


WHCA ACTION GUIDE

World Health Communication Associates



The “Unofficial” WHCA Action Guide to the:

WHO—68th

World Health Assembly

WHO—89th

A large, circular graphic is positioned on the left side of the central text. It contains a stylized globe with swirling lines in shades of blue, green, and red, suggesting global connectivity and movement. The text is centered and layered over this graphic and the background.

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The “Unofficial” World Health
Communication Associates (WHCA)
Action Guide to the:

WHO – 68th World Health Assembly

18–26 May 2015, Geneva

INTRODUCTION

This “unofficial” WHCA Action Guide is a compilation of information from the WHO website for the 68th World Health Assembly. It is presented for use by World Health Communication Associates (WHCA), World Health Professions Alliance (WHPA), World Health Editors Network (WHEN) members and participants in the **WHCA/WHEN 2015 Enhancing global health literacy: Journalism and Health Initiative** and is not intended for sale or general circulation. It includes useful information regarding the Assembly, including texts of key discussion papers and resolutions. It serves as a background document to the WHEN workshop and mentoring activities during WHA68 in Geneva, 16–21 May 2015. Video and presentations from these activities will be published on the WHCA/WHEN website at www.whcaonline.org.

The aim of this year’s WHEN training and mentoring initiative is to raise journalist global health literacy; strengthen scientist–journalist communications; and explore the development of Regional Health Communication networks that can enhance epidemic coverage and serve as watchdogs to monitor global health commitments. Senior journalists attending the training are joined by student journalists selected through a competition amongst UK-based and other European schools of journalism: see <http://www.whcaonline.org/when/2014-when-world-health-assembly.html>.

A big thank you to WHCA Associates Carinne Allinson and Tuuli Sauren for the compilation and design of this document. We would also like to thank the Swiss Agency for Development and Cooperation, the World Health Professions Alliance (WHPA), the Graduate Institute of Geneva Global Health Programme and the International Federation of Pharmaceutical Manufacturers (IFPMA) for their support of the WHEN initiatives.

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The **World Health Editors Network** (WHEN) is an international, inter-professional exchange and action platform dedicated to exploring and strengthening communications as a positive determinant of health. Through participation in events, editors get early access to global health news and experts and importantly, key international health agency agenda-setting intelligence. WHEN development is being facilitated by the World Health Professional Alliance and its constituent association members, including the International Council of Nurses (ICN), the International Pharmaceutical Federation (FIP), the FDI World Dental Federation, and the World Medical Association (WMA). WHCA serve as Secretariat to WHEN.

The **World Health Communication Associates** (www.whcaonline.org) works to improve health by helping public health advocates and organisations acquire the knowledge, savvy and resources to enable their messages to stand out and positively shape health choices, behaviours and perceptions in local, national and global information marketplaces. WHCA focuses exclusively on health and

environmental issues and does no product promotion. The Associates are an independent network of active, strategically placed communicators, with practical experience in health and environment reporting, investigative journalism, policy advocacy, intergovernmental and nongovernmental public and press relations, international conference organisation and cross-border campaigning.

The MediaWise Trust (www.mediawise.org.uk) was set up in 1993 by victims of 'media abuse' to assist those affected by inaccurate, intrusive or unethical journalism in the UK. It provides advice, information, research and training on media ethics and now operates internationally to improve standards of journalism. Its specialisms include reporting on children, suicide, diversity and migration issues, as well as press freedom, media accountability and health communications. It works with journalism organisations and UN agencies and has been a long-term partner with WHCA and WHEN.

The News Minute (www.thenewsminute.com) is among a handful of English news portals in India that have been launched recently. It seeks to bring journalism back to where it belongs – in the realm of public service, accountable to the public, as a vibrant fourth pillar of democracy. Towards this goal, the portal holds all actors in society – from governments to NGOs, academics, the private sector and the media most importantly – responsible for progress or lack of it in any area of development and economic growth. The News Minute has a special focus on public health and the promoters and editors believe public health is also a public good. To focus on public health, a special platform called Media's pH Value has been launched to bring together the world of journalism and public health in a coherent and mutually respectful manner in order to build a responsible dialogue on issues ranging from disease-burden to funding and government policies.

TABLE OF CONTENTS

Introduction

Section I : Introduction to the WHO World Health Assembly

Section II : Overview of the 68th World Health Assembly agenda

Section III : Selected Agenda discussion topics, decisions and resolutions – to be discussed in Committee A – Agenda items 13–17

- 13. **Noncommunicable diseases**
 - 13.1 Outcome of the Second International Conference on Nutrition
 - 13.5 Global burden of epilepsy and need for a coordinated action at the country level to address its health, social and public knowledge implications
- 14. **Promoting health through the life course**
 - 14.2 Health in the post-2015 development agenda
 - 14.5 Contributing to social and economic development: sustainable action across sectors to improve health and health equity (follow-up of the 8th Global Conference on Health Promotion)
 - 14.6 Health and the environment: addressing the health impact of air pollution
- 15. **Preparedness, surveillance and response**
 - 15.1 Antimicrobial resistance
 - 15.3 Implementation of the International Health Regulations (2005)
 - 15.4 WHO response in severe, large-scale emergencies
- 16. **Communicable diseases**
 - 16.1 2014 Ebola virus disease outbreak and follow-up to the Special Session of the Executive Board on Ebola
 - 16.2 Malaria: draft global technical strategy: post 2015
 - 16.4 Global vaccine action plan
- 17. **Health systems**
 - 17.1 Strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage
 - 17.3 Substandard/spurious/falsely-labelled/falsified/counterfeit medical products
 - 17.5 Global strategy and plan of action on public health, innovation and intellectual property

ANNEX 1. STRUCTURE OF WHO

ANNEX 2. INFORMATION OFFICERS

SECTION I : INTRODUCTION TO WHO AND THE WORLD HEALTH ASSEMBLY

(Adapted from WHO website, www.who.int, accessed April 2015)

The World Health Organization (WHO) is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.

WHO experts produce health guidelines and standards, and help countries to address public health issues. WHO also supports and promotes health research. Through WHO, governments can jointly tackle global health problems and improve people's well-being. WHO's Constitution came into force on 7 April 1948 – a date now celebrated every year as World Health Day. WHO and its Member States work with many partners, including UN agencies, donors, nongovernmental organisations, WHO collaborating centres and the private sector.

World Health Assembly

The World Health Assembly is the supreme decision-making body for WHO. It generally meets each year in May in Geneva and is attended by delegations from all 194 Member States. Its main function is to determine the policies of the Organization. The Health Assembly appoints the Director-General, supervises the financial policies of the Organization, and reviews and approves the Proposed programme budget. It similarly considers reports of the Executive Board, which it instructs in regard to matters upon which further action, study, investigation or report may be required. All World Health Assembly documentation is available at <http://apps.who.int/gb/>.

Executive Board

The Executive Board is composed of 34 members technically qualified in the field of health. Members are elected for three-year terms. The main Board meeting, at which the agenda for the forthcoming Health Assembly is agreed upon and resolutions for forwarding to the Health Assembly are adopted, is held in January, with a second shorter meeting in May, immediately after the Health Assembly, for more administrative matters. The main functions of the Board are to give effect to the decisions and policies of the Health Assembly, to advise it and generally to facilitate its work. All Executive Board documentation is available at <http://apps.who.int/gb/>.

WHO Staff

More than 7000 people from more than 150 countries work for the Organization in 150 offices in countries, territories and areas, six regional offices (see Annex 1) and at the headquarters in Geneva, Switzerland. In addition to medical doctors, public health specialists, scientists and epidemiologists, WHO staff include people trained to manage administrative, financial, and information systems, as well as experts in the fields of health statistics, economics and emergency relief.

Regional Committees

The six WHO Regional Committees meet separately once every year to set policy and approve budgets and programmes of work for their respective regions. Each meeting addresses the specific public health needs of the area represented by the region.

