all stages in these value chains including research, patenting and IP protection, production, pricing, regulation, health systems, procurement, and health care financing.

The configuration of these value chains, through which access is shaped, varies widely across different products, institutional settings and countries. Nevertheless we can identify, in general, some of the main barriers and possible solutions at different points across the chain.

Research, research capacity and research funding

More research funding is required, with funding redistributed to conduct research into developing interventions to neglected diseases which disproportionately impact LMICs and therefore hold smaller financial incentives for pharmaceutical companies. An R&D binding convention proposed in 2013 to ensure sustainable financing and equitable access would serve as an effective mechanism to address this issue and should be discussed by MS and WHO

further (read more here). This should also be complemented by the R&D Observatory as per the original proposal of the CEWG.

Research funding should be delinked from IP protection and monopoly pricing. This can be implemented by research funding sponsors, including public research councils whereby a funding requirement would be for the recipient to have a global access plan, for example to retain their IP rights or pursue non-exclusive licensing.

Development partnerships and technology transfer can serve as mechanisms to facilitate the strengthening of research and innovation capacity in LMICs. This can also serve to increase clinical trials conducted in LMICs which are often neglected even in treatments for diseases with high burden.

Patenting and IP

Open innovation refers to the sharing of patents, design, copyright and technical know-how. It is necessary to allow disseminated local production and continued product development. This will facilitate improved safety and efficacy, cheaper production and lower prices and therefore should be a key recommendation to increase access.

Pricing

By increasing transparency over pharmaceutical pricing thereby showing how much each country pays, it would allow comparison and strengthen countries negotiating leverage, facilitating fairer pricing and better access. This would particularly benefit countries with less negotiating power, and would protect against secret inequitable pricing strategies.

Full use of TRIPS flexibilities would allow more local production of pharmaceuticals, building longer term public sector production capacity thereby circumventing monopoly pricing at a global level and associated price gouging.

Transparency regarding development costs

Pharma and its advocates claim that high prices are necessary to allow for the recovery of huge investments in R&D. However, the costs of drug development are far from transparent and the actual costs borne by Big Pharma are even less so.

Over the last two decades the underlying business model of pharmaceutical development has evolved into a pattern referred to as financialisation. In accordance with this model, the basic research upon which all therapeutics are based is largely publicly funded. Likewise the early development work, more deliberately directed to clinically useful outcomes, generally receives a significant amount of public funding. As a particular line of work shows promise the researchers are encouraged to start up dedicated development enterprises, often with the support of venture capital investors. Some of these startups will fail and the cost of failure will be borne by the principals and investors. However, those startups which show more promise are now acquired by the large pharmaceutical corporations, including their patents, designs and knowhow. Acquisition by Big Pharma adds to stock value and encourages further outside investment.

From this point share price manipulation (including public relations initiatives, stock buybacks, shareholder payouts, and executive bonuses) plays a key role in pharma strategy. Pharmaceutical companies spend more on mergers and acquisitions than in-house 'R&D'.

The argument that high prices are necessary to recoup R&D costs is largely smoke and mirrors with a complete lack of transparency. While the costs of basic research and early development work (including unsuccessful startups) may be significant, under the financialisation paradigm, these costs are not borne by Big Pharma. Rather Big Pharma can wait until the more promising startups emerge, buy them cheaply and then inflate their market value.

The development of health products is expensive and under the logic of the patent system it is appropriate to price the final product at a level which covers *those costs of R&D which were borne by the vendor*. However, while financing of R&D and the distribution of costs remain so untransparent there are firm grounds for concern that market prices set under the protection of patent protection may be too high.

Improving access to expensive therapeutics could be greatly enhanced if unreasonable prices were exposed through greater transparency regarding financing and costs.

Marketing

The dominant narrative justify high prices is to allow recovery of research and development investments by pharmaceutical companies. Yet, companies often spend more on marketing than on R&D. Tighter regulation of such activities would reduce a key 'cost'. One route to achieve this would be for governments to adequately fund independent expert prescribing advice, including through social marketing and academic detailing and directed to both providers and consumers.

Health system strengthening

PHM appreciates the emphasis on the crucial role of primary health care (PHC) in facilitating affordable access to various health products, including for rare and orphan diseases.

Improving access requires a focus on health systems strengthening as well as attention to the development and marketing of pharmaceuticals and other health care products. Key areas to address are pharmaceutical procurement; pooled procurement in which a consortium of hospitals, regions or at national level jointly purchase pharmaceuticals mitigates price gouging and permits stronger negotiating power and thus lower prices.

The public sector should provide healthcare without user charges. The World Bank's model of UHC as comprising mixed service delivery financed through competitive health insurance markets is a recipe for increased costs both for government and for health insurance purchasers.

Regulation system strengthening

Regulatory capacity is critical if the safety and efficacy of novel therapies are to be assured and if their utilisation is appropriately directed.

The harmonisation of regulatory standards has benefits for both the manufacturers and for governments but standard setting needs to be protected from corporate influence variously directed to preventing competition and allowing scope for price inflation.

Ensuring safety and efficacy as well as enhancing access depends on the probity and accountability of the regulators, including standard setting institutions.

Macroeconomic reform

Reform is also needed to address the revenue limitations facing the governments of low and middle income countries. These include low tax small government regimes driven by the international financial institutions (and by investor extortion); the choking of export opportunities in a global economy facing a growing overhang of productive capacity over purchasing capacity; and the loss of social solidarity associated with widening economic inequality.

Key reforms to enhance access to medicines in L&MICs must include addressing the fiscal constraints they face, starting with global tax justice and fair trade.

Part B. Market transparency

EB148/9 provides a useful review of a range of initiatives underway directed to promoting market transparency, including price, patent status, and research, development and production costs.

A key set of initiatives are directed to addressing the legal barriers to publication of prices, including through tying price transparency to marketing approval and legislative reform regarding ‘commercial in confidence’.

These initiatives are commendable. We look forward to hearing updates regarding MS implementation of transparency so that it becomes an embedded legislated norm.

8. GSPoA on PHIIP

In focus

The EB148/10 report has been submitted in response to the request made in WHA73(11) (2020) for a report on the progress made on implementing the decision. The Report also provides the implementation plan for further action on the prioritized recommendations of the review panel established at the request of WHA68.18 (2015) to conduct an overall programme review of the GSPOA PHI.

In the light of para 1 of decision WHA71(9) (2018) member states were also requested to respond to a questionnaire to gather information on the implementation of the recommendations of the review panel which were addressed to the member states. Secretariat has analysed the responses and will publish the findings in a report by end of January, 2021.

Paragraph 5 refers to an informal consultation between the secretariat and Member States on 3 December 2020 to discuss the recommendations of the review panel referred to in paragraph 2 of decision WHA71(9) (2018) as "not emanating from the global strategy and plan of action on public health, innovation and intellectual property" and the "recommendations of the review panel on promoting and monitoring transparency of medicines prices and actions to prevent shortages" (see note on typo by KEI here). Useful KEI piece here summarising the informal consultation report.

Background

The GSPOA was adopted in 2008 to *promote new thinking on innovation and access to medicines and to secure an enhanced and sustainable basis for needs driven essential health research and development relevant to diseases that disproportionately affect developing countries*. (See Tracker links to GSPOA, in particular WHA61 in 2008.)

An 'Overall Program Review' was appointed in 2015 and reported in 2017.

The Assembly's most recent decision on GSPOA (WHA71(9) 2018) followed quite intense debate at EB142 (see M7 and M10) over the recommendations of the expert panel for the Overall Program Review of the GSPOA (summarised in EB142/14 Rev.1) and the draft decision proposed by the Secretariat to "to take forward the recommendations of the review panel" (EB142/14 Add.1).

The US and Switzerland proposed revising the draft decision in EB142/14 Add.1 (supported by Japan), but strongly opposed by many countries (Brazil, Thailand, the Netherlands, Libya, Algeria (on behalf of the member states of the African Region), Sri Lanka, Pakistan, Vietnam, Colombia, the Dominican Republic, Burundi, the United Republic of Tanzania, Benin), who argued that delays to adopting the decision "could be construed as serving to protect the interests of the pharmaceutical industry." Canada, France, Sweden and Italy proposed a drafting group restricted to 'minor' changes as a compromise.

While the drafting group reached a compromise, leaks from delegates participating in the drafting group (see "Member states clash as WHO mulls …") suggested that not everyone was happy with the revised decision, and that it was a pragmatic choice "so as not to risk losing the whole report altogether." The revised decision (EB142(4)) distinguished between recommendations "emanating from the GPSOA" (which were to be implemented) and recommendations "not emanating from the GSPOA" (which were to be further discussed) and was adopted at WHA71 (2018) as (WHA71(9), see four main components, listed above).

In October 2019 the WHO Secretariat circulated a questionnaire for member states to inform the further development of the draft Implementation Plan and the implementation of related resolutions such as WHA72.8 on medicines transparency.

The EB146(10) recommended the WHA73 to urge MS to implement the recommendations of the GSPOA. It called for the secretariat to hold further informal consultations with MS regarding the recommendations of the review panel referred to in paragraph 2 of decision WHA71(9) (the recommendations 'not emanating from the GSPOA' and the promotion and monitoring transparency of medicines prices and actions to prevent shortages. It reiterated the need for sufficient funding to ensure success of the implementation plan and requested an update from the DG including the paragraphic 2 discussions.

This was accepted at WHA73(11) through silent procedure.

See Tracker links to previous documents, debates and decisions on the GSPOA.

- For a prehistory of GSPOA, see PHM comment on EB136 item 10.5 (2015), which discusses the origins and report of the 2006 Commission on IP, Innovation and Public Health and the subsequent debates which led to the GSPOA.

- For a fuller analysis of the Overall Program Review's 2017 report (including its recommendations) and a comparison with the Secretariat's 2016 Comprehensive Evaluation see PHM comment on EB142 item 3.7 (2018).

See Secretariat index page for Medicines: innovation, access and use.

See Medicines and Intellectual Property: 10 Years of the WHO Global Strategy by Germán Velásquez, South Centre Research Paper 100, December 2019 for an insider perspective on the achievements and disappointments of the GSPOA.

Recent GB discussions of the GSPoA

Secretariat topic page on IP and Trade

PHM Comment

We welcome the report identifying the set of actions, indicators and deliverables for realisation of the elements of the GSPOA.

Member state accountability

It may be noted that the implementation plan annexed with the report will have to be read and revised in light of the findings of the Secretariat based on the responses of the member states to the questionnaire related to baseline information on national context of HIP. We look forward to reading the MS updates on their implementation of the GSPOA. However it is disappointing this wasn't made available in time for the EB148 to allow discussion and review, particularly given we are already almost half way into the implementation plan time period.

Promoting research and development

Steps responding to Recommendation 7 merely mirrors the submission of the DG in EB146/15 viz. "*by 2021 all research supported or published by WHO will be available for immediate access*". There is however no update on the extent to which such publication has been successful and the extent to which it has been available to MS. Nor is there information on specific steps taken by WHO secretariat to achieve this.

Improving research capacity

We urge that the efforts for strengthening the collaborative registration processes responding to Recommendation 9 be supplemented by developing pathways supporting public sharing of clinical trial results and any associated public funding for the same.

Innovation sharing and technology transfer

Recommendation 14 featured the next step of the Secretariat to produce a report on mechanisms to facilitate technology transfer. It is promising to read "Key actions to facilitate increased manufacturing capacity, voluntary sharing of intellectual property, data and knowledge, and licensing, for example, through C-TAP, are essential to concretely bring results on implementation of the GSPA-PHI" was highlighted as a key action in the informal consultations held between the secretariat and the MS.

However, this sharing should also include technical know-how and should take a more obligatory framework as per the PIP framework, rather than voluntary. Furthermore, the success of innovation sharing and technology transfer is conditional upon the development of domestic manufacturing capacity which needs to be developed in tandem. We look forward to further discussions and concrete next steps on how this will be implemented by MS.

The steps to be taken in response to Recommendation 17 should include encouraging MS to publish all licenses with member states to support global collective bargaining in demand and prices.

The report, in response to Recommendation 18, suggests working with Medicines Patent Pool (MPP) and other organisations to promote further development of products and access to them. The recommended steps however fail to question the progress made in the five year strategy adopted in May 2018 by the MPP to expand its activities to cover all patented essential medicines, which requires engagement with many new stakeholders (and noted in EB 146/15). Examining progress on this strategy would help better recommend future action on expanding MPP's portfolio.

Delivery and access

In steps to be taken for supporting Recommendation 21 in promoting and monitoring transparency in medicine prices, we urge that in addition to the steps recommended by the report, the DG considers developing a mechanism that allows transparency of R&D costs.

Insufficient funding and approaching deadline

A recognised historical barrier to the successful implementation is insufficient funding. WHA73(11) requested the DG to reiterate the need to 'allocate the necessary resources'. However, MS should untie their funding to mitigate earmarking of fundings, allowing sustainable effective funding of the secretariat's work, including the implementation of the GSPOA implementation plan. The informal consultation summary report stated that USD 16.9 million is required for 2020 - 2022 but it's not clear if this has been fulfilled. The implementation plan is due to expire in 2022 as per the WHA68.18, therefore the DG and MS should consider the extension of the GSPOA beyond this time.

The overarching obstacle to the GSPOA

As we have highlighted in previous discussions of the GSPOA, there is one glaring omission - the paradox of harmonising public health with innovation and intellectual property within a system which is driven by private financial incentives. The full realisation of the vision of the GSPOA would in due course require the disruption of pharmaceutical companies' business model.

9. Antimicrobial Resistance

In focus

The Secretariat advises:

> Pursuant to resolution WHA72.5 (2019), the Director-General will submit a report (EB148/11) that: outlines progress in implementing the global action plan on antimicrobial resistance; provides an update on activities towards achieving the five strategic objectives of the global action plan, on progress in global coordination and tripartite partnership efforts; and highlights the main country-level and global challenges in programme implementation.
>
> The Board will be invited to note the report and provide guidance on accelerating Member States' implementation of national action plans on antimicrobial resistance and on enhancing feedback from health ministries on the process to review the Codex Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance.

Background

AMR, one of the topmost public health problems of our time is being discussed at WHO since EB 134 and can be read here- Recent GB discussions of AMR. AMR has reached UN level discussions, with the first ever High-level Meeting on Antimicrobial Resistance (AMR) in 2016 that led to adoption of "Political declaration of the high-level meeting of the General Assembly on antimicrobial resistance" at the UN. Following the Political Declaration's mandate, the Secretary-General of the United Nations convened an Ad Hoc Interagency Coordination Group (IACG) on Antimicrobial Resistance which submitted its report, following which the UN Secretary-General issuing his report in May 2019. On 14th April, a High-Level Interactive Panel on Anti-microbial Resistance was scheduled to be held on 14 April 2020 at the UN Headquarters in New York but has been postponed due to the global public health emergency (COVID-19).

AMR governance includes the tripartite (including WHO and OIE) and the aims of the collective action of the tripartite including links to their respective works can be accessed here. AMR topic page from WHO can be accessed here- Secretariat topic page on AMR.

PHM Comment

PHM appreciates this report, particularly, in terms of improving the knowledge base for ongoing decision-making. While the report identifies the challenges well, a roadmap to resolve them is missing.

The implementation of NAPs has been slow despite the fact that the Global Action Plans were adopted in 2015. The monitoring indicators are still focused on whether the sources of funding of NAPs have been identified [C-E] or not. The October 2020 TRACSS Report shows that

progress in some areas is very slow. The TRACSS data are self-report and have a strong response bias so the mediocre achievement of Fig 7.4 is particularly worrying, particularly in view of Fig 7.2 and 7.5.

More technical assistance is needed for developing countries to improve their surveillance systems to enrol them in the Global Antimicrobial Resistance and Use Surveillance System (GLASS) as well as on the new SDG indicator 3.d.2.

AMR stewardship needs responsive health systems and better access. The Access-Watch-Reserve (AWaRe) categorization of antibiotics, targets and resources are useful, but the fact that only 34 countries have adopted this in their national essential medicines list is disappointing. **While we expect other countries to adopt AWaRe, we need to recognize that unless we have a baseline data of use, it would be difficult to achieve our targets by 2024.**

Promoting the rational use of drugs and regulating unethical marketing practices, that increase the irrational use of antimicrobials, both need to be emphasized to ensure the success of stewardship programs. **PHM is concerned about the increasing role of Pharma companies in AMR stewardship grants** as has been the case in India and Latin America among others, despite the known fact that the commercial information sources (pharma), instead of independent expert guidelines have a negative impact on stewardship and rational prescription.

Actions against AMR cannot be separated from the economic reforms needed to address the fiscal constraints on LMICs. Despite lower per capita use of antibiotics in LMICs, the higher resistance rates clearly point towards the systemic determinants, such as poor public health spending, sanitation and IPC as extant research prove. The AMR problem undermines progress towards both UHC and SDG.

The ecological and ethical aspects of global meat consumption patterns have direct implications on AMR given the overconsumption of antimicrobials in factory farming. **As the Codex review process draws close, PHM reiterates the position that preventive and growth promotive use of antibiotics in animals is not a therapeutic use.**

The AMR Action Fund is focused on ‘a sustainable antibiotic market’ but not on access and affordability. While the discovery of newer antibiotics is a top priority, WHO needs to introduce measures for access as newer antibiotics are exponentially more expensive than their predecessors.

Given the limitations of AMR Action Fund on affordability as well as narrow focus on late stage molecules, creating prospects for a public sector-led Impact Investment Fund is a pressing need.

The tripartite approach is necessary. However, given the difference in country-wide presence of these organizations, WHO should reach out more actively to all relevant civil society sectors across the sectors at the domestic level through its country offices.

CSOs have a critical role in the campaign against AMR as they can mobilize public opinion, strengthen transnational advocacy to prioritize AMR and provide insight on actions at the community level to balance adaptive and technical regulations. For more, see this South Centre paper "How Civil Society Action can Contribute to Combating Antimicrobial Resistance", is an important read.

12 Immunization agenda

In focus

In the Annotated Agenda the Secretariat advises:

> Following the request in decision WHA73(9) (2020), the Director-General will submit a report (EB148/14) on the finalization of the operational elements outlined in the Immunization Agenda 2030. The Board will be invited to note the report and to provide guidance on the proposed frameworks for ownership and accountability, for monitoring and evaluation and preparations for implementation.
>
> Besides noting and making general recommendations, the EB is especially invited to provide suggestions for indicators. See also the November 2020 Briefing Paper (Implementing the Immunisation Agenda 2020).

Background

See Tracker links to previous discussions of vaccines and immunisation.

See WHO Secretariat page on Vaccines and Immunisation

PHM Comment

PHM urges that member states and the Secretariat give close attention to the following issues in finalising ownership and accountability, monitoring and evaluation, and implementation plans.

Managing power imbalances in partnerships: affirming national sovereignty (relevant to ownership and implementation)

Immunisation Agenda 2030 rightly emphasises country ownership of immunisation programs and the importance of partnerships in implementation. However it does not consider the power imbalances that characterise relationships between governments of the Global South and the financially and politically influential partners (such as Gavi or the Bill & Melinda Gates Foundation) that finance and support immunisation campaigns.

These imbalances in power and resources potentially limit the realisation of country ownership. For example, in the past GAVI and WHO have been criticised for pressuring L&MICs to add new and expensive vaccines to their schedule without appropriate opportunity cost considerations.

The opportunity costs of adding new or ‘under-used’ (but expensive) vaccines to national schedules need to be considered closely by NITAGs. The decision to introduce new vaccines must be based on country specific epidemiology, health system capability, and financing. For this reason the capacity of NITAGs to undertake these analyses is of critical importance to the implementation of GVAP.

Strategic Priority Objective 4.3 simply speaks of accelerating the introduction of new vaccines without regard to local circumstance (nor capacity to pay after graduation from Gavi eligible).

Country ownership needs to be based on respect for national sovereignty and support for technical and regulatory capacity building.

Affirming and strengthening the role of frontline health workers, in particular, community health workers (relevant to ownership, implementation and monitoring and evaluation)

Health workers are the backbone of vaccination campaigns. Primary health care (PHC) workers in particular should be recognised as a key constituency when it comes to building national ownership and accountability. Their commitment is critical to both managing the logistical challenges and addressing vaccine hesitancy.

Health systems, particularly in the Global South, have long suffered from shortages of human resources for health compared to the health needs of their populations. Such shortages have been exacerbated during the Covid-19 pandemic as health workers are sometimes unable to work (due to illness or the need to self-isolate) and many have died.

Many countries, particularly in the Global South, are relying on short-term contract workers or community health workers (CHWs) to deliver primary care, including supporting immunisation campaigns. The quality of CHW training and their access to supportive supervision is fragmented and uneven in many countries, which may affect the quality of vaccination programs, and workers within this sector are often subject to exploitative and precarious working conditions.

A recognition of and commitment to addressing these health system weaknesses must be part of the implementation of Immunisation Agenda 2030. PHM urges close links between immunisation programs and other policy initiatives around workforce development.

Ability to use TRIPS flexibilities in vaccine procurement (relevant to implementation and monitoring and evaluation)

Some vaccines are expensive. National procurement agencies must have full access to the flexibilities provided for in the TRIPS Agreement. This requires national enabling legislation.

Relevant indicators for monitoring and evaluation would include: (i) the number of countries who have domesticated the full range of flexibilities available under the TRIPS Agreement; (ii) the number of countries to whom WHO has given technical assistance in designing and institutionalising such enabling legislation; (iii) the number of countries who have used TRIPS flexibilities to facilitate vaccine procurement.

Pooled procurement (regional ownership, implementation)

Regional procurement can be effective in assuring supply at lower cost. The PAHO Revolving fund and the UNICEF procurement of Meningitis C vaccines illustrate models which work.

Domestic funding: need to address the fiscal constraints facing L&MIC governments (relevant to ownership and implementation)

Moving to increased domestic funding of immunisation programs needs to be linked to a recognition of the economic reforms needed to address the fiscal constraints facing L&MIC governments, starting with global tax justice and fair trade.

Local production and technology transfer (relevant to implementation, monitoring and evaluation)

PHM urges closer attention to supporting the local production of vaccines as critical to ensuring expansion and sustainability of vaccine supplies.

Strategic Objective 6 focuses on “Supply and Sustainability” of vaccines but the three indicators proposed under this objective focus on mapping the structure of the global health vaccine market, and recording donor and Member State (MS) expenditure on vaccines.

Strategic Priority Objective 7.3 is to “Evaluate promising innovations and scale up innovations, as appropriate, at the national level based on the best available evidence” although no global strategic priority objective indicators are specified for this measure.

The provisions of the TRIPS Agreement can impede local production of vaccines (and medicines) but the plans for implementing and monitoring the *Immunisation Agenda 2030* largely ignore this barrier to equitable access.

PHM urges MS give further attention to optimising TRIPS flexibilities in domestic legislation in order to enable domestic manufacture.

We urge inclusion in the monitoring and evaluation framework indicators that monitor: (i) MS investment in local manufacturing capacity; (ii) Technology transfer cooperation agreements concluded or in development; and (iii) Reporting and transparency on research and development (R&D) financing and costs, including specifying public and private financing for R&D.

Lessons from Covid (relevant to implementation)

Covid-19 has illustrated dramatically the need for timely access to vaccines in confronting new and emerging diseases, particularly in L&MICs. Structural impediments to timely access include the fact that L&MICs,

(1) Cannot afford to engage in pre-purchase agreements and thus get locked out of the market for new vaccines due to artificially created supply shortages;

(2) Struggle to secure financing to pay the high prices of new vaccines;
(3) Struggle to expedite regulatory processes and approvals of new vaccines;
(4) May not have access to new vaccines that have been trialled in a relevant epidemiological context; and
(5) May not have the technical infrastructure (e.g. sub-zero refrigeration) required for distributing and administering new vaccines safely and efficaciously.

Timely access to vaccines may be facilitated by pooled regional procurement mechanisms, greater price transparency, and strengthening domestic manufacturing capacity (particularly state owned production capacity).

The Covid example has seen massive public support for vaccine development but generally without any conditionalities around price transparency or technology sharing. The boycotting of the C-TAP proposal and the opposition to the Indian South African TRIPS waiver proposal reflect the structural barriers to boosting local manufacturing.

Local public sector innovation and production (implementation)

Capacity building for domestic research and production should be a key strategy in the Agenda, (not just implementation research). Public pharmaceutical laboratories (as in Argentina, Brazil, Cuba and Indonesia), if connected to a well structured immunization program, may turn out to be a virtuous example of a sustainable and affordable vaccine chain and even national economic development.

The CoronaVac vaccine, coordinated by Chinese Sinovac Biotech company, was a good example of using public laboratories for clinical trials, technological transfer and local production in two countries: Brazil (Instituto Butantan) and Indonesia (PT Bio Farma). Brazil, as well, entered the ChAdOx vaccine (Oxford/AstraZeneca vaccine) through a federal public laboratory: Biomanguinhos (a unity of research-led Oswaldo Cruz Foundation - Fiocruz).

PHM urges reconsideration of the international R&D treaty proposed by the Commission on Innovation, Intellectual Property and Public Health, including open licensing as a condition of public support for vaccine development.

Vaccines as public goods

The idea of vaccines as public goods recognises that data exclusivity, patents and industrial secrets are a barrier to widespread affordable access to vaccines. During Covid the R&D process has been largely funded by the public sector (e.g. ChAdOx - Oxford University, Pfizer/BioNTech). Recognising vaccines as public goods also underlines the importance of transparency in relation to prices, R&D costs, and clinical trials.

The implementation plan should address these issues and indicators that capture progress on these dimensions should be included in the monitoring and evaluation provisions.

13. Integrated people-centred eye care, including preventable vision impairment and blindness

In focus

In the annotated agenda the Secretariat advises:

> Pursuant to resolution WHA73.4 (2020), the Director-General will submit a report (EB148/15) with recommendations for feasible global targets for 2030 on effective coverage of both treatment of refractive error and cataract surgery, for consideration by the Seventy-fourth World Health Assembly. The Board will be invited to note the report and provide further guidance.

Background

Tracker links to previous discussions of integrated people centred eye care.

Recalling the previous resolutions (for eye health) WHA 51.11 - global elimination of blinding trachoma; WHA 56.26 on elimination of global blindness; WHA 59.25 and WHA 62.1 on prevention of blindness and visual impairment leading to adoption of GAP-2013-2019.

In EB146/1, it was agreed to include an item on Integrated people-centered eye care on the provisional agenda and reports were drawn from the WHO's World Report on Vision.

In EB146/13 the EB was invited to note the report and provide guidance on the future directions. The report noted that almost 80% of the visual impairment and blindness are due to avoidable causes - uncorrected refractive errors and low coverage of cataract surgeries. Therefore, targeting these two avoidable causes of blindness and by including them in UHC can help achieve the SDG-3.

The board recommended (in EB146.R8) that the WHA adopt a resolution, adopted as WHA73.4, which requested DG to provide technical support to MS to implement the recommendations of the World Report on Vision; develop additional guidance on evidence based, cost-effective eye care; create global research agenda for eye care; prepare feasible global targets for 2030, and report on the progress of resolution to the 77th WHA in 2025.

Para 3(4) of WHA73.4 explicitly asks for the feasible global targets to be submitted at EB148. The rest of the requests are to be reported at WHA77 (2024).

See Consultation Page for the Discussion Paper and Contributions to the Consultation. The discussion paper provides further detail regarding the logic of the proposed targets.

PHM Comment

PHM appreciates that eye care will be part of regular reporting and agenda in the WHA. The report by DG EB148/15, pursuant to the resolution WHA 73.4, recommends global targets for the increase in effective coverage of refractive error (eCRE) and cataract surgical coverage (eCSC) by 2030. It recommends a point increase in effective coverage of 40 percentage for refractive error (eCRE) and 30 percentage for cataract surgical coverage (eCSC). The Member States have to be cognizant of the fact even though these two targets have been identified as highly cost-effective interventions and ideal proxy indicators to track changes in the availability, accessibility and quality of eye care services at the global level, the discussion paper concedes that a comprehensive range of input, output and outcome indicators are required to monitor eye care at the national level.

The two global targets need to be addressed under the framework of integrated people-centred eye care. The DG's report includes "Integrated People-Centred Eye Care" (IPEC) in the title but has excluded the key indicators of the very framework in the monitoring of the two targets. PHM strongly feels that the suggested indicators should not pave the way for fragmenting eye care services or lead to the construction of a 'condition-specific' vertical program. And eventually, culminate in the privatisation of eye-care services. The discussion paper identifies the private sector as a stakeholder, yet fails to mention lack of availability of eye care services in public health systems as a major barrier to access particularly in low-income countries.

It is therefore important that the indicators thus delineated focus on building and supporting primary health care, designing service priorities on life-course needs, and envisage a prominent role for community health workers and community involvement in planning, accountability and prevention. The report also fails to emphasise on strengthening the role of public sector providers to work closely with communities on social and environmental determinants of ocular health. IPEC should address the full spectrum of eye conditions beyond 'medical coverage'.

The indicators should also take into account that causes of blindness and visual impairment vary depending on socio-economic conditions and the availability, accessibility and affordability of eye health services. In LICs and especially very poor areas, the prevalence of blindness is higher due to cataract and corneal scarring (from trachoma and vitamin A deficiency). Whereas, among communities with better socio-economic conditions, improved nutrition, sanitation and access to primary eye care, corneal scarring is less of a problem. It is, therefore, important to consider specific determinants before target settings for all the countries. And in addition to the mobilisation of new resources; strengthening primary health care is needed for comprehensive eye care services. Thus, paying attention to these two avoidable causes is important, but while chasing these targets care has to be taken that other conditions – trachoma, retinopathy of prematurity, diabetic retinopathy, corneal scarring, glaucoma and so on – are not overlooked. As these can be prevented effectively with strengthening of the public health infrastructure.

To achieve an increase in both the quantity and quality of effective refractive coverage and cataract surgery, availability and access to basic diagnostics (suited to community and demographics); medicines, low-cost intraocular lenses; spectacles, assistive devices/aids and adequate numbers of trained human resources (allied ophthalmic personnel, and community health workers) is imperative. Therefore, due emphasis has to be laid on the provisioning of free refractive screening and spectacle disbursement

services; and free- surgeries. Hence, training of the health workforce, access to diagnostics and screening facilities at the primary level and strengthening of public health systems has to be ensured so that regions with difficult topography are not neglected.

Those in need of rehabilitation and assistive aids/devices and those who have untreated vision impairment and blindness have been left behind. Therefore, indicators and monitoring mechanisms must include strengthening of vision rehabilitation services at the community level and inclusion of assistive aids (as per Priority Assistive Product List) and their disbursement, a key component of progress.

14.1 Covid-19 Response

In focus

The Secretariat advises:

> Further to the document submitted to the Executive Board at its fifth special session (on the COVID-19 response), the Director-General will submit a report (EB148/16) to provide the Board with an update on the Secretariat's activities to combat the pandemic of coronavirus (COVID-19).

Background

Recent GB discussions of Covid-19

Secretariat Covid-19 portal

Website of Independent Panel

WHO Media Release (24 Dec 2020), WHO's Covid-19 Response

WHO's Timeline of the Covid-19 response

GHF report on US Brazil Governance Reform Proposals

PHM Comment

The WHO Secretariat has done a commendable job in the Covid response. This needs to be acknowledged, particularly in view of the vile abuse which has been directed at WHO from the US president and his acolytes.

However, this report (EB14816), focused solely on WHO's activities during the pandemic, is not very useful, either in terms of evaluating the performance of WHO or learning lessons for the continuing (or the next) pandemic.

The report studiously avoids any comment on the performance of different member states in managing the pandemic or any lessons which might be learned from the variations in response and outcomes.

Paras 2 to 10 provide lots of numbers regarding plans, websites, meetings, events, guidelines and teams and there can be little doubt that these activities have made a huge contribution to managing the pandemic. However, the data are not presented in the context of the evolving pandemic so it is difficult to make sense of them. For example, the report advises that more than 33 million diagnostic products, including polymerase chain reaction tests and sample collection kits, have been shipped to 142 countries across all WHO regions. Presented out of context it is not possible to know if this was too many or too few.

Even across the limited scope adopted for this report some important activities have been ignored, including, the C-TAP proposal, the Secretariat's role in the ACT Accelerator (including Covax), the failure of the Solidarity vaccine trials proposal, the DG's support for the India/South Africa waiver proposal and the current investigation into origins. There is no mention of any advice provided to the DG by the IHR Review Committee (see EB148/19).

The C-TAP proposal was adopted by the WHA and supported by the DG. It was a bold, forward looking initiative which was ignored by the rich countries and sneered at by representatives of Pharma. This report should be calling for continuing to explore alternative innovation regimes.

The ACT Accelerator was deliberately constructed as a multi-stakeholder public private partnership outside the reach of the World Health Assembly. WHO has been used to give legitimacy to the initiative, but the Bill and Melinda Gates Foundation plays a far stronger role in its governance than the World Health Assembly. Despite being sidelined in this way the WHO secretariat still has an obligation to report to the MS on what positions it took in these bodies and the progress that each of the four pillars are making.

There is no reference in this report to the Solidarity vaccine trials proposal which appears to have been boycotted by all the major vaccine developers and manufacturers. As a consequence, as vaccination is being rolled out in many countries, we still have no head to head comparative data regarding the performance of candidate vaccines. This is a major failure of global health governance which should have been explained in this report.

To his credit, the DG supported the Indian and South African TRIPS waiver proposal which remains a live proposition and quite critical in terms of scaling up the production worldwide of Covid related health products. It is unfortunate that there is no reference to the logic of this proposal in this report.

Even accepting this sole focus on WHO activities there is no reference to the possibility of mistakes occurring and lessons being learned from such mistakes. There is no clarification of (what appeared to be) WHO's acceptance of Chinese assurances in January 2020 regarding the 'lack of evidence of human to human transmissability'. There is no reference to the debate over the role of aerosol transmission and the place of population wide masking to prevent transmission. There are no reflections on the role of travel restrictions on transmission during the Covid pandemic having regard to the widespread use of such restrictions and the traditional opposition of WHO to the use of such measures.

This report is about the Secretariat's response, not that of the member states. However, the report highlights the role of the Secretariat in monitoring the pandemic and national responses including the maintenance of essential health services and providing guidance and advice.

The extensive use of lock-downs, organized by security personnel and lacking public health guidance contributed to a great deal of avoidable pain and suffering, especially affecting migrants.

The lack of surge capacity in many MS impacted on essential health services, including public health services upon which poor people depend. Re-purposing such essential health services for Covid19 response is unacceptable. Health system surge capacity needs to be recognised as a key element of health systems preparedness, an obligation under IHRs.

In many countries private health care resources have been recruited into the Covid response but the coordination arrangements needed to seamlessly integrate public and private personnel and facilities were not in place.

There is a critical need to reflect upon, and learn from, the experience of the Covid pandemic so as to strengthen emergency preparedness and response for next time.

The rich countries have racked up huge debts to mobilise resources for the response and to cushion the economic impact of the pandemic. However, the opportunities for such commercial borrowing are much more restricted for L&MICs. Accordingly they have been more dependent, for the funding of measures to ameliorate hardship, on the International Financial Institutions, in particular the IMF and the World Bank. However, IMF and WB lending to support L&MICs through the pandemic has been meagre and subject to tight restrictions. The paper does not report any advocacy by WHO in relation to this failure.

14.3 Mental health preparedness and response for the COVID-19 pandemic

In focus

In the Annotated Agenda the Secretariat advises:

> At the recommendation of the Officers of the Executive Board, the Director-General will submit a report (EB148/20) on addressing the mental health dimension of the COVID-19 pandemic, including the essential place that mental health should have in all preparedness actions and responses to COVID-19, and on ensuring that mental health is included in universal health coverage as countries recover from the pandemic. The Board will be invited to note the report and provide further guidance.

Background

Tracker links to previous GB discussions of mental health.

From WHO Euro (27 March 2020) article on mental health and psychological resilience during the COVID-19 pandemic; highlighting the potential mental health impacts on children and the elderly.

From AIHW (1 Nov 2020) Mental health impact of Covid in Australia

From IPS News (Bangladesh, 12 Dec 2020) The Impact of COVID-19 on Child Marriage and Other Gender-Based Violence

From The Guardian (Au edition, 28 Dec 2020) Covid poses 'greatest threat to mental health since second world war'

PHM Comment

The report (EB148/20) reviews some of the pathways through which the Covid experience has impacted on mental health. These include:

- Disruption of care in MH institutions and disruptions to service provision in the community, including
- Heightened risk of Covid in MH institutions
- Heightened risk of stigma and discrimination living with mental illness;
- Social and economic adversity consequent on social disruption associated with public health and social measures as part of the Covid response with consequent anxiety, depression, PTSD, and intimate partner violence
- Isolation with consequent anxiety and depression, exacerbation of dementia
- Heightened risk of harm from gambling and alcohol and drug use, and consequent heightened risk of infection and risk of domestic violence;

- Covid related neurological disorders

This list of pathways should also include

- The anxiety of front line health care workers (especially those working under impossible burdens including the risks of PTSD
- The anxiety of people who have been sick with Covid, including those suffering from PTSD after hospitalisation
- The anxiety of the families of sufferers
- The distress of families who are separated by lockdowns (including families with members in aged care)
- The anxiety provoked and exacerbated by political conflict over public health and social measures (masks, lockdown, isolation, quarantine, testing, etc) and inconsistency and volatility in policy recommendations. Community anxiety has also been provoked by the appearance of experts facing uncertainty and robust debate.

The paper highlights the importance of incorporating MH policies and programs in emergency preparedness and response, and maintaining services, including remote service provision through teletherapy.

It would be helpful if WHO were to also highlight the mental health for children and young people, who are paying now for the lack of social contact and the lack of school, will pay in the future for the missed opportunities in 2020 and for the economical disaster due to the pandemic. Likewise attention needs to be directed to rehabilitation services for Covid neurological injuries.

PHM urges WHO to give greater attention to the inherent resources of communities in providing collective psychosocial care rather than focusing solely on the services of individual professionals. A critical part of the emergency preparedness and response involves validating, encouraging and facilitating the inherent resilience of communities.

Finding opportunities within the crisis, the paper looks to learn from the pandemic and build mental health services for the future. It foreshadows:

- the reorganization of national services that shift care away from institutions to a broad range of community-based mental health services and support services;
- ensuring that mental health is part of universal health coverage by including care for mental, neurological and substance use disorders in health care benefit packages and insurance schemes;
- building human resource capacity to deliver mental health and social care;
- organizing community-based services that protect and promote people's human rights and actively involve people with mental health conditions and psychosocial disabilities in the design, implementation and monitoring of services.

PHM deplores the continued references in WHO documents to a model of UHC which is to be delivered through mixed public private service delivery funded through insurance markets and benefit packages. This is particularly unfortunate in relation to mental health. The experience of

many countries demonstrates that private sector mental health care, funded through ‘benefit packages’, tends to be individualised, sickness focused, medically dominated and concentrated in wealthy districts.

There is nothing in this paper about addressing the social determinants of health as revealed in the Covid response, particularly the different responses of different cultures to public health and social measures such as masks, social distancing and lock downs. There are important lessons here about the benefits of cultures which value solidarity, trust and community resilience.

The influence of cultural norms and political practices on mental health have been very much on show globally. The conflict and chaos common in cultures characterised by division, individualism and suspicion of expertise contrasts with the experience of cultures where there is a stronger sense of solidarity and trust in relation to science and government.

Culture shapes and is shaped by economics and politics. The neoliberal hostility to government and community has contributed to a loss of trust in government and confidence in science in many countries as well as widening inequality, communal suspicion, and loss of solidarity. The political ascendance (and increasing wealth) of the transnational capitalist class has contributed to a widespread alienation from any vision of a better world, the corollary of which is the rise of fascism.

The Covid crisis has demonstrated the devastating mental health impacts of these cultural trends. However, there is no suggestion in this paper of any strategy to address the challenge of resisting deepening inequality, economic heartlessness, and protofascism.

There is no reference in this paper to the Independent Evaluation of the global Covid response or the deliberations of the Review Committee and the importance of both of these reviews taking full cognisance of the lessons regarding MH from the Covid response.

14.4 Nagoya Protocol

In focus

The Secretariat advises:

> Pursuant to decision WHA72(13) (2019), the Director-General will submit a report (EB148/21) on current pathogen-sharing practices and arrangements, the implementation of access and benefit-sharing measures, and the potential public health outcomes and other implications of implementation of the Nagoya Protocol. The Board will be invited to note the report and consider recommending that the Health Assembly request the Secretariat to continue its work in this area.
>
> See TWN report (12 June 2019) of the debate in WHA72 (May 2019) which led to WHA72(13).

Background

Previous discussions about the Nagoya Protocol

Access and benefit sharing for pathogens: An overview of the issues facing the 2021 World Health Assembly and WHO Executive Board by Edward Hammond (December 2020)

The politics of pathogen sharing by Priti Patnaik, Geneva Health Files, 15 Jan 2021

PHM Comment

PHM affirms that:

- pathogen sharing, including both physical samples and genetic sequence data, is a critical capacity for global public health;
- pathogen sharing should be subject to the principles of the Nagoya Protocol (including benefit sharing, prior informed consent and mutually agreed terms);
- that the sharing of physical samples and genetic sequence data should both be subject to Nagoya principles;
- the PIP Framework demonstrates the logistic benefits of an agreed multilateral framework for pathogen sharing, consistent with Nagoya principles;
- agreed multilateral frameworks for pathogen sharing (beyond pandemic influenza) are needed;
- provision for the prompt sharing of genetic sequence data (in accordance with Nagoya principles) in emergency situations must be included in such frameworks.

Decision WHA72(13) asked “information on current pathogen-sharing practices and arrangements, the implementation of access and benefit-sharing measures, as well as the potential public health outcomes and other implications”.

Fulfillment of the request in WHA71(13) should provide an information base sufficient to identify precedents and lessons which would assist in defining options for wider pathogen sharing in accordance with the above six criteria.

There are significant disagreements between Member States (and industry opposition) regarding the above six criteria which means that design work in this area needs to be approached carefully and with as much useful data as possible.

The report provided in EB148/21 does not provide a sufficient information base regarding 'practices and arrangements' and 'potential public health outcomes'. The sample size is small and quite uncertain as to its representativeness. The detail collected regarding practices and arrangements and outcomes is too limited. Until a thorough and comprehensive description of practices and arrangements, as requested, is provided, Member States should be cautious about proceeding to designing new arrangements for pathogen sharing.

15.1 Polio eradication

In focus

The Secretariat advises:

> In line with the request in resolution WHA61.1 (2008), the Director-General will submit an update (EB148/22) on: efforts to interrupt remaining wild poliovirus transmission; the responses to outbreaks due to circulating vaccine-derived poliovirus type 2 and the introduction of novel oral polio vaccine type 2; the impact of COVID-19 on the polio eradication programme; a review of the governance of the Global Polio Eradication Initiative and the process for developing a new strategy; and the financing situation at end-2020.
>
> The Board will be invited to note the report.

Background

Previous GB discussions of Polio (see PHM's overview of GPEI from May 2019)

Secretariat's Topic Page on Polio

Statement of the 25th Polio IHR Emergency Committee, June 2020

Emergency call to action for measles and polio outbreak response and prevention

WHO global action plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use (GAPIII)

PHM Comment

Overview

PHM notes with concern the considerable setback that the eradication of polio campaign is facing because of the three challenges- the persistence of wild virus type 1 in two nations and spread within one of these two to previously polio free areas, the rise and spread of outbreaks of Circulating Vaccine Derived Poliovirus type 2 virus across much of Africa as well as in Afghanistan, Philippines and Malaysia, and the setback to anti-polio control programs due to the COVID-19 pandemic. The problem is at its peak in Afghanistan and Pakistan, where a very adverse geo-political situation, combines with very weak health systems and with the setback due to COVID-19 response measures. Not only in these two countries- but in most of Africa the diversion of resources and attention due to the COVID-19 response is directly leading to a situation where a 200% increase in affected districts is expected and anti-polio immunization campaigns have to resume in many countries.

Further, in June 2020, the Emergency Committee of International Health Regulations (2005)– assessed that the risk of international spread of polioviruses remained in category of "a public health emergency of international concern" and further stated that the "current situation is extraordinary, with clear ongoing and increasing risk of international spread and ongoing need for coordinated international response."

This points to a major policy lapse that WHO must urgently correct. It is obligatory under the task of the IHR for WHO and Member States to ensure epidemic preparedness. Henceforth this should mean the ability to sustain all essential health services during a crisis. Such resilience in health systems is not currently part of the IHR mandate, but henceforth this should be explicitly stated. Re-purposing of health workers for crisis management functions should not be at the cost of other essential health services. Where absolutely unavoidable, it should be for the shortest period of time and with addition supplementation by paid short-term volunteers. Further WHO should call out the Member States who are deficient in human resources in front-line primary health care positions and public health duties, so that the international community and the MS themselves are aware of where the vulnerability to epidemics are higher.

Primary health care systems in the countries facing the largest setback have been minimalist-restricting themselves to minimal package of services and minimum numbers of regular staff, and under-funding on public provisioning of services. The fact that many countries at risk of Polio virus utilised their frontline health workers engaged and trained in Polio virus activities for the control of SARS-CoV-2 shows the potential of this work force beyond the vertical program that paid for them. This shows the potential of a strong cadre of these multi-skilled frontline health workers in reaping benefits other than the Poliovirus eradication. Further, in addition to inadequacy in numbers and training there has been systematic weakening of such primary health care systems due to poor terms of employment of the workforce. Too many of these frontline workers are still volunteers or hired on ad-hoc contractual basis.

PHM calls for

- further strengthening of the frontline health workers by adequate pay for work and benefits and regular terms of employment,
- Increased investment in strengthening public health systems, especially primary care.

Social determinants of health: The resolution places its entire reliance only on vaccination.

With an increasing gap in the sanitation facilities and availability of potable water, the eradication of polio will fail to cross the final hurdles. Further new viruses and pathogens will spread though similar water-borne transmission. With urbanisation happening at a rapid pace, there must be a clear commitment of governments to ensure that the newly emerging housing communities as well as peri-urban slums have access to sanitation and drinking water facilities. At no cost can the provision of drinking water be "delegated" to the private bodies. Very often

the communities affected by Polio are the same marginalised communities affected by other communicable diseases.

PHM calls for all countries to invest in sewerage facilities and drinking water availability. The advantages extend far beyond the eradication of polio, but are also immediately need to sustain and retain the progress made on polio eradication.

Vaccine

The vaccine for Polio virus has brought us near the goal of eradication. But at the same time, we are also witnessing a much higher number of cases of circulating Vaccine Derived Polio Virus (cVDPV). PHM appreciates the efforts of the scientific community in trying to bring out the novel Oral Polio Vaccine (nOPV2). WHO has already issued an Emergency Use Listing recommendation for the nOPV2.

Once we stop the transmission of all strains of wild poliovirus (currently only type 1 remaining), live-attenuated viruses used in OPV will be the only source of live virus and pose a risk of re-emergence. Therefore, it will have to phased out completely and only Inactivated Polio Vaccine will be used. But the supply of Inactivated Polio Vaccine (IPV) has been erratic. WHO position paper on Polio vaccines notes that "2 fractional doses instead of 1 full dose[ST1] [AR2], increases the immunogenicity of IPV and can extend coverage if supplies are limited". All countries must be encouraged to switch to the fractional doses, if not already.

PHM calls for

- WHO to bring out a blueprint of exit plan on polio immunization with time schedules for phasing out of OPV, with availability of nOPV2 and ensure that the supply of nOPV2 be prioritised to the areas they are most needed and later the phasing out of IPV.
- Faster technology transfer to more global domestic manufacturers for production of IPV.

Poliovirus Containment

In the light of breach or release incidents of Poliovirus that happened from facilities in three countries, PHM asks WHO to bring out a detailed report on investigation of such events and also to conduct a risk assessment of all labs at the earliest.

Governance

A governance review was conducted in GPEI, the findings showed ways how we can improve the functioning and accountability. While PHM appreciates the idea of expanding the

membership of Polio Oversight Board (POB) and Strategic Committee (SC), we caution against the inclusion of donors in the highest decision bodies since it can lead to a potential conflict of interest. The expansion to include countries and CSOs will give space for diverse perspectives into how the eradication can be achieved.

LMICs entered into polio eradication campaign, on the promise that current expenditures would be offset by future savings as vaccination becomes unnecessary. But as the recommendations are currently to expand vaccines against polio (bOPV plus two doses IPV plus nOPV) it is important that all these supplies are provided free to the LMICs along with donor support for the universal vaccination effort.

The effort to strengthen the polio campaign must be closely linked to strengthen public health systems as a whole.

15.2 Polio transition planning and post-certification

In focus

The Secretariat advises:

> Pursuant to decision WHA70(9) (2017), the Director-General will provide a status update (EB148/23) on the implementation of WHO's Strategic Action Plan on Polio Transition for the period 2019–2023, with a focus on measures taken to address those COVID-19 restrictions that risk impeding its implementation, as well as a summary of progress with priority country action plans. The Board will be invited to note the report.

Background

Previous GB discussions of Polio

Secretariat's Topic Page on Polio

Strategic Action Plan on Polio Transition (A71/9)

PHM Comment

Transition and Integration in the context of COVID-19.

PHM appreciates the setting up of "Integrated Public Health Teams" in WHO country offices in Polio transition priority countries as a move in the right direction. But our concern is that it is limited in description to integrating the polio program to the COVID-19 program. This is still very much in the frame of vertical stand-alone interventions. In practice, the polio workers have in most contexts got re-purposed as COVID-19 workers and this has been at the cost of the polio program. Merely changing their name will not change this reality. Therefore, Integrated Public Health Teams should not only be looking at COVID-19 and Polio but the entire range of public health functions including NCDs. Which means a larger density of multi-skilled frontline teams . The current draft could be taken to mean that such integrated public health teams are for country and sub-national levels. On the other hand, integrated public health teams must also be part of a network of primary health care facilities which has enough staff reserves and auxiliaries to respond to any outbreaks.

It must be ensured that CSOs and independent experts from within the country must also be brought on board in the Integrated Public Health Teams of the country and sub-national management levels. This diversity will allow the building of strong capabilities for disease surveillance in the context of the marginalised communities in the country.

Budget, Planning and Human Resources

Polio programme of the WHO has been one of its biggest in terms of budget and human resources (staff and contractual). Funding is based entirely on voluntary contributions. While the eradication itself may be delayed given the challenges that come from COVID-19, there is a significant concern that funding may be cut down significantly without the adequate strengthening of infectious diseases and vaccine preventable disease surveillance.

PHM calls upon WHO to ensure that continued funding enables a sustained transition where in the countries are able to continue to build strong infectious disease surveillance and outbreak response systems, where the AFP surveillance/ Environmental surveillance currently stands.

16 Social determinants of health

In focus

The Secretariat advises:

> At the recommendation of the Officers of the Executive Board (EB146/1 (annotated)), the Director-General will submit a report (EB148/24) on addressing social determinants of health, namely, the conditions in which people grow, learn, live, work and age that have negative consequences on many health outcomes and on health equity, as illustrated by COVID-19. The Board will be invited to note the report and provide further guidance.

Background

Previous GB discussions of the social determinants of health

WHO Social Determinants Webpage

PHM Comment

This report addresses the social determinants of health generally and specifically in the context of Covid.

The report restates the importance of addressing the social, environmental and economic determinants of health and reviews the work of the Secretariat in this area over the last three years. In particular, the report reviews the Covid pandemic from a social determinants and health equity perspective and highlights instances showing how the Secretariat has built a social determinants perspective into its Covid response.

The focus in the report on the impact of the upstream determinants of health (point 4) is good and reflects many of the points in the People's Health Charter. However, the paper is vague on what action on SDH involves. While certain social determinants are listed (housing, working conditions, education) very few specific examples are given. The paper is surprisingly short on specific recommendations for action. It also does not refer to the very many still relevant recommendations of the CSDH (full report can be accessed here https://www.who.int/social_determinants/thecommission/en/).

PHM commends Dr Tedros for his repeated insistence on solidarity as a critically important element of the Covid response, globally, nationally and at the community levels. Solidarity has been a hugely important social determinant of health in the Covid context. This includes:

- solidarity in global and national financing;
- solidarity in complying with social distancing measures and sharing the burden of lockdown;

- solidarity in reaching out to support groups living in vulnerable circumstances, including those particularly vulnerable to the virus and those vulnerable to the social, emotional and economic consequences of travel restrictions, social distancing, and lockdown;
- solidarity in sharing the of personal protective equipment, test reagents, oxygen, and new vaccines;
- solidarity expressed in the resilience of many communities.

However, in many settings the absence of solidarity has been most evident.

Conflict over the implementation of public health and social measures has been common, leading in many cases to inconsistency, half-hearted gestures, delays and implementation failure; manifest in repeated surges, heavy morbidity and crushing burdens on health workers.

Vaccine nationalism and the failure to fully fund the ACT Accelerator serve as indicators of the lack of solidarity globally and have huge implications for people in the Global South.

The opposition of the wealthy countries to the proposed TRIPS waiver, preferring instead to privilege the profits of Pharma, likewise projects a stark challenge in terms of addressing the social determinants of health, globally.

While the rich countries have racked up huge debts to cushion the economic impact of the pandemic, the opportunities for such commercial borrowing are much more restricted for L&MICs. Accordingly they are more dependent for funding special economic measures on the International Financial Institutions, in particular the IMF and the World Bank. However, IMF and WB lending to support L&MICs through the pandemic has been very meagre and subject to tight restrictions. Solidarity has been lacking.

Trust is also vital as a social determinant of health during Covid. In those jurisdictions where there is a relatively high level of trust in official experts - trust given and earned - the virus has been far better controlled.

The Covid pandemic has laid bare the role of neoliberal ideology through its impact on solidarity and trust in determining the health chances of people everywhere. Neoliberalism denies community (“no such thing as society”); drives inequality; preaches small government, favours the private sector and low tax. The neoliberal hostility to government and community has contributed to a loss of trust in government and confidence in science in many countries as well as widening inequality, communal suspicion, and loss of solidarity.

Covid-19 is not the only health-related crisis the world faces. Social and commercial determinants must tackle not just the recovery from the pandemic but also deal with the epidemic of non-communicable disease and the challenge of global warming and other environmental disasters in a co-ordinated manner.

If WHO is to promote effective action on the social determinants of health it needs to return to what the Commission on the Social Determinants of Health described as the need to redistribute “power, money and resources”. Achieving this redistribution would mean

addressing the forces which reproduce the inequities in the distribution of power, money and resources:

- Trade agreements and the ways in which they favour rich countries;
- The overriding power of trans-national corporations (TNCs) and the extractive capitalism they sit astride; an extraction which exacerbates inequities between and within countries and has an especially negative impact on indigenous peoples around the world;
- Widespread tax evasion and avoidance, including the extortion of tax benefits by foreign investors;
- The power of US capital over the lending practices and conditions of the IMF and the World Bank (both quite limited in their support of L&MICs during the pandemic);
- The push to privatise many services even though the pandemic has shown the failure of many privatised services including in contract tracing and in aged and disability care.

PHM congratulates Dr Tedros on the creation of the Council on the Economics of Health for All. However, it will be critical that the Council looks at the barriers to development inherent in the current configuration and governance of the global economy including attention to unfair trade and tax justice. PHM urges the Council to look at the macroeconomic determinants of health as well as the economics of health care;

WHO must invest resources in understanding the impact of commercial determinants of health and make clear recommendations for Member States to follow including stronger and better resourced public regulation of the private sector in the interests of health and wellbeing.

PHM urges the WHO and its Member States to adopt means of assessing the health impact of all commercial and social determinants of health in such a way that improvements can be made that promote health and well-being over those of profits

PHM urges WHO and member states to pay as much attention to social vaccines (public policy designed to promote health and wellbeing) as they do to biological vaccines. Social vaccines will protect populations and especially those in vulnerable situations.

Approaches to recovery from COVID much incorporate measures to mitigate climate change and deal with the epidemic of non-communicable diseases.

PHM urges the Commission to look at the investment needed in research, development and production of health care products in low and middle income countries and the reforms needed in the governance of intellectual property to allow this to happen.

Finally PHM asks for a perspective which argues for a response to social determinants of health which would address the following:

- Institute measures that will address the very uneven distribution of power, money and resources both between and within countries including progressive taxation, closing of taxation loopholes for the ultra rich and TNCs, renegotiate trade agreements so that they favour low and middle income countries
- Draw on genuine rather than tokenistic models of engagement with communities
- Provide a guaranteed minimum income to all citizens
- Address discrimination and racism
- Provide a publicly funded and run universal health system grounded in a comprehensive primary health care approach
- Address climate change to avoid its impacts on human health

19.1 WHO Transformation

In focus

The Secretariat advises:

> In response to the recommendation made by the Programme, Budget and Administration Committee of the Executive Board (EB146/3), with which the Executive Board had concurred at its 146th session, the Director-General will submit a report (EB148/32) to update the Board on progress made in implementing the transformation agenda.

Background

The Transformation Agenda

- aims to better position the Organization to deliver the Triple Billion and the SDGs and to strengthen country-based work including closer coherence across the UN system at the country level;
- promises priority to country based work and closer alignment of the work of the three levels of WHO;
- promises a culture that will 'enable effective internal and external collaboration';
- promises a *'new approach to communications and resource mobilization, and bolstering partnerships, so that WHO is positioned to shape global health decisions and generate appropriate and sustainable financing'*;
- involves a range of strategies for redesigning Secretariat processes;
- involves a new 'operating model' for work in country offices, regional offices and headquarters which enhances cooperation and alignment across levels and reduces duplication (see para 22 in A72/48);
- involves cultural change directed to optimising 'collaboration, performance and impact'; and
- commits to reform of WHO's country work so as to enable closer alignment of UN agencies at the country level.

For an alternative perspective on WHO Reform refer to Germán Velásquez's commentary for the South Centre

Previous discussions of WHO Reform

Government of India, "Approach on WHO Reforms". Health Emergencies and public health threats, particularly those at the level of epidemics and pandemics, have become a global challenge requiring a coordinated and prompt global response. It is important to ensure that the global health governance and support structures with the WHO at its core are robust and suited to deal with such emerging challenges as COVID 19 pandemic. The COVID Pandemic is not only an unprecedented challenge confronting the world with its socio-economic impact beyond

the health sector but also a historic opportunity to build a new global partnership with reformed and effective multilateralism. More

See very useful report from Geneva Health Files "WHO REFORMS DISCUSSIONS GAIN MOMENTUM" (8 Jan). Thanks Priti.

PHM Comment

The Transformation Agenda described A72/48 and reported upon in EB148/32 is explained in and obscured by a jungle of impenetrable managerial jargon. The reforms as described appear very sensible but it is sometimes difficult to know what some of the references (eg to culture and agility) mean in practice.

EB148/32, paragraph 9 is critical. This para describes four themes which have emerged from the country level reviews and broader feedback from country offices and Member States.

1. There are shortfalls in country work which are partly due to the rigidities of WHO financing (dependence on highly earmarked donor funding), but are also due to changing expectation of country level functions (does this mean that the operating model at the heart of the Transformation Agenda is in some respects obsolete or does it mean that WHO's 'partners' / donors demand that their needs be prioritised?)
2. Necessary transformations in WHO's human resources processes and mechanisms is dependent on ongoing changes in WHO's 'culture, financing and approach to resource mobilization' (what are the issues here; what are the causes?)
3. Operational and programmatic agility, and WHO's ability to respond and adapt rapidly to changing country needs will depend on addressing WHO's unpredictable and inflexible financing, highly reliant on a limited number of donors and tightly earmarked voluntary contributions.
4. Countries and regions are different and flexibility is needed between an organisation wide 'operating model' and the dynamic and unique needs being confronted in different settings.

Lift the freeze on ACs! Untie the VCs!

19.5 Engagement with NSAs

In focus

The Secretariat advises:

Report on the implementation of the Framework of Engagement with Non-State Actors

In accordance with resolution WHA69.10 (2016) and the Framework of Engagement with Non-State Actors (subparagraph 68(a)), the Director-General will submit the annual report (EB148/39) on WHO's implementation of the Framework of Engagement with Non-State Actors, illustrating engagements with entities and reporting on the different aspects of the implementation of the Framework at the three levels of the Organization. The Board will be invited to note the report.

Non-State actors in official relations with WHO

In line with the provisions of the Framework of Engagement with Non-State Actors, the Executive Board is mandated, through its Programme, Budget and Administration Committee, to consider applications for admittance of non-State actors into official relations and to review collaboration with one third of the non-State actors in official relations in order to decide whether to maintain, defer the review or discontinue their official relations. The Board will be invited to note the report (EB148/40) and to consider a draft decision.

Background

The Framework of engagement with non-state actors (FENSA) was adopted in May 2016.

In WHA69.10 which endorsed the FENSA, the Assembly also requested an initial evaluation of the Framework and its impact to be undertaken in 2019. The report of the Initial Evaluation was submitted to the EB in EB146/38 Add.2.

According to the report EB146/38 Add.2, the initial evaluation "did not assess the FENSA as a framework in itself but rather the implementation of the FENSA". It nevertheless includes statements on the relevance, such as: "The FENSA constitutes a coherent and integrated framework compared to previously separated and discrete engagement policies for different non-State actors" and "the existence of the FENSA is a significant accomplishment in its own right and a precedent for the wider United Nations system." (page 3).

What is lauded in the report as "integrated" approach has been criticised by civil society organizations in their public calls (earlier overview here) and statements at WHO governing body meetings, as reported by Rodwin (2020, p.2): "FENSA's use of the term non-state actors put business-based and public-interest-based actors on an equal footing. Furthermore, it legitimized for-profit firms' (and affiliated not-for-profit trade associations') participation in WHO policy development,

failed to adequately control conflicts of interest frequently arising from engagement with commercial firms, and did not employ the standard definition of (Conflicts of Interest) used in the law and dictionaries, thereby confusing analysis and undercutting effective responses".

See: Previous discussions of FENSA and NSAs more generally

As "factors affecting FENSA implementation", EB146/38 Add.2 (p.8, paras 30-37) highlighted the following:

- *The perception that senior management's endorsement and support was initially lacking*
- *The absence of an overarching Organization-wide actionable implementation strategy for engagement*,
- *The absence of an accompanying change management and communications strategy.*
- *Limited absorptive capacity in the Organization due to the ongoing transformation (change fatigue*). In this para, we find the remarkable statement: "Staff perception is that WHO is increasingly paralysed due to resolutions, rules, regulations and frameworks without prioritization and that the FENSA as a major organizational endeavour has been somewhat buried under a larger set of changes."
- *Insufficient resources to support implementation.*
- *Focus on reporting requirements at output and activity level, rather than on the effects of implementation.*

As a result, FENSA implementation is reported as "undertaken in an ad hoc, fragmented and unsystematic manner across the Organization" (p. 4, para 14)

The evaluation report's sections on "lessons" (p.10, paras 38-39) and "recommendations" (p.11, paras 42-47) built on this analysis. Here the set of recommendations (titles only):

1. Enhance communication on the FENSA
2. Strengthen understanding, ownership and management of risks and benefits of engagement.
3. Enhance access to specialized knowledge and apply expert technical advice.
4. Strengthen the data environment by establishing a systematic monitoring and tracking mechanism
5. Enhance learning.
6. Develop, finalize and implement an engagement strategy with non-State actors.

FENSA at EB 148

EB148/39, now before the Board, combines a 'management response' to the recommendations of the Initial Evaluation (see above, EB146/38 Add.2) and the annual report on FENSA implementation requested in WHA69.10.

EB148/39 refers to the challenge any assessments or recommendations made by the Initial Evaluation Report EB146/38 Add.2, but states that, "to facilitate implementation of the recommendations and in order to prepare the management response to the initial evaluation, a

series of elements have been developed and consultations have been conducted across the three levels of the Organization." and that "the outcomes of the consultations have led to the preparation of a comprehensive management response document".

This "comprehensive management response document" itself is not included in the EB documentation.

EB148/39 then mainly reports on the implementation of the recommendation (under recommendation 5, "Enhance learning") to reactivate a "FENSA Focal Points Network" and a "FENSA Proposal Review Committee". The Secretariat also reports that a plan has been developed to respond to respond to the recommendations on communication, capacity and learning and promises the development of an engagement strategy

In its general report on FENSA implementation EB148/39 reviews implementation in each of the regional offices and the W^HO Headquarters and in various hosted partnerships as well as the implementation of FENSA during the Covid emergency.

EB148/40 presents for PBAC and the Board the Secretariat's recommendations regarding NSAs in Official Relations.

PHM Comment

Follow-up of Initial Evaluation (EB 148/39, paras 4-14)

As the Evaluation report itself, the related section of EB148/39 mainly shows how the Secretariat struggles with FENSA implementation throughout the three levels of the Organization.

This section and the report as a whole are written within the overall FENSA narrative and are not particularly interesting, maybe with the exception of the section on the "implementation of an engagement strategy with non-State actors" where the EB148/39 states (para 14): "In consultation with the three levels of the Organization, the Secretariat will develop a strategy and proposed plan for its implementation."

This announcement of "a (single?) engagement strategy" contradicts expectations and demands by civil society for a specific Civil Society Engagement Strategy (as announced earlier). We hope that this is rather a typo than the plan.

Annual report on FENSA implementation (EB 148/39, para 15-60)

Again, this is FENSA mainstream narrative, if you like it or (rather) not: "As an enabling policy, the Framework of Engagement with Non-State Actors provides a firm basis for strengthening engagement; it prioritizes the need to expand, deepen and strengthen engagements that will have a positive impact on public health, while balancing risks against expected benefits." (para 16)

In the section on FENSA implementation at regional level (paras 17-44) we appreciate the formal provision for NSAs to participate in some RC meetings.

In its section on the Secretariat's implementation of FENSA (paras 45-53), the most interesting para is the one on the Secretariat "working on revising its policy on consultants" (para 47), but the outcome of this review is not yet reported/available. The sneaky replacement of formally employed WHO staff by consultants needs to be carefully watched.

And, yes, the report includes a remark that "with regard to their participation at WHO meetings, non-State actors have expressed concern about the modalities governing their participation." (para 52). O yes, indeed. See agenda item 19.2

Secretariat's recommendations regarding NSAs in Official Relations (EB148/40)

This is a routine document and procedure, nothing particular to be noted.

21 Staffing issues

This page carries a single integrated comment on Items 21.1-21.3 of the EB148 agenda.

21.1 Statement of Staff Associations

Document EB148/INF./1

Previous presentations by the Staff Associations to the EB

21.2 Report of the Ombudsman

Documents EB148/INF./2 and EB148/INF./3

Previous reports from the Ombudsman to the Board

Controversy over report on early Italian response: As this matter has been referred to the Ombudsman it is worth reviewing the posts from Health Policy Watch:

- World Health Organization's Censorship Of Report On Italy's Pandemic Response Sets Dangerous International Precedent – Critics Say (Nicoletta Dentico & Elaine Ruth Fletcher, 15/12/2020)
- WHO Playbook For Responses To Media Queries On Suppressed Italian COVID-19 Report – Raises More Questions than Answers (Elaine Ruth Fletcher & Nicoletta Dentico, 15/12/2020)

21.3 Human resources: update

Document EB148/44

The Secretariat advises:

> The Director-General will provide an update (EB148/44) on the implementation of the Organization-wide human resources strategy and its three pillars (attracting talent, retaining talent and an enabling working environment), together with an analysis of workforce data. In response to requests made at recent meetings of the governing bodies, and in the context of its consideration of human resources matters, the Board will also receive information on progress towards achieving the relevant aspects of the United Nations System-wide Action Plan on Gender Equality and the Empowerment of Women (UN-SWAP).

Previous annual HR reports to the Board

PHM Comment (integrated comment on staffing issues)

The COVID-19 crisis has put unprecedented stress on staff members at all levels of the Organization. In EB 148 /INF./2 the Ombudsman reports that "… the emotional toll resulting from trying to perform in these conditions has been dire … many, such as temporary staff and

consultants, also feared about their future careers, because of the precarious nature of their contracts … several tasks were cancelled or made irrelevant as a result of the pandemic …". While many staff members are overworked, others have little or nothing to do.

While the Ombudsman is no doubt correct in attributing these stresses in part to the COVID-19 pandemic, there is a deeper structural problem which has plagued the Organization for years. Staff on short-term contracts (over 20% of all WHO staff) are particularly vulnerable. Most of these are supported by specified (earmarked) voluntary funding, making them vulnerable to job loss and in the present context, limiting the flexibility of the Organization to re-assign then to critical pandemic-related tasks. While the Representative of the WHO staff associations (EB 148 /INF./2) notes that "… plans to improve the use of existing contractual arrangements, in particular regarding temporary appointments …" are underway, it is unlikely that that significant progress can be made until the WHO's dependence on voluntary specified contributions and reliance on private sector financing can be addressed (also see People's Health Movement, Medact, Third World Network et al. "Money Talks at the World Health Organization." In Global Health Watch 5. Zed Books. London. 2017.)

To address this complex issue, the People's Health Movement recommends that:

- Member states must reverse the trend towards voluntary specified contributions and reliance on private sector financing.
- Payment of assessed contributions must be in full and on time.
- The maximum of allowed voluntary specified contributions per donor must be established at 50 per cent (of the total contribution by the donor).
- There should be agreement on a multi-year strategy to move towards a 50/50 ratio for voluntary flexible and voluntary specified contributions.
- A threshold of assessed or voluntary flexible contributions must be set for eligibility to make voluntary specified contributions (VCS). For member states, no VCs should be allowed unless fully paid up on assessed contributions. For non-state partners, no VCs to be allowed unless an equal voluntary flexible contribution is made.
- Contributions from non-state 'partners' must be accompanied with signed agreements that guarantee commitment to UN standards, in particular to not engage in other programmes and funding that undermine the achievement of the WHO and UN mandates, including the achievement of the Sustainable Development Goals (SDGs). Violations would result in expulsion from partnerships and forfeiture of contributions, and non-eligibility for contractual and procurement options.
- The Framework for Engagement with Non-State Actors (FENSA) must be refined to distinguish between non-state partners in general and dominant donors. The latter need to comply with a distinct agreement as befits their size and influence.