

Third report of Committee A

(Draft)

Committee A held its third, fourth and fifth meetings on 24 and 25 May 2022 chaired by Dr Hiroki Nakatani (Japan), Dr Maryam Abdool-Richards (Trinidad and Tobago) and Dr Tamar Gabunia (Georgia).

It was decided to recommend to the Seventy-fifth World Health Assembly the adoption of the attached two decisions and two resolutions relating to the following agenda items:

Pillar 4: More effective and efficient WHO providing better support to countries

13. Sustainable financing: report of the Working Group

One decision entitled:

- Sustainable financing

Pillar 2: One billion more people better protected from health emergencies

16. Public health emergencies: preparedness and response

16.2 Strengthening WHO preparedness for and response to health emergencies

One decision

One resolution entitled:

- Strengthening health emergency preparedness and response in cities and urban settings

One resolution entitled:

- Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination

Agenda item 13

Sustainable financing

The Seventy-fifth World Health Assembly, having considered the report of the Working Group on Sustainable Financing, including its associated recommendations,¹

Decided:

- (1) to adopt the recommendations of the Working Group on Sustainable Financing, contained in Appendix 2 to the report of the Working Group on Sustainable Financing; and
- (2) to request the Director-General to put in place measures to ensure the implementation of these recommendations.

¹ Document A75/9.

Agenda item 16.2

Strengthening WHO preparedness for and response to health emergencies

The Seventy-fifth World Health Assembly, having considered the report of the Member States Working Group on Strengthening WHO Preparedness and Response to Health Emergencies,¹

Decided:

- (1) to welcome the report;
- (2) with respect to targeted amendments to the International Health Regulations (2005),
 - (a) to continue the Working Group on strengthening WHO Preparedness and Response to Health Emergencies, with a revised mandate, including as appropriate and if agreed within each region, the rotation of the Bureau, and name (the “Working Group on amendments to the International Health Regulations (2005)” (WGIHR)) to work exclusively on consideration of proposed targeted amendments to the International Health Regulations (2005), consistent with decision EB150(3) (2022), for consideration by the Seventy-seventh World Health Assembly in 2024;
 - (b) to request the Director-General to convene an Review Committee on the International Health Regulations (2005) (IHR Review Committee), as early as possible but no later than 1 October 2022, in accordance with Part IX, Chapter III of the International Health Regulations (2005), in particular Article 50, paragraphs 1(a) and 6, with particular attention to be paid to the fulfilment of the letter and spirit of Article 51, paragraph 2, to make technical recommendations on the proposed amendments referred to in subparagraph (c) below, with a view to informing the work of the WGIHR;
 - (c) to invite proposed amendments to be submitted by 30 September 2022. All such proposed amendments to be communicated by the Director-General to all States Parties without delay;
 - (d) to request the WGIHR to convene its organizational meeting no later than 15 November 2022, and to coordinate with the process of the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (INB), including through regular coordination between the two Bureaus and alignment of meeting schedules and workplans, as both the International Health Regulations (2005) and the new instrument are expected to play central roles in pandemic prevention, preparedness and response in the future;
 - (e) to request that the IHR Review Committee submit its report to the Director-General no later than 15 January 2023, with the Director-General communicating it without delay to the WGIHR; and

¹ Document A/75/17.

(f) to request the WGIHR to establish a programme of work, consistent with decision EB150(3), and taking into consideration the report of the IHR Review Committee, to propose a package of targeted amendments, for consideration by the Seventy-seventh World Health Assembly, in accordance with Article 55 of the International Health Regulations (2005);

(3) to encourage Member States to continue to review and consider the possible actions contained in Appendix 3 of document A75/17, in relation to health emergency prevention, preparedness and response, including through relevant ongoing WHO governing body processes, while noting that those possible actions are complementary and additional to existing mandates already under implementation by the Secretariat;

(4) to request the Director-General:

(a) to submit a report to the Seventy-sixth World Health Assembly, under a substantive agenda item, on:

(i) the Secretariat's progress to implement actions which have been previously mandated by WHO's governing bodies and which are related to the activities mentioned in paragraph 3, in accordance with existing reporting requirements; and

(ii) as appropriate, views from the WHO Secretariat on possible modalities for carrying forward the activities mentioned in paragraph 3 which are not presently under implementation; and

(b) to support the WGIHR, by (i) convening its first meeting no later than 15 November 2022, and subsequent meetings at the request of the co-Chairs as frequently as necessary; and (ii) providing the WGIHR with the necessary services and facilities for the performance of its work, and complete, relevant and timely information and advice.