SECTION II : OVERVIEW OF THE 68TH WORLD HEALTH ASSEMBLY AGENDA

Provisional Agenda

PLENARY

1. Opening of the Assembly
 - 1.1 Appointment of the Committee on Credentials
 - 1.2 Election of the President
 - 1.3 Election of the five Vice-Presidents, the Chairmen of the main committees, and establishment of the General Committee
 - 1.4 Adoption of the agenda and allocation of items to the main committees
2. Reports of the Executive Board on its 135th and 136th sessions
3. Address by Dr Margaret Chan, Director-General
4. Invited speaker
5. Admission of new Members and Associate Members [if any]
6. Executive Board: election
7. Awards
8. Reports of the main committees
9. Closure of the Health Assembly

COMMITTEE A

10. Opening of the Committee¹
11. WHO reform
 - 11.1 Overview of reform implementation
 - 11.2 Framework of engagement with non-State actors
12. Programme and budget matters
 - 12.1 Implementation and financing of Programme budget 2014–2015: mid-term review
 - 12.2 Proposed programme budget 2016–2017
13. **Noncommunicable diseases**
 - 13.1 Outcome of the Second International Conference on Nutrition
 - 13.2 Maternal, infant and young child nutrition: development of the core set of indicators
 - 13.3 Update on the Commission on Ending Childhood Obesity
 - 13.4 Follow-up to the 2014 high-level meeting of the United Nations General Assembly to undertake a comprehensive review and assessment of the progress achieved in the prevention and control of noncommunicable diseases
 - 13.5 Global burden of epilepsy and need for a coordinated action at the country level to address its health, social and public knowledge implications
14. **Promoting health through the life course**
 - 14.1 Monitoring the achievement of the health-related Millennium Development Goals
 - 14.2 Health in the post-2015 development agenda
 - 14.3 Adolescent health

¹ Including election of Vice-Chairmen and the Rapporteur.

- 14.4 Women and health: 20 years of the Beijing Declaration and Platform for Action
- 14.5 Contributing to social and economic development: sustainable action across sectors to improve health and health equity (follow-up of the 8th Global Conference on Health Promotion)
- 14.6 Health and the environment: addressing the health impact of air pollution
- 15. **Preparedness, surveillance and response**
 - 15.1 Antimicrobial resistance
 - 15.2 Poliomyelitis
 - 15.3 Implementation of the International Health Regulations (2005)
 - 15.4 WHO response in severe, large-scale emergencies
- 16. **Communicable diseases**
 - 16.1 2014 Ebola virus disease outbreak and follow-up to the Special Session of the Executive Board on Ebola²
 - 16.2 Malaria: draft global technical strategy: post 2015
 - 16.3 Dengue: prevention and control
 - 16.4 Global vaccine action plan
- 17. **Health systems**
 - 17.1 Strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage
 - 17.2 WHO Global Code of Practice on the International Recruitment of Health Personnel
 - 17.3 Substandard/spurious/falsely-labelled/falsified/counterfeit medical products
 - 17.4 Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination
 - 17.5 Global strategy and plan of action on public health, innovation and intellectual property
- 18. **Progress reports**
 - Noncommunicable diseases**
 - A. Comprehensive mental health action plan 2013–2020 (resolution WHA66.8)
 - B. Comprehensive and coordinated efforts for the management of autism spectrum disorders (resolution WHA67.8)
 - C. Disabling hearing loss (resolution WHA48.9)
 - Communicable diseases**
 - D. Eradication of dracunculiasis (resolution WHA64.16)
 - E. Elimination of schistosomiasis (resolution WHA65.21)
 - F. Neglected tropical diseases (resolution WHA66.12)
 - G. Prevention and control of sexually transmitted infections: global strategy (resolution WHA59.19)
 - Promoting health through the life course**
 - H. Newborn health (resolution WHA67.10)
 - I. Working towards universal coverage of maternal, newborn and child health interventions (resolution WHA58.31)

² Resolution EBSS3.R1 on Ebola: ending the current outbreak, strengthening global preparedness and ensuring WHO's capacity to prepare for and respond to future large-scale outbreaks and emergencies with health consequences.

- J. Implementation of the recommendations of the United Nations Commission on Life-Saving Commodities for Women and Children (resolution WHA66.7)

Health systems

- K. Social determinants of health (resolution WHA65.8)
L. Sustainable health financing structures and universal coverage (resolution WHA64.9)
M. Strategy for integrating gender analysis and actions into the work of WHO (resolution WHA60.25)
N. Progress in the rational use of medicines (resolution WHA60.16)

Preparedness, surveillance and response

- O. Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits (resolution WHA64.5)
P. Smallpox eradication: destruction of variola virus stocks (resolution WHA60.1)

COMMITTEE B

19. Opening of the Committee³
20. Health conditions in the occupied Palestinian territory, including east Jerusalem, and in the occupied Syrian Golan
21. Financial matters
 21.1 Financial report and audited financial statements for the year ended 31 December 2014
 21.2 Status of collection of assessed contributions, including Member States in arrears in the payment of their contributions to an extent that would justify invoking Article 7 of the Constitution
 21.3 Special arrangements for settlement of arrears [if any]
 21.4 Scale of assessments for 2016–2017
 21.5 Assessment of new Members and Associate Members [if any]
22. Audit and oversight matters
 22.1 Report of the External Auditor
 22.2 Report of the Internal Auditor
 22.3 Appointment of the External Auditor
23. Staffing matters
 23.1 Human resources
 23.2 Report of the International Civil Service Commission
 23.3 Amendments to the Staff Regulations and Staff Rules
 23.4 Report of the United Nations Joint Staff Pension Board
 23.5 Appointment of representatives to the WHO Staff Pension Committee
24. Management matters
 24.1 Real estate: update on the Geneva buildings renovation strategy
25. Collaboration within the United Nations system and with other intergovernmental organizations

³ Including election of Vice-Chairmen and the Rapporteur.

SECTION III : SELECTED AGENDA DISCUSSION TOPICS, DECISIONS AND RESOLUTIONS

13. Noncommunicable diseases

13.1 Outcome of the Second International Conference on Nutrition

Document A68/8 (Report by the Director-General):

Outcome of the Second International Conference on Nutrition

1. This report responds to the request of the Executive Board in decision EB134(2) in January 2014 to the Director-General to report to the Sixty-eighth World Health Assembly, through the Board at its 136th session, on the outcome of the Second International Conference on Nutrition. The Executive Board at its 136th session considered an earlier version of this report.⁴ The Board also adopted decision EB136(4).⁵ In response to comments made by Member States during the discussions, further clarifications have been made to paragraphs 27 and 34. The Secretariat has also modified paragraph 32 to reflect the continuing process at the United Nations General Assembly.

2. The joint working group established by the Director-General in response to decision EB134(2) to prepare a draft outcome document for the Conference met several times. Its output, namely the draft political declaration and framework for action, was finalized by an open-ended working group of Member States that met in Rome on 10–12 October 2014.

3. The Conference was held in Rome on 19–21 November 2014. Participants included representatives of 164 Members of FAO and WHO, observers (including United Nations and other intergovernmental organizations), ministers and other high-level government officials, special guests and civil society and private sector organizations, totalling more than 2200 people. Over the two days before the Conference special meetings were organized for civil society organizations, private sector representatives and parliamentarians. The Conference itself included thematic roundtables and side events.

4. At its first session, the Conference adopted the two outcome documents, namely the Rome Declaration on Nutrition (Annex 1) and its companion Framework for Action (Annex 2).

OUTCOME DOCUMENTS

Context

5. The Rome Declaration acknowledges that undernutrition, vitamin and mineral deficiencies, obesity and diet-related noncommunicable diseases are global challenges, that different forms of malnutrition coexist within most countries, that current food systems are being increasingly challenged to provide adequate, safe, diversified and nutrient-rich food for all, and that trade policies are to be conducive to fostering food security and nutrition for all. It recognizes that the root causes of malnutrition are complex and multidimensional, and expresses deep concern that, notwithstanding significant achievements in many countries, recent decades have seen modest and uneven progress in reducing malnutrition in all its forms. It sets out a vision for a world with coherent policies to promote a diversified, balanced and healthy diet at all stages of life, with

⁴ See document EB136/8, and the summary records of the Executive Board at its 136th session, twelfth meeting, section 2.

⁵ See document EB136/2015/REC/1 for the decision, and for the financial and administrative implications for the Secretariat of the adoption of the decision.

national health systems integrating nutrition, coordinated action among different actors and sectors, empowerment of consumers, and policies that pay special attention to women.

National commitments

6. The Rome Declaration reaffirms the commitments made at the first International Conference on Nutrition (in 1992), the World Food Summits held in 1996 and 2002, and the World Summit on Food Security (2009). It also reaffirms the commitment of WHO's Member States to attain the six global nutrition targets for 2025 adopted by the Health Assembly in May 2012⁶ and the nine global noncommunicable disease targets for 2025 adopted by the Health Assembly in May 2013.⁷

7. In paragraph 15 of the Rome Declaration Members of FAO and WHO commit themselves inter alia:

- to increase investments for effective interventions and actions to improve people's diets and nutrition, including in emergency situations;
- to develop coherent public policies from production to consumption and across relevant sectors to provide year-round access to food that meets people's nutrition needs and promote safe and diversified healthy diets;
- to raise the profile of nutrition within relevant national strategies, policies, action plans and programmes, and align national resources accordingly;
- to strengthen human and institutional capacities to address all forms of malnutrition;
- to strengthen and facilitate contributions and action by all stakeholders to improve nutrition and promote collaboration within and across countries;
- to develop policies, programmes and initiatives for ensuring healthy diets throughout the life course;
- to empower people and create an enabling environment for making informed choices about food products for healthy dietary practices and appropriate infant and young child feeding practices;
- to implement the commitments through the Framework for Action.

8. The Framework for Action recommends a set of 60 voluntary policy options and strategies that cover: an enabling environment; sustainable food systems promoting healthy diets; international trade and investment; nutrition education and information; social protection; health systems delivery of direct nutrition interventions and health services to improve nutrition; water, sanitation and hygiene; and food safety and antimicrobial resistance. The recommendations will be used as a benchmark to assess the implementation of the commitments.

International commitments

9. Paragraph 15 of the Rome Declaration also calls on Member States to give due consideration to integrating its vision and commitments into the post-2015 development agenda.

⁶ Resolution WHA65.6 on comprehensive implementation plan for maternal, infant and young child nutrition. See document WHA65/2012/REC/1, Annex 2 for the six global targets.

⁷ Resolution WHA66.10 on follow-up to the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, in which the Health Assembly endorsed the global action plan for the prevention and control of noncommunicable diseases 2013–2020. See document WHA66/2013/REC/1, Annex 4, Appendix 2 for the nine targets.

10. In paragraph 17 it recommends that the United Nations General Assembly endorse the Rome Declaration on Nutrition and the Framework for Action and that it consider declaring a Decade of Action on Nutrition from 2016 to 2025 within existing structures and available resources.

WHO's role in the follow-up to the conference

Technical assistance to Member States

11. Paragraph 16 of the Rome Declaration calls on FAO and WHO, in collaboration with other United Nations agencies, funds and programmes, as well as other international organizations, to support national governments, upon request, in developing, strengthening and implementing their policies, programmes and plans to address the multiple challenges of malnutrition.

12. The Secretariat, recognizing that policies for the different areas of the Framework for Action have not been developed equally in different countries, will provide support in several forms.

13. In 2015–2016, WHO will expand its evidence-informed guidance to cover the policy areas identified in the Framework for Action. In response to different recommendations, WHO will review and update the guidelines on healthy diets (recommendation 13), develop measures to gradually reduce the content of saturated fat, sugars and salt/sodium and trans-fat in foods and beverages (recommendation 14), review regulatory and voluntary instruments to promote healthy diets including the work of the Codex Alimentarius Commission (recommendation 15), establish food or nutrient-based standards to make accessible healthy diets and safe drinking water in public facilities (recommendation 16), develop measures to improve the availability and marketing of complementary foods (recommendation 39), review effective interventions on breastfeeding, childhood wasting, stunting, and overweight and women's anaemia (recommendations 29–43), develop or update international food safety guidance and standards including through the Codex Alimentarius Commission (recommendation 53 and 54).

14. In 2015, the Secretariat has started developing a series of policy papers that provide the rationale, operational details and necessary elements for the calculation of costs and benefits of the recommended policies. The policy papers will be discussed with Member States and development partners and will be the object of public consultations. The intention is that Member States will use them for advocacy purposes.

15. In 2015–2016, the Secretariat will facilitate the establishment of multilateral initiatives at global and regional levels aimed at sharing experience on implementing different policy approaches or legislative tools, following the model of the "Action networks" established by Member States in the WHO European Region. The aim of these initiatives, work on which is now under way, will be to accelerate the achievement of the six global nutrition targets endorsed by the Health Assembly and thus may focus on recommendations 29–43 in the Framework (see paragraph 14). They will build on the policy briefs developed for the six global nutrition targets and launched in November 2014.⁸

16. In 2015–2016, the Secretariat, jointly with FAO, will complete the end-of-project evaluation of the FAO/WHO Project and Fund for Enhanced Participation in Codex (Codex Trust Fund) and launch a successive initiative in order to continue to support Member States' participation in Codex activities (recommendation 54). Also jointly with FAO, it will continue to encourage Member States to participate in the activities of International Food Safety Authorities Network (recommendation 55).

⁸ WHA Global Nutrition Targets 2025: policy brief series. http://www.who.int/nutrition/topics/nutrition_globaltargets2025/en/ (accessed 3 December 2014).

17. In 2015, the Secretariat is submitting to the Health Assembly a draft global action plan to combat antimicrobial resistance,⁹ which has been developed through a consultative process and in collaboration with partner agencies, including FAO (recommendation 56).

18. In 2015–2016, the Secretariat will review WHO's guidance on primary care to ensure the inclusion of effective direct nutrition interventions or health interventions with an impact on nutrition (recommendations 44–49), including operational guidance and costing through use of the nutrition module of the OneHealth Tool.¹⁰

Supporting the engagement of other sectors than health in country nutrition plans

19. In response to recommendation 2 to support nutrition policy development in countries the Secretariat will collaborate with bodies in the United Nations system and other intergovernmental organizations to create a repository of examples of country nutrition plans as well as plans in agriculture and trade, social protection, education, health and the environment that are relevant to nutrition in 2015–2016. The repository will expand WHO's existing global database for the implementation of nutrition actions. The Secretariat will also develop guidelines for nutrition impact analysis of sectoral policies.

Contribution of the Secretariat to joint United Nations mechanisms

20. The Framework for Action calls on the United Nations system agencies, programmes and funds to coordinate policies, strategies and programmes within their respective mandates (recommendation 7). In order to provide integrated support, particularly in the development of multisectoral plans, the Secretariat will work through existing multiagency coordination mechanisms, currently the United Nations Standing Committee on Nutrition, the Renewed Efforts Against Child Hunger and undernutrition partnership, the High Level Task Force on the Food Security Crisis and the United Nations Inter-Agency Task Force on the Prevention and Control of Non-communicable Diseases. The Secretariat is working with all organizations in the United Nations system to make the interagency collaboration and joint country support more efficient and effective through the development of a United Nations global nutrition agenda and the adjustment of collaborative arrangements taking account of respective organizations' mandates.

Facilitation and enhancement of coordination of activities, multistakeholder engagement and action across sectors

21. The Framework for Action calls for the establishment of national cross-government, intersectoral, multistakeholder mechanisms for food security and nutrition to oversee implementation of policies, strategies, programmes and other investments in nutrition (recommendation 3). In 2015–2016 the Secretariat will be preparing a policy brief on different platforms, based on existing experience and good practices, to complement the risk assessment and management tools for conflict of interest.

22. At global level, the Secretariat is collaborating with the multistakeholder forums dealing with nutrition, including the Committee on World Food Security (through its Advisory Group), the Scaling Up Nutrition movement (through its United Nations Network for Scaling Up Nutrition), the global coordination mechanism on the prevention and control of noncommunicable diseases¹¹ (by providing technical contributions to the working groups).

⁹ See document A68/20.

¹⁰ WHO. Planning and costing nutrition actions: the OneHealth Tool. Geneva: World Health Organization; 2014 (document WHO/NMH/NHD/NPU/14.1).

¹¹ See document WHA67/2014/REC/3, summary record of seventh meeting of Committee A of the Sixty-seventh World Health Assembly, section 2.

23. The Secretariat will engage with civil society and the private sector, following the practice initiated during the preparation of the Conference, in line with the guidance to be provided by the Health Assembly on the interaction with non-State actors.

Mobilization of financial resources for the implementation of nutrition policies and programmes

24. The Framework for Action calls for an increase in responsible and sustainable investment in nutrition and the generation of resources through innovative financing tools (recommendation 4). The Secretariat will collaborate with existing mechanisms in order to facilitate the provision of resources for nutrition programmes and will contribute to the establishment of new funding facilities, as appropriate.

25. The Secretariat will also establish a dialogue with international financial institutions on the inclusion of a nutrition impact analysis for investments in agriculture.

Development of an accountability framework

26. Recommendation 59 of the Framework for Action calls for FAO and WHO to compile jointly reports on the implementation of the commitments of the Rome Declaration, in close collaboration with other United Nations agencies, funds and programmes and other relevant regional and international organizations, building on existing accountability frameworks.

27. Given the voluntary nature of the Framework for Action, the Secretariat will have to work with Member States to ensure that nutrition targets are established and will compile a register of the actions that Member States commit to implement in each of the areas indicated by the Framework for Action. For the purpose of accountability, the Framework for Action adopted existing global targets for improving maternal, infant and young child nutrition and for noncommunicable disease risk factor reduction to be achieved by 2025. Software to facilitate target-setting and tracking has been developed. Subsequently, a system of periodic assessment of compliance with the commitments will be established, based on country self-assessments.

28. The Secretariat will continue monitoring country progress and compile the information in its global database on the implementation of nutrition actions. The information will also be integrated with other information available through other monitoring and accountability mechanisms of country actions.

Reporting progress on implementation of the outcomes of the Conference

29. As requested in recommendation 60 in the Framework for Action, reports on the overall follow-up to the Conference should be included on the provisional agendas of the regular meetings of WHO's governing bodies, including the regional committees, possibly on a biennial basis. The Directors-General of FAO and WHO are also requested to transmit such reports to the United Nations General Assembly as appropriate.

30. The Secretariat will continue collaborating with other United Nations bodies, international organizations and other partners for the preparation of an annual Global Nutrition Report.

Endorsement

United Nations General Assembly

31. A draft resolution¹² entitled "Improving nutrition" was proposed for consideration by the General Assembly at its sixty-ninth session by the Plurinational State of Bolivia on behalf of States

¹² Document A/69/L.50, available at http://www.un.org/ga/search/view_doc.asp?symbol=A/69/L.50 (accessed 30 March 2015).

Members of the United Nations that are members of the G77, and China. It is expected that, in line with the draft resolution, the General Assembly will decide to endorse the outcome documents of the Second International Conference on Nutrition and to recommend that the Decade of Action on Nutrition (from 2016 to 2025) is proclaimed by the General Assembly at its seventieth session. With a view to reaching consensus on the draft resolution, the Permanent Mission of Ireland to the United Nations in New York has convened a series of informal consultations among Member States and has requested FAO and WHO, in full collaboration with other United Nations agencies, funds and programmes and other relevant regional and international organizations, to submit a draft concept note setting out the scope and purpose of the Decade for Action. In order to facilitate consideration of the Decade of Action on Nutrition by the United Nations General Assembly (see paragraph 10), the Secretariat may be asked to prepare a road map, including milestones, priority action for governments, international organizations and other actors, in consultation with other United Nations agencies, funds and programmes and other relevant regional and international organizations.

Interparliamentary Union

32. The special event for parliamentarians (Rome, 18 November 2014) urged the 132nd Inter-Parliamentary Union Assembly to include nutrition and the Second International Conference on Nutrition on its agenda and to endorse the outcome documents. The Secretariat will add its support.

Contribution to the post-2015 sustainable development agenda

33. The Secretariat has drafted a document that gives an extrapolation for 2030 of the 2025 global nutrition targets. Working with other organizations in the United Nations system, it has prepared a policy paper indicating potential areas for the inclusion of nutrition in the 17 currently proposed post-2015 sustainable development goals with relevant indicators.

ACTION BY THE HEALTH ASSEMBLY

34. Based on the recommendation of the Executive Board in decision EB136(4), the Health Assembly is invited to consider the following draft resolution:

The Sixty-eighth World Health Assembly,

1. ENDORSES the Rome Declaration on Nutrition, as well as the Framework for Action, which provides a set of voluntary policy options and strategies for use by governments;
2. CALLS on Member States¹³ to implement commitments of the Rome Declaration through a set of voluntary policy options within the Framework for Action;
3. REQUESTS the Director-General, in collaboration with the Director-General of FAO and other United Nations agencies, funds and programmes and other relevant regional and international organizations, to prepare a biennial report to the World Health Assembly on the status of implementation of commitments of the Rome Declaration on Nutrition.

¹³ And, where applicable, regional economic integration organizations.

ANNEX 1

ROME DECLARATION ON NUTRITION

Welcoming the participation of Heads of State and Government and other high-level guests,

1. We, Ministers and Representatives of the Members of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), assembled at the Second International Conference on Nutrition in Rome from 19 to 21 November 2014, jointly organized by FAO and WHO, to address the multiple challenges of malnutrition in all its forms and identify opportunities for tackling them in the next decades.
2. Reaffirming the commitments made at the first International Conference on Nutrition in 1992, and the World Food Summits in 1996 and 2002 and the World Summit on Food Security in 2009, as well as in relevant international targets and action plans, including the WHO 2025 Global Nutrition Targets and the WHO Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013-2020.
3. Reaffirming the right of everyone to have access to safe, sufficient, and nutritious food, consistent with the right to adequate food and the fundamental right of everyone to be free from hunger consistent with the International Covenant on Economic, Social and Cultural Rights and other relevant United Nations instruments.

Multiple challenges of malnutrition to inclusive and sustainable development and to health

4. Acknowledge that malnutrition, in all its forms, including undernutrition, micronutrient deficiencies, overweight and obesity, not only affects people's health and wellbeing by impacting negatively on human physical and cognitive development, compromising the immune system, increasing susceptibility to communicable and noncommunicable diseases, restricting the attainment of human potential and reducing productivity, but also poses a high burden in the form of negative social and economic consequences to individuals, families, communities and States.
5. Recognize that the root causes of and factors leading to malnutrition are complex and multidimensional:
 - a) poverty, underdevelopment and low socio-economic status are major contributors to malnutrition in both rural and urban areas;
 - b) the lack of access at all times to sufficient food, which is adequate both in quantity and quality which conforms with the beliefs, culture, traditions, dietary habits and preferences of individuals in accordance with national and international laws and obligations;
 - c) malnutrition is often aggravated by poor infant and young child feeding and care practices, poor sanitation and hygiene, lack of access to education, quality health systems and safe drinking water, foodborne infections and parasitic infestations, ingestion of harmful levels of contaminants due to unsafe food from production to consumption;
 - d) epidemics, such as of the Ebola virus disease, pose tremendous challenges to food security and nutrition.
6. Acknowledge that different forms of malnutrition co-exist within most countries; while dietary risk affects all socio-economic groups, large inequalities exist in nutritional status, exposure to risk and adequacy of dietary energy and nutrient intake, between and within countries.

7. Recognize that some socioeconomic and environmental changes can have an impact on dietary and physical activity patterns, leading to higher susceptibility to obesity and noncommunicable diseases through increasing sedentary lifestyles and consumption of food that is high in fat, especially saturated and trans-fats, sugars, and salt/sodium.
8. Recognize the need to address the impacts of climate change and other environmental factors on food security and nutrition, in particular on the quantity, quality and diversity of food produced, taking appropriate action to tackle negative effects.
9. Recognize that conflict and post conflict situations, humanitarian emergencies and protracted crises, including, *inter alia*, droughts, floods and desertification as well as pandemics, hinder food security and nutrition.
10. Acknowledge that current food systems are being increasingly challenged to provide adequate, safe, diversified and nutrient rich food for all that contribute to healthy diets due to, *inter alia*, constraints posed by resource scarcity and environmental degradation, as well as by unsustainable production and consumption patterns, food losses and waste, and unbalanced distribution.
11. Acknowledge that trade is a key element in achieving food security and nutrition and that trade policies are to be conducive to fostering food security and nutrition for all, through a fair and market-oriented world trade system, and reaffirm the need to refrain from unilateral measures not in accordance with international law, including the Charter of the United Nations, and which endanger food security and nutrition, as stated in the 1996 Rome Declaration.
12. Note with profound concern that, notwithstanding significant achievements in many countries, recent decades have seen modest and uneven progress in reducing malnutrition and estimated figures show that:
 - a) the prevalence of undernourishment has moderately declined, but absolute numbers remain unacceptably high with an estimated 805 million people suffering chronically from hunger in 2012–2014;
 - b) chronic malnutrition as measured by stunting has declined, but in 2013 still affected 161 million children under five years of age, while acute malnutrition (wasting) affected 51 million children under five years of age;
 - c) undernutrition was the main underlying cause of death in children under five, causing 45% of all child deaths in the world in 2013;
 - d) over two billion people suffer from micronutrient deficiencies, in particular vitamin A, iodine, iron and zinc, among others;
 - e) overweight and obesity among both children and adults have been increasing rapidly in all regions, with 42 million children under five years of age affected by overweight in 2013 and over 500 million adults affected by obesity in 2010;
 - f) dietary risk factors, together with inadequate physical activity, account for almost 10% of the global burden of disease and disability.

A common vision for global action to end all forms of malnutrition

13. We reaffirm that:

- a) the elimination of malnutrition in all its forms is an imperative for health, ethical, political, social and economic reasons, paying particular attention to the special needs of children, women, the elderly, persons with disabilities, other vulnerable groups as well as people in humanitarian emergencies;

- b) nutrition policies should promote a diversified, balanced and healthy diet at all stages of life. In particular, special attention should be given to the first 1,000 days, from the start of pregnancy to two years of age, pregnant and lactating women, women of reproductive age, and adolescent girls, by promoting and supporting adequate care and feeding practices, including exclusive breast feeding during the first six months, and continued breastfeeding until two years of age and beyond with appropriate complementary feeding. Healthy diets should be fostered in preschools, schools, public institutions, at the workplace and at home, as well as healthy eating by families;
- c) coordinated action among different actors, across all relevant sectors at international, regional, national and community levels, needs to be supported through cross-cutting and coherent policies, programmes and initiatives, including social protection, to address the multiple burdens of malnutrition and to promote sustainable food systems;
- d) food should not be used as an instrument for political or economic pressure;
- e) excessive volatility of prices of food and agricultural commodities can negatively impact food security and nutrition, and needs to be better monitored and addressed for the challenges it poses;
- f) improvements in diet and nutrition require relevant legislative frameworks for food safety and quality, including for the proper use of agrochemicals, by promoting participation in the activities of the Codex Alimentarius Commission for the development of international standards for food safety and quality, as well as for improving information for consumers, while avoiding inappropriate marketing and publicity of foods and non-alcoholic beverages to children, as recommended by resolution WHA63.14;
- g) nutrition data and indicators, as well as the capacity of, and support to all countries, especially developing countries, for data collection and analysis, need to be improved in order to contribute to more effective nutrition surveillance, policy making and accountability;
- h) empowerment of consumers is necessary through improved and evidence-based health and nutrition information and education to make informed choices regarding consumption of food products for healthy dietary practices;
- i) national health systems should integrate nutrition while providing access for all to integrated health services through a continuum of care approach, including health promotion and disease prevention, treatment and rehabilitation, and contribute to reducing inequalities through addressing specific nutrition-related needs and vulnerabilities of different population groups;
- j) nutrition and other related policies should pay special attention to women and empower women and girls, thereby contributing to women's full and equal access to social protection and resources, including, *inter alia*, income, land, water, finance, education, training, science and technology, and health services, thus promoting food security and health.

14. We recognize that:

- a) international cooperation and Official Development Assistance for nutrition should support and complement national nutrition strategies, policies and programmes, and surveillance initiatives, as appropriate;
- b) the progressive realization of the right to adequate food in the context of national food security is fostered through sustainable, equitable, accessible in all cases, and resilient and diverse food systems;
- c) collective action is instrumental to improve nutrition, requiring collaboration between governments, the private sector, civil society and communities;

- d) non-discriminatory and secure access and utilization of resources in accordance with international law are important for food security and nutrition;
- e) food and agriculture systems, including crops, livestock, forestry, fisheries and aquaculture, need to be addressed comprehensively through coordinated public policies, taking into account the resources, investment, environment, people, institutions and processes with which food is produced, processed, stored, distributed, prepared and consumed;
- f) family farmers and small holders, notably women farmers, play an important role in reducing malnutrition and should be supported by integrated and multisectoral public policies, as appropriate, that raise their productive capacity and incomes and strengthen their resilience;
- g) wars, occupations, terrorism, civil disturbances and natural disasters, disease outbreaks and epidemics, as well as human rights violations and inappropriate socio-economic policies, have resulted in tens of millions of refugees, displaced persons, war affected non-combatant civilian populations and migrants, who are among the most nutritionally vulnerable groups. Resources for rehabilitating and caring for these groups are often extremely inadequate and nutritional deficiencies are common. All responsible parties should cooperate to ensure the safe and timely passage and distribution of food and medical supplies to those in need, which conforms with the beliefs, culture, traditions, dietary habits and preferences of individuals, in accordance with national legislation and international law and obligations and the Charter of the United Nations;
- h) responsible investment in agriculture,¹⁴ including small holders and family farming and in food systems, is essential for overcoming malnutrition;
- i) governments should protect consumers, especially children, from inappropriate marketing and publicity of food;
- j) nutrition improvement requires healthy, balanced, diversified diets, including traditional diets where appropriate, meeting nutrient requirements of all age groups, and all groups with special nutrition needs, while avoiding the excessive intake of saturated fat, sugars and salt/sodium, and virtually eliminating trans-fat, among others;
- k) food systems should provide year-round access to foods that cover people's nutrient needs and promote healthy dietary practices;
- l) food systems need to contribute to preventing and addressing infectious diseases, including zoonotic diseases, and tackling antimicrobial resistance;
- m) food systems, including all components of production, processing and distribution should be sustainable, resilient and efficient in providing more diverse foods in an equitable manner, with due attention to assessing environmental and health impacts;
- n) food losses and waste throughout the food chain should be reduced in order to contribute to food security, nutrition, and sustainable development;
- o) the United Nations system, including the Committee on World Food Security, and international and regional financial institutions should work more effectively together in order to support national and regional efforts, as appropriate, and enhance international cooperation and development assistance to accelerate progress in addressing malnutrition;
- p) EXPO MILANO 2015, dedicated to "feeding the planet, energy for life", among other relevant events and fora, will provide an opportunity to stress the importance of food security and nutrition, raise public awareness, foster debate, and give visibility to the ICN2 outcomes.

¹⁴ The term agriculture includes crops, livestock, forestry and fisheries.

Commitment to action

15. We commit to:

- a) eradicate hunger and prevent all forms of malnutrition worldwide, particularly undernourishment, stunting, wasting, underweight and overweight in children under five years of age; and anaemia in women and children among other micronutrient deficiencies; as well as reverse the rising trends in overweight and obesity and reduce the burden of diet-related noncommunicable diseases in all age groups;
- b) increase investments for effective interventions and actions to improve people's diets and nutrition, including in emergency situations;
- c) enhance sustainable food systems by developing coherent public policies from production to consumption and across relevant sectors to provide year-round access to food that meets people's nutrition needs and promote safe and diversified healthy diets;
- d) raise the profile of nutrition within relevant national strategies, policies, actions plans and programmes, and align national resources accordingly;
- e) improve nutrition by strengthening human and institutional capacities to address all forms of malnutrition through, *inter alia*, relevant scientific and socio-economic research and development, innovation and transfer of appropriate technologies on mutually agreed terms and conditions;
- f) strengthen and facilitate contributions and action by all stakeholders to improve nutrition and promote collaboration within and across countries, including North-South cooperation, as well as South-South and triangular cooperation;
- g) develop policies, programmes and initiatives for ensuring healthy diets throughout the life course, starting from the early stages of life to adulthood, including of people with special nutritional needs, before and during pregnancy, in particular during the first 1,000 days, promoting, protecting and supporting exclusive breastfeeding during the first six months and continued breastfeeding until two years of age and beyond with appropriate complementary feeding, healthy eating by families, and at school during childhood, as well as other specialized feeding;
- h) empower people and create an enabling environment for making informed choices about food products for healthy dietary practices and appropriate infant and young child feeding practices through improved health and nutrition information and education;
- i) implement the commitments of this Declaration through the Framework for Action which will also contribute to ensuring accountability and monitoring progress in global nutrition targets;
- j) give due consideration to integrating the vision and commitments of this Declaration into the post-2015 development agenda process including a possible related global goal.

16. We call on FAO and WHO, in collaboration with other United Nations agencies, funds and programmes, as well as other international organizations, to support national governments, upon request, in developing, strengthening and implementing their policies, programmes and plans to address the multiple challenges of malnutrition.

17. We recommend to the United Nations General Assembly to endorse the Rome Declaration on Nutrition, as well as the Framework for Action which provides a set of voluntary policy options and strategies for use by governments, as appropriate, and to consider declaring a Decade of Action on Nutrition from 2016 to 2025 within existing structures and available resources.

ANNEX 2

FRAMEWORK FOR ACTION

FROM COMMITMENTS TO ACTION

Background

1. There has been a significant improvement in reducing hunger and malnutrition of the world's population since the 1992 International Conference on Nutrition (ICN). Yet, progress in reducing hunger and undernutrition has been uneven and unacceptably slow. The fundamental challenge today is to sustainably improve nutrition through implementation of coherent policies and better coordinated actions across all relevant sectors.

Purpose and targets

2. The nature of this Framework for Action is voluntary. Its purpose is to guide the implementation of the commitments of the Rome Declaration on Nutrition adopted by the Second International Conference on Nutrition held in Rome, Italy, on 19–21 November 2014. Building on existing commitments, goals and targets, this Framework for Action provides a set of policy options and strategies which governments¹⁵, acting in cooperation with other stakeholders, may incorporate, as appropriate, into their national nutrition, health, agriculture¹⁶, development and investment plans, and consider in negotiating international agreements to achieve better nutrition for all.

3. As governments have primary responsibility for taking action at country level, in dialogue with a wide range of stakeholders, including affected communities, the recommendations are principally addressed to government leaders. They will consider the appropriateness of the recommended policies and actions in relation to national needs and conditions, as well as regional and national priorities, including in legal frameworks. For the purpose of accountability, this Framework for Action adopts existing global targets for improving maternal, infant and young child nutrition¹⁷ and for noncommunicable disease risk factor reduction¹⁸ to be achieved by 2025.

Recommended set of policy and programme options

4. The following set of policy and programme options are recommended to create an enabling environment and to improve nutrition in all sectors.

Recommended actions to create an enabling environment for effective action

- Recommendation 1: Enhance political commitment and social participation for improving nutrition at the country level through political dialogue and advocacy.
- Recommendation 2: Develop – or revise, as appropriate – and cost National Nutrition Plans, align policies that impact nutrition across different ministries and agencies, and strengthen legal frameworks and strategic capacities for nutrition.

¹⁵ The term 'governments' is understood to include the European Union and other regional organizations on matters of their competency.

¹⁶ In this document, the term 'agriculture' comprises crops, livestock, forestry and fisheries.

¹⁷ Namely: (1) 40% reduction of the global number of children under five who are stunted; (2) 50% reduction of anaemia in women of reproductive age; (3) 30% reduction of low birth weight; (4) no increase in childhood overweight; (5) increase exclusive breastfeeding rates in the first six months up to at least 50%; and (6) reduce and maintain childhood wasting to less than 5%.

¹⁸ Namely: (1) to reduce salt intake by 30%; and (2) to halt the increase in obesity prevalence in adolescents and adults.

- Recommendation 3: Strengthen and establish, as appropriate, national cross-government, inter-sector, multi-stakeholder mechanisms for food security and nutrition to oversee implementation of policies, strategies, programmes and other investments in nutrition. Such platforms may be needed at various levels, with robust safeguards against abuse and conflicts of interest.
- Recommendation 4: Increase responsible and sustainable investment in nutrition, especially at country level with domestic finance; generate additional resources through innovative financing tools; engage development partners to increase Official Development Assistance in nutrition and foster private investments as appropriate.
- Recommendation 5: Improve the availability, quality, quantity, coverage and management of multisectoral information systems related to food and nutrition for improved policy development and accountability.
- Recommendation 6: Promote inter-country collaboration, such as North-South, South-South and triangular cooperation, and information exchange on nutrition, food, technology, research, policies and programmes.
- Recommendation 7: Strengthen nutrition governance and coordinate policies, strategies and programmes of United Nations system agencies, programmes and funds within their respective mandates.

Recommended actions for sustainable food systems promoting healthy diets

- Recommendation 8: Review national policies and investments and integrate nutrition objectives into food and agriculture policy, programme design and implementation, to enhance nutrition sensitive agriculture, ensure food security and enable healthy diets.
- Recommendation 9: Strengthen local food production and processing, especially by smallholder¹⁹ and family farmers, giving special attention to women’s empowerment, while recognizing that efficient and effective trade is key to achieving nutrition objectives.
- Recommendation 10: Promote the diversification of crops including underutilized traditional crops, more production of fruits and vegetables, and appropriate production of animal-source products as needed, applying sustainable food production and natural resource management practices.
- Recommendation 11: Improve storage, preservation, transport and distribution technologies and infrastructure to reduce seasonal food insecurity, food and nutrient loss and waste.
- Recommendation 12: Establish and strengthen institutions, policies, programmes and services to enhance the resilience of the food supply in crisis-prone areas, including areas affected by climate change.
- Recommendation 13: Develop, adopt and adapt, where appropriate, international guidelines on healthy diets.

¹⁹ Smallholder farmers include agriculture and food workers, artisanal fisherfolk, pastoralists, indigenous peoples and the landless (Committee on World Food Security, Global Strategic Framework for Food Security and Nutrition, 2013).

- Recommendation 14: Encourage gradual reduction of saturated fat, sugars and salt/sodium and trans-fat from foods and beverages to prevent excessive intake by consumers and improve nutrient content of foods, as needed.
- Recommendation 15: Explore regulatory and voluntary instruments – such as marketing, publicity and labelling policies, economic incentives or disincentives in accordance with Codex Alimentarius and World Trade Organization rules – to promote healthy diets.
- Recommendation 16: Establish food or nutrient-based standards to make healthy diets and safe drinking water accessible in public facilities such as hospitals, childcare facilities, workplaces, universities, schools, food and catering services, government offices and prisons, and encourage the establishment of facilities for breastfeeding.

Recommended actions in international trade and investment

- Recommendation 17: Encourage governments, United Nations agencies, programmes and funds, the World Trade Organization and other international organizations to identify opportunities to achieve global food and nutrition targets, through trade and investment policies.
- Recommendation 18: Improve the availability and access of the food supply through appropriate trade agreements and policies and endeavour to ensure that such agreements and policies do not have a negative impact on the right to adequate food in other countries.²⁰

Recommended actions for nutrition education and information

- Recommendation 19: Implement nutrition education and information interventions based on national dietary guidelines and coherent policies related to food and diets, through improved school curricula, nutrition education in the health, agriculture and social protection services, community interventions and point-of-sale information, including labelling.
- Recommendation 20: Build nutrition skills and capacity to undertake nutrition education activities, particularly for front line workers, social workers, agricultural extension personnel, teachers and health professionals.
- Recommendation 21: Conduct appropriate social marketing campaigns and lifestyle change communication programmes to promote physical activity, dietary diversification, consumption of micronutrient-rich foods such as fruits and vegetables, including traditional local foods and taking into consideration cultural aspects, better child and maternal nutrition, appropriate care practices and adequate breastfeeding and complementary feeding, targeted and adapted for different audiences and stakeholders in the food system.

Recommended actions on social protection

- Recommendation 22: Incorporate nutrition objectives into social protection programmes and into humanitarian assistance safety net programmes.
- Recommendation 23: Use cash and food transfers, including school feeding programmes and other forms of social protection for vulnerable populations to improve diets through better access to food which conforms with the beliefs, culture, traditions, dietary habits and preferences of individuals in accordance with national and international laws and obligations, and which is nutritionally adequate for healthy diets.

²⁰ United Nations General Assembly resolution A/RES/68/177, paragraph 25.

- Recommendation 24: Increase income for the most vulnerable populations by creating decent jobs for all, including through the promotion of self-employment.

Recommended actions for strong and resilient health systems

- Recommendation 25: Strengthen health systems and promote universal health coverage,²¹ particularly through primary health care, to enable national health systems to address malnutrition in all its forms.
- Recommendation 26: Improve the integration of nutrition actions into health systems through appropriate strategies for strengthening human resources, leadership and governance, health system financing and service delivery, as well as the provision of essential medicines, information and monitoring.
- Recommendation 27: Promote universal access to all direct nutrition actions and relevant health actions impacting nutrition through health programmes.
- Recommendation 28: Implement the WHO Global Strategy on Infant and Young Child Feeding, the WHO Comprehensive Implementation Plan on Maternal, Infant and Young Child Nutrition 2012–2025, and the WHO Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020 through commensurate financing and adequate policies.

Recommended actions to promote, protect and support breastfeeding

- Recommendation 29: Adapt and implement the International Code of Marketing of Breast-milk Substitutes and subsequent relevant World Health Assembly resolutions.
- Recommendation 30: Implement policies and practices, including labour reforms, as appropriate, to promote protection of working mothers.²²
- Recommendation 31: Implement policies, programmes and actions to ensure that health services promote, protect and support breastfeeding, including the Baby-Friendly Hospital Initiative.
- Recommendation 32: Encourage and promote – through advocacy, education and capacity building – an enabling environment where men, particularly fathers, participate actively and share responsibilities with mothers in caring for their infants and young children, while empowering women and enhancing their health and nutritional status throughout the life course.
- Recommendation 33: Ensure that policies and practices in emergency situations and humanitarian crises promote, protect and support breastfeeding.

²¹ In accordance with preambular paragraph 9 of resolution WHA67.14, universal health coverage implies that all people have access without discrimination to nationally determined sets of the needed promotive, preventive, curative, palliative and rehabilitative essential health services and essential, safe, affordable, effective and quality medicines, while ensuring that the use of these services does not expose the users to financial hardship with a special emphasis on the poor, vulnerable and marginalized segments of the population.

²² As specified in the International Labour Organization's Maternity Protection Convention No. 183 and corresponding Recommendation 191.

Recommended actions to address wasting

- Recommendation 34: Adopt policies and actions, and mobilize funding, to improve coverage of treatment for wasting, using the community-based management of acute malnutrition approach and improve the integrated management of childhood illnesses.
- Recommendation 35: Integrate disaster and emergency preparedness into relevant policies and programmes.

Recommended actions to address stunting

- Recommendation 36: Establish policies and strengthen interventions to improve maternal nutrition and health, beginning with adolescent girls and continuing through pregnancy and lactation.
- Recommendation 37: Establish health policies, programmes and strategies to promote optimal infant and young child feeding, particularly exclusive breastfeeding up to six months, followed by adequate complementary feeding (from six to 24 months).

Recommended actions to address childhood overweight and obesity

- Recommendation 38: Provide dietary counselling to women during pregnancy for healthy weight gain and adequate nutrition.
- Recommendation 39: Improve child nutritional status and growth, particularly by addressing maternal exposure to the availability and marketing of complementary foods, and by improving supplementary feeding programmes for infants and young children.
- Recommendation 40: Regulate the marketing of food and non-alcoholic beverages to children in accordance with WHO recommendations.
- Recommendation 41: Create a conducive environment that promotes physical activity to address sedentary lifestyle from the early stages of life.

Recommended actions to address anaemia in women of reproductive age

- Recommendation 42: Improve intake of micronutrients through consumption of nutrient-dense foods, especially foods rich in iron, where necessary, through fortification and supplementation strategies, and promote healthy and diversified diets.
- Recommendation 43: Provide daily iron and folic acid and other micronutrient supplementation to pregnant women as part of antenatal care; and intermittent iron and folic acid supplementation to menstruating women where the prevalence of anaemia is 20% or higher, and deworming, where appropriate.

Recommended actions in the health services to improve nutrition

- Recommendation 44: Implement policies and programmes to ensure universal access to and use of insecticide-treated nets, and to provide preventive malaria treatment for pregnant women in areas with moderate to high malaria transmission.
- Recommendation 45: Provide periodic deworming for all school-age children in endemic areas.

- Recommendation 46: Implement policies and programmes to improve health service capacity to prevent and treat infectious diseases.²³
- Recommendation 47: Provide zinc supplementation to reduce the duration and severity of diarrhoea, and to prevent subsequent episodes in children.
- Recommendation 48: Provide iron and, among others, vitamin A supplementation for pre-school children to reduce the risk of anaemia.
- Recommendation 49: Implement policies and strategies to ensure that women have comprehensive information and access to integral health care services that ensure adequate support for safe pregnancy and delivery.

Recommended actions on water, sanitation and hygiene

- Recommendation 50: Implement policies and programmes using participatory approaches to improve water management in agriculture and food production.²⁴
- Recommendation 51: Invest in and commit to achieve universal access to safe drinking water, with the participation of civil society and the support of international partners, as appropriate.
- Recommendation 52: Implement policies and strategies using participatory approaches to ensure universal access to adequate sanitation²⁵ and to promote safe hygiene practices, including hand washing with soap.

Recommended actions on food safety and antimicrobial resistance

- Recommendation 53: Develop, establish, enforce and strengthen, as appropriate, food control systems, including reviewing and modernizing national food safety legislation and regulations to ensure that food producers and suppliers throughout the food chain operate responsibly.
- Recommendation 54: Actively take part in the work of the Codex Alimentarius Commission on nutrition and food safety, and implement, as appropriate, internationally adopted standards at the national level.
- Recommendation 55: Participate in and contribute to international networks to exchange food safety information, including for managing emergencies.²⁶
- Recommendation 56: Raise awareness among relevant stakeholders on the problems posed by antimicrobial resistance, and implement appropriate multisectoral measures to address antimicrobial resistance, including prudent use of antimicrobials in veterinary and human medicine.
- Recommendation 57: Develop and implement national guidelines on prudent use of antimicrobials in food-producing animals according to internationally recognized standards adopted by competent international organizations to reduce non-therapeutic use of

²³ Including prevention of mother-to-child transmission of HIV, immunization against measles and antibiotic treatment for girls with urinary infections.

²⁴ Including by reducing water wastage in irrigation, strategies for multiple use of water (including wastewater), and better use of appropriate technology.

²⁵ Including by implementing effective risk assessment and management practices on safe wastewater use and sanitation.

²⁶ FAO/WHO International Network of Food Safety Authorities (http://www.who.int/foodsafety/areas_work/infosan/en/).

antimicrobials and to phase out the use of antimicrobials as growth promoters in the absence of risk analysis as described in Codex Code of Practice CAC/RCP61-2005.

Recommendations for accountability

- Recommendation 58: National governments are encouraged to establish nutrition targets and intermediate milestones, consistent with the timeframe for implementation (2016–2025), as well as global nutrition and noncommunicable disease targets established by the World Health Assembly. They are invited to include – in their national monitoring frameworks – agreed international indicators for nutrition outcomes (to track progress in achieving national targets), nutrition programme implementation (including coverage of interventions) and the nutrition policy environment (including institutional arrangements, capacities and investments in nutrition).²⁷ Monitoring should be conducted, to the fullest possible extent, through existing mechanisms.
- Recommendation 59: Reports on implementation of the commitments of the Rome Declaration on Nutrition will be compiled jointly by FAO and WHO, in close collaboration with other United Nations agencies, funds and programmes and other relevant regional and international organizations, as appropriate, based on country self-assessments as well as information available through other monitoring and accountability mechanisms (e.g. Scaling Up Nutrition self-assessment reports, reports to the FAO Conference and the World Health Assembly, and the Global Nutrition Report).
- Recommendation 60: The governing bodies of FAO and WHO, and other relevant international organizations are requested to consider the inclusion of reports on the overall follow-up to ICN2 on the agendas of the regular FAO and WHO governing body meetings, including FAO regional conferences and WHO regional committee meetings, possibly on a biennial basis. The Directors-General of FAO and WHO are also requested to transmit such reports to the United Nations General Assembly as appropriate.

DECISION 13.1:

Executive Board Decision EB136(4): Outcome of the Second International Conference on Nutrition

The Executive Board, recalling relevant WHO international targets and action plans, including the WHO 2025 Global Nutrition Targets²⁸ and the WHO global action plan for the prevention and control of noncommunicable diseases 2013–2020,²⁹ and having considered the report by the Director-General on the outcome of the Second International Conference on Nutrition,³⁰ decided the following:

- (1) to note the commitments of the Rome Declaration on Nutrition and the recommendations of the Framework for Action;

²⁷ Monitoring frameworks may be developed based on the Global Monitoring Framework for Maternal, Infant and Young Child Nutrition, the Monitoring Framework for the Global Action Plan on Noncommunicable Diseases, as well as indicators for monitoring food security (FAO prevalence of undernutrition, food insecurity experience scale, and other widely used indicators).

²⁸ See document WHA65/2012/REC/1, Annex 2 for the six global nutrition targets for 2025 adopted by the World Health Assembly in 2012; also see: http://www.who.int/nutrition/topics/nutrition_globaltargets2025/en/ (accessed 5 February 2015).

²⁹ See resolution WHA66.10; see also document WHA66/2013/REC/1, Annex, 4, Appendix 2.

³⁰ Document EB136/8.

(2) to request the Director-General:

- (a) to provide technical support to Member States³¹ to implement the commitments of the Rome Declaration on Nutrition across multiple sectors, by expanding WHO's evidence-informed guidance to cover the policy areas identified in the Framework for Action in the fields covered by WHO's mandate; by developing, as needed, policy papers informed by the best available, robust quality scientific evidence providing the rationale, operational details and necessary elements for the calculation of costs and benefits of the recommended policies, with active involvement of all relevant stakeholders;³² by strengthening multilateral initiatives at global and regional levels aimed at sharing experience on implementing different policy approaches or legislative tools; and by creating, together with the Director-General of FAO and in cooperation with other United Nations agencies, a repository of examples of country nutrition plans, including on increased investments to improve people's diet and nutrition, as well as plans that are relevant to nutrition in health, agriculture and trade, social protection, education, water, sanitation, hygiene and the environment;
- (b) to contribute, together with the Director-General of FAO, to joint United Nations mechanisms on nutrition, such as the United Nations System Standing Committee on Nutrition, the Renewed Efforts Against Child Hunger and Undernutrition (REACH) initiative, the High Level Task Force on the Global Food Security Crisis and the United Nations Interagency Task Force on the Prevention and Control of Non-communicable Diseases, by improving the existing multiagency coordination mechanisms and by developing a United Nations global nutrition agenda, taking account of organizations' respective mandates;
- (c) to facilitate and enhance the coordination of activities and actions across sectors, based on existing experiences and good practice by preparing policy briefs, as needed, and collaborating, as appropriate, with the Committee on World Food Security and the Global Coordination Mechanism on the prevention and control of noncommunicable diseases; and by maintaining engagement, including with different multistakeholder platforms such as the Scaling Up Nutrition movement, in line with the guidance to be provided by the Health Assembly on engagement with non-State actors;
- (d) to contribute, together with the Director-General of FAO, and in close collaboration with other United Nations partners, to accountability, including by inviting Member States to register their commitments in each of the areas indicated by the Framework for Action, as appropriate;
- (e) to facilitate consideration of a Decade of Action on Nutrition from 2016 to 2025, within existing structures and available resources, by the United Nations General Assembly in 2015 by preparing a road map jointly with the Director-General of FAO and in cooperation with other United Nations agencies, including proposed milestones, and priority action for governments, international organizations and other actors, and by contributing to informal discussions among Member States;³³
- (f) to facilitate informal discussions among Member States with a view to enabling national parliaments to address the follow-up to the Second International Conference on Nutrition at the 132nd Inter-Parliamentary Union Assembly in 2015;

(3) to recommend to the Sixty-eighth World Health Assembly that it:

- (a) endorse the Rome Declaration on Nutrition, as well as the Framework for Action, which provides a set of voluntary policy options and strategies for use by governments;

³¹ And where applicable, regional economic integration organizations.

³² In line with the guidance to be provided by the World Health Assembly on engagement with non-State actors.

³³ And, where applicable, regional economic integration organizations.

- (b) call on Member States³⁴ to implement commitments of the Rome Declaration through a set of voluntary policy options within the Framework for Action;
- (c) request the Director-General, in collaboration with the Director-General of FAO and other United Nations agencies, funds and programmes and other relevant regional and international organizations, to prepare a biennial report to the World Health Assembly on the status of implementation of commitments of the Rome Declaration on Nutrition.

³⁴ And, where applicable, regional economic integration organizations.

13.5 Global burden of epilepsy and need for a coordinated action at the country level to address its health, social and public knowledge implications

Document A68/12 (Report by the Secretariat)

Global burden of epilepsy and the need for coordinated action at the country level to address its health, social and public knowledge implications

1. The Executive Board at its 136th session considered document EB136/13³⁵ and adopted resolution EB136.R8.2

ACTION BY THE HEALTH ASSEMBLY

2. The Health Assembly is invited to adopt the draft resolution recommended by the Executive Board in resolution EB136.R8.³⁶

Document EB136/13 (Report by the Secretariat)

Global burden of epilepsy and the need for coordinated action at the country level to address its health, social and public knowledge implications

BURDEN AND IMPACT OF EPILEPSY

1. Epilepsy is one of the most common serious chronic neurological diseases affecting people of all ages globally. It is characterized by recurrent seizures. It has many causes. In some cases, there is an underlying genetic basis. Other common causes of epilepsy include brain damage from prenatal or perinatal injuries (for example, a loss of oxygen or trauma during birth); congenital abnormalities or brain malformations; head injury; stroke; neurological infections, such as meningitis, encephalitis and neurocysticercosis; and brain tumour. In about half the cases of epilepsy, the cause cannot be identified.
2. More than 50 million people worldwide have epilepsy, more than three quarters living in low- and middle-income countries. An estimated 2.4 million new cases occur each year. Epilepsy accounts for 0.5% of the total global burden of disease.
3. The risk of premature death in people with epilepsy is 2–3 times higher than for the general population in high-income countries and more than six times higher in low- and middle-income countries. People with epilepsy often suffer from comorbidities such as depression and anxiety, associated intellectual disabilities, especially in children, and physical injuries (for instance, fractures and burns).
4. People with epilepsy are often subjected to stigmatization and discrimination because of misconceptions and negative attitudes surrounding the disease. Some common misconceptions are “possession by evil spirits”, “epilepsy is contagious” or its equivalence to “madness”. Stigmatization leads to human rights violations and societal exclusion. For example, in some settings children with

³⁵ See summary record of the 136th session of the Executive Board, thirteenth meeting and fourteenth meeting, section 1.

³⁶ See document EB136/2015/REC/1 for the resolution, and for the financial and administrative implications for the Secretariat of the adoption of the resolution.

epilepsy may not be allowed to go to school and adults may not find suitable employment or be able to marry.

5. In addition to its social implications, epilepsy results in huge economic costs. In the WHO European Region, for example, these costs have been estimated at €20 000 million per year.³⁷

CHALLENGES AND GAPS IN EPILEPSY CARE

6. Up to 75% of people with epilepsy can live a normal life, free from seizures, if they are appropriately treated with antiepileptic medicines. Treatment with first-line antiepileptic medicines (phenobarbital, phenytoin, carbamazepine and valproic acid) is among the identified “best buys” for neurological diseases with the cost of treatment with phenobarbital as low as US\$ 5 per person per year.³⁸ All the medicines are included in the WHO Model List of Essential Medicines.

7. Despite the availability of affordable treatment, up to 90% of people with epilepsy may not be properly diagnosed or treated in resource-poor settings. The so-called “treatment gap” (the percentage of people with epilepsy whose seizures are not being appropriately treated at a given point in time) is estimated to be 75% in low-income countries and substantially higher in rural areas than in urban areas.

8. Such a wide treatment gap may result from a combination of, for instance, inadequate capacities of health care systems and inequitable distributions of resources, particularly in resource-poor and rural areas. Factors that widen the gap, many of which are interconnected, include an insufficiency of staff, poor access to antiepileptic medicines, societal ignorance and misconceptions, poverty, and low prioritization for the treatment of epilepsy.

9. Only limited numbers of specialist health professionals are available in low- and middle-income countries; for example, the median number of neurologists in low-income countries is only 0.03/100 000 population. Epilepsy can be treated at primary health care level but very often the health care workers there are not adequately trained to diagnose or treat epilepsy.

10. Many barriers to accessing antiepileptic medicines exist. The price often remains unjustifiably high, even for generic medicines. Data and information necessary for planning, forecasting and budgeting are often lacking. Certain regulatory policies prevent wider use of some antiepileptic medicines, particularly those associated with the procurement of phenobarbital. Although national essential medicines lists frequently include first-line antiepileptic medicines, their inclusion does not guarantee availability in public health care facilities.

11. An analysis of availability, price and affordability of antiepileptic medicines in public hospitals and primary health care facilities from surveys in 46 Member States estimated the average availability of generic oral antiepileptic medicines as less than 50%. Prices charged to patients in the public sector for generic carbamazepine and phenytoin were 4.95 and 17.50 times higher than international reference prices, respectively. The lowest-paid government worker in the countries

³⁷ International League Against Epilepsy, International Bureau for Epilepsy, World Health Organization. Global campaign against Epilepsy. Epilepsy in the WHO European Region: fostering epilepsy care in Europe. Hoofddorp, The Netherlands: Global Campaign Against Epilepsy, 2010 (see http://www.who.int/mental_health/neurology/epilepsy/euro_report.pdf?ua=1, accessed 24 November 2014).

³⁸ Abegunde D. Essential medicines for non-communicable diseases: background paper. Geneva: World Health Organization (http://www.who.int/medicines/areas/policy/access_noncommunicable/EssentialMedicinesforNCDs.pdf, accessed 24 November 2014).

surveyed would spend between 1.1 and 2.6 days' wages to buy a month's supply of phenytoin; the comparable figure for carbamazepine was between 2.7 and 16.2 days' wages.³⁹

12. Lack of knowledge or misperceptions about epilepsy may affect health-seeking behaviour. People with epilepsy may not access treatment from health care facilities and instead might seek help from other sources that may be ineffective. They also may not seek regular follow-up care or adhere to medications as prescribed.

INTERNATIONAL CONTEXT AND THE SECRETARIAT'S ACTIVITIES

13. In 2003, the Health Assembly noted the report on the control of neurocysticercosis with its references to epilepsy,⁴