Agenda item 16.2

Strengthening health emergency preparedness and response in cities and urban settings

The Seventy-fifth World Health Assembly,

Recalling Member States' commitments to the Sustainable Development Goals, including to strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks;

Recalling the Thirteenth General Programme of Work, 2019–2023, and its strategic priority of one billion more people better protected from health emergencies by 2023;

Recalling resolution WHA73.1 (2020) on COVID-19 response, in which the Seventy-third World Health Assembly requested the Director-General to, inter alia, continue to build and strengthen the capacities of WHO at all levels to fully and effectively perform the functions entrusted to it under the International Health Regulations (2005);

Recalling also resolution WHA73.8 (2020) on strengthening preparedness for health emergencies: implementation of the International Health Regulations (2005), which recognizes that urban settings are especially vulnerable to infectious disease outbreaks and epidemics, and that urban planning is a key element of preparedness and response;

Reaffirming resolution WHA74.7 (2021) on strengthening WHO preparedness for and response to health emergencies, which underlines that preparing for and responding to health emergencies is primarily the responsibility and crucial role of governments;

Recognizing the important role that cities and local authorities have in preventing, preparing for and responding to health emergencies;

Acknowledging the High-level Conference on Preparedness for Public Health Emergencies: Challenges and Opportunities in Urban Areas held in Lyon, France, on 3–4 December 2018, which acknowledged that urbanization leads to new challenges for global health and that multisectoral coordination, including that at local level, and engagement of local authorities and local communities, as well as urban leaders, play an important role in emergency preparedness and response;

Recognizing the work of the technical working group on advancing health emergency preparedness in cities and urban settings in COVID-19 and beyond,¹ which led to the development of the framework for strengthening health emergency preparedness in cities and urban settings² and the operational guidance for national and local authorities,³ and encouraging broader engagement of Member States in the discussions within this technical working group;

¹ WHO and the Government of Singapore co-hosted the virtual technical working group from February to April 2021 to advance the topic.

² <https://apps.who.int/iris/handle/10665/348351>, accessed 12 May 2022.

³ <https://apps.who.int/iris/handle/10665/351721>, accessed 12 May 2022.

Noting with concern that the COVID-19 pandemic has revealed serious shortcomings in preparedness – especially at the city and urban levels – for timely and effective prevention and detection of, as well as response to, potential health emergencies, including in the capacity and resilience of health systems, indicating the need to better prepare for future health emergencies;

Stressing the key role of coordination between the national, regional and local levels, as well as of effective community engagement, in preparedness for and response to health emergencies;

Highlighting the disruptions caused by the COVID-19 pandemic and public health measures taken in response to the pandemic on cities and urban settings, including in informal settlements;

Highlighting the concern regarding lack of adequate resources for health emergency preparedness and response, particularly at the subnational level, and that resources available are predominantly at the national level,

1. URGES Member States:¹

- (1) to sustain political commitment at the highest level and to give due attention to preparedness for and response to health emergencies in cities and urban settings, recognizing their unique vulnerabilities;
- (2) to provide adequate resources and to strengthen capacities and capabilities in urban health emergency preparedness and response;
- (3) to strengthen multisectoral, multilevel and multistakeholder collaboration in national health emergency preparedness and response policies;
- (4) to develop, strengthen and implement health emergency preparedness and response plans, recognizing that such plans should be context specific, given the heterogeneity of cities and urban settings;
- (5) to consider conducting simulation exercises and intra- and after-action reviews through adopting a multisectoral, multilevel and multistakeholder approach;
- (6) to collaborate and support learning and sharing of good practices with international partners including national public health institutes, the WHO Global Strategic Preparedness Network, and other relevant national and international organizations working on the urban health emergency preparedness agenda;

¹ And, where applicable, regional economic integration organizations.

2. REQUESTS the Director-General:

- (1) to provide technical support to Member States,¹ upon request, to strengthen capacities and capabilities in urban health emergency preparedness and response;
- (2) to take appropriate measures for securing adequate financial and human resources at all levels of WHO for providing this support, in line with the priorities of the Thirteenth General Programme of Work, 2019–2023;
- (3) to provide support to Member States, upon their request, in the implementation of the framework for strengthening health emergency preparedness in cities and urban settings;
- (4) to submit a progress report on the implementation of this resolution to the Seventy-seventh World Health Assembly in 2024.

¹ And, where applicable, regional economic integration organizations.

Agenda item 16.2

Strengthening clinical trials¹ to provide high-quality evidence on health interventions and to improve research quality and coordination

The Seventy-fifth World Health Assembly,

Recalling resolutions WHA58.34 (2005) acknowledging that high-quality, ethical research and the generation and application of knowledge are critical in achieving internationally agreed health-related development goals, WHA63.21 (2010) outlining WHO's role and responsibilities in health research, WHA66.22 (2013) and WHA69.23 (2016) on the follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, WHA67.20 (2014) on regulatory system strengthening for medical products, WHA67.23 (2014) on health intervention and technology assessment in support of universal health coverage, WHA74.6 (2021) on strengthening local production of medicines and other health technologies to improve access, and WHA74.7 (2021) on strengthening WHO preparedness for and response to health emergencies, which notes the importance of basic and clinical research and recognizes the critical role of international collaboration in research and development, including in multicountry clinical and vaccine trials, as well as rapid diagnostics test and assay development, while acknowledging the need for further rigorous scientific evidence;

Noting the recommendations made by the Independent Panel for Pandemic Preparedness and Response in their review "COVID-19: make it the last pandemic"² relating to health research and development, including clinical trials;

Recognizing that well-designed³ and well-implemented clinical trials are indispensable for assessing the safety and efficacy of health interventions;

Noting the role of clinical trials in the development of safe and efficacious new health interventions, and in informing associated comparative cost-effectiveness evaluations vis-à-vis existing interventions with a view to promoting the affordability of health products;

¹ "A clinical trial is defined by WHO as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials." Joint statement on public disclosure of results from clinical trials, 2017 (<https://www.who.int/news/item/18-05-2017-joint-statement-on-registration>, accessed 25 May 2022).

² Independent Panel for Pandemic Preparedness and Response. COVID-19: make it the last pandemic, 2021 (https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf, accessed 25 May 2022).

³ Throughout this resolution "well-designed trials" refers to trials that are scientifically and ethically appropriate. For submission to medical product regulatory authorities, trials should adhere to International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use guidelines and some Member States may consider International Coalition of Medicines Regulatory Authorities guidelines. In order to generate evidence that is robust enough to support decision-making, such as widespread use of therapeutics or preventives, trials should be designed, conducted, analysed and reported appropriately. A well-designed trial must also be practically feasible to conduct.

Noting also that clinical trials on new health interventions are likely to produce the clearest result when carried out in diverse settings, including all major population groups the intervention is intended to benefit, with a particular focus on under-represented populations;

Recognizing the potential benefits available from collaboration, coordination and the exchange of information between public and non-public funders of clinical trials, while actively preventing and managing conflicts of interest, and noting the potential benefits from public and non-public funders of clinical trials taking steps to ensure funding is targeted towards well-designed and well-implemented clinical trials that will produce actionable evidence regarding health interventions that address public health priorities and in particular the health needs of developing countries, such as neglected tropical diseases, while seeking to strengthen the capability in developing countries to conduct scientifically and ethically sound clinical trials;

Recognizing also the essential contribution of clinical trial participants;

Underscoring that clinical trials should be health-needs driven, evidence based, well designed, well implemented and be guided by established ethical guidance, including principles of fairness, equity, justice, beneficence and autonomy; and that clinical trials should be considered a shared responsibility;

Acknowledging the importance of promoting equity in clinical trial capability, including by enhancing the core competencies of research personnel, ensuring human subject protections from the risks of clinical trials and acknowledging the shared benefits from the results generated from clinical research and development, including clinical trials, both by strengthening the clinical trial global ecosystem to evaluate health interventions and by working to strengthen country capacities to conduct clinical trials that provide the highest protections to human subjects and meet relevant regulations and internationally harmonized standards by considering: (a) systematic assessment of country-level clinical trial capabilities to promote the ability to conduct rigorous clinical trials compliant with international guidelines and the ability to safeguard human subjects; (b) strengthened global clinical trial capabilities, in coordination with existing organizations and structures, in order to promote well-designed and well-implemented clinical trials that produce high-quality evidence, as well as to ensure trials are designed to reflect the heterogeneity of those who will ultimately use or benefit from the intervention being evaluated, and are conducted in diverse settings, including all major population groups the intervention is intended to benefit, with a particular focus on under-represented populations; (c) where possible, inclusion of all trial stakeholders, including representatives of patient groups, according to best practices in the development of clinical trials with affected communities to ensure that the health interventions address their needs, such as solutions on neglected tropical diseases; (d) that clinical trial participants include all major population groups that the intervention is intended to benefit; (e) promoting transparent and voluntary sharing, while ensuring information and data security, both of well-designed clinical trial methodologies and the results of clinical trials, including negative results, through open-source methods internationally to enable capability-building in diverse settings; and (f) that regulatory measures and other related processes be solidly defined and implemented, including for public health emergencies of international concern;

Recognizing that data from clinical trials play an important role in informing cost-effectiveness assessments of new health interventions and their comparison with existing interventions in order to assess their affordability within the context of national health systems,

1. CALLS ON Member States,¹ in accordance with their national and regional legal and regulatory frameworks and contexts and, as appropriate:

- (1) to prioritize the development and strengthening of national clinical trial capabilities able to comply with international standards of trial design and conduct and human subject protections as well as strengthening and developing national regulatory and quality-control frameworks and authorities;
- (2) to increase clinical trials capability, and strengthen clinical trials policy frameworks, particularly in developing countries, to enable a greater number of clinical trial sites that can conduct well-designed and well-implemented clinical trials, and to ensure readiness for coordination of trials through existing, new or expanded clinical trial networks that meet relevant regulations and internationally harmonized standards, promoting sharing of information and best practices on efficient and ethical clinical trial design and delivery, and in designing, preparing and conducting clinical trials;
- (3) to coordinate clinical trials research priorities based on public health needs of Member States including collaborative and, as appropriate, multicountry and multiregional clinical trials when mutually beneficial, while avoiding unnecessary duplication of work, taking into account that aligning clinical trials across countries will require preparatory work, including the coordination, as appropriate, in national regulatory practices and funding frameworks;
- (4) to collaborate with private-sector funders and academic institutions, while actively preventing and managing conflicts of interest, to encourage the targeting of clinical trials towards the development of health interventions that address public health priorities and concerns of global, regional and national importance including communicable and noncommunicable diseases, with a focus on the health needs of developing countries, and that evaluate the safety and efficacy of health interventions, including having special regard to common diseases in low- and middle-income countries, unmet medical needs, rare diseases and neglected tropical diseases;
- (5) to note and, as appropriate, benefit from the potential role of regional organizations in coordinating clinical trials and recruiting participants;
- (6) to encourage research funding agencies to prioritize and fund clinical trials that are well-designed and well-implemented, conducted in diverse settings and include all major population groups the intervention is intended to benefit, have adequate statistical power, and relevant control groups and interventions in order to generate the scientifically robust and actionable evidence needed to inform public health policy, regulatory decisions and medical practice while preventing underpowered, poorly designed clinical trials and avoiding the exposure of clinical trials participants to unjustified and unnecessary risk, in normal times as well as in public health emergencies of international concern, including through:
 - (a) encouraging investment in well-designed clinical trials, including through clinical trials networks that are developed in collaboration with affected communities, with a view to addressing their public health needs and with the potential for trials to contribute to clinical trial capabilities, including strengthening the core competencies of research personnel, particularly in developing countries;

¹ And, where applicable, regional economic integration organizations.

- (b) introducing grant conditions for funding clinical trials to encourage the use of standardized data protocols where available and appropriate and to mandate registration in a publicly available clinical trial registry within the WHO International Clinical Trials Registry Platform or any other registry that meets its standards;
 - (c) promoting, as appropriate, measures to facilitate the timely reporting of both positive and negative interpretable clinical trial results in alignment with the joint statement on public disclosure of results from clinical trials¹ and the International Coalition of Medicines Regulatory Authorities and WHO joint statement on transparency and data integrity,² including through registering the results on a publicly available clinical trial registry within the WHO International Clinical Trials Registry Platform and encouraging timely publication of the trial results, preferably in an open-access publication;
 - (d) promoting transparent translation of results, including comparison with existing treatments and data on effectiveness, based on thorough assessment, into clinical guidelines where appropriate;
 - (e) exploring measures during public health emergencies of international concern to encourage researchers to rapidly and responsibly share interpretable results of clinical trials, including negative results, with national regulatory bodies or other appropriate authorities, including WHO, for clinical guideline development and emergency use listing, to support rapid regulatory decision-making and emergency adaptation of clinical and public health guidelines as appropriate, including through pre-print publication;
- (7) to support ethics committees and regulatory authorities to enable efficient governance processes to focus on the fundamental scientific and ethical principles that underpin randomized controlled trials, maintaining patient and other trial participant protections, including personal data protection and acting proportionately to risk, to best support well-designed and well-implemented clinical trials and facilitate the development of preparedness for clinical trials including, when appropriate, multicountry trials during public health emergencies of international concern, where scientifically appropriate, while embracing flexibility and innovation;
- (8) to support new and existing mechanisms to facilitate rapid regulatory decision-making during public health emergencies of international concern, so that:
- (a) safe, ethical, well-designed clinical trials can be approved and progress quickly;
 - (b) data from clinical trials can be assessed rapidly, including through WHO Emergency Use Listing procedure, and health interventions deemed safe and effective swiftly authorized;

¹ Joint statement on public disclosure of results from clinical trials, 2017 (<https://www.who.int/news/item/18-05-2017-joint-statement-on-registration>, accessed 25 May 2022).

² International Coalition of Medicines Regulatory Authorities and WHO joint statement on transparency and data integrity, 2021 ([https://www.who.int/news/item/07-05-2021-joint-statement-on-transparency-and-data-integrityinternational-coalition-of-medicines-regulatory-authorities-\(icmra\)-and-who](https://www.who.int/news/item/07-05-2021-joint-statement-on-transparency-and-data-integrityinternational-coalition-of-medicines-regulatory-authorities-(icmra)-and-who), accessed 25 May 2022).

(9) to facilitate – while protecting confidentiality of information when appropriate, in normal times as well as in public health emergencies of international concern – sharing among regulatory authorities of:

(a) their assessments of clinical trial protocols to enable the implementation of rigorous protocols in practice;

(b) assessment reports on health interventions with potential significance and public health importance to inform, when possible, decision-making processes in other countries, including for potential regulatory assessments and decisions related to the inclusion of health interventions in their national health system, as well as for safety monitoring;

(10) to support new and existing mechanisms to facilitate the rapid interpretation of data from clinical trials to develop or amend, as necessary, relevant guidelines during public health emergencies of international concern;

(11) to facilitate collaboration and synergies among actors, institutions and networks in the clinical evidence ecosystem throughout the continuum from clinical research to utilization of data from clinical trials in clinical practice through comparative evidence evaluations, evidence synthesis, health technology assessments, regulatory decisions, comparative cost-effectiveness analysis vis-à-vis existing health interventions and, as appropriate, development of evidenced based guidelines and monitoring of implementation in clinical practice;

2. INVITES nongovernmental international organizations and other relevant stakeholders to explore opportunities to coordinate research priorities, and promote investments in clinical trial research and the effective, equitable and timely deployment of resources and funding, while actively preventing and managing conflicts of interest, to support robust, quality clinical trials as well as to strengthen clinical trial research capacities globally, particularly in developing countries and for diseases disproportionately affecting developing countries;

3. REQUESTS the Director-General:

(1) to organize, in a transparent manner, stakeholder consultations, in line with the Framework of Engagement with Non-State Actors, with Member States, nongovernmental organizations including patient groups, private-sector entities including international business associations, philanthropic foundations and academic institutions, as appropriate, on the respective roles of WHO, Member States¹ and non-State actors, and to identify and propose to Member States, for consideration in governing bodies, best practices and other measures to strengthen the global clinical trials ecosystem, taking into account relevant initiatives where appropriate;

(2) to review existing guidance and develop, following the standard WHO processes, new guidance as needed on best practices for clinical trials, including on strengthening the infrastructure needed for clinical trials, to be applied in normal times and with provisions for application during a public health emergency of international concern, taking into account relevant initiatives and guidelines as appropriate, such as those led by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use and other organizations by providing, as appropriate:

¹ And, where applicable, regional economic integration organizations.

- (a) guidance on best practices to help to guide Member States' implementation of scientifically and ethically sound clinical trials within their national and regional contexts;
 - (b) guidance on best practices for non-State actors in the design and conduct of clinical trials and in strengthening the global clinical trials ecosystem to meet the needs of major population groups that the intervention is intended to benefit, with a particular focus on under-represented populations, developed in consultation with Member States¹ and relevant non-State actors;
- (3) to provide to Member States, on their request, guidance, taking into account relevant initiatives and guidelines, as appropriate, on best practices for developing the legislation, infrastructure and capabilities required for clinical trials taking into account national and regional contexts;
- (4) to engage with, as appropriate, relevant non-State actors in line with the Framework of Engagement with Non-State Actors to strengthen clinical trial capabilities, particularly in developing countries, on innovations that meet the needs of major population groups that the intervention is intended to benefit, with a particular focus on under-represented populations;
- (5) to present a substantive report outlining progress in the activities requested of the Director-General in this resolution for consideration by the Seventy-sixth World Health Assembly through the Executive Board at its 152nd session in 2023.

= = =

¹ And, where applicable, regional economic integration organizations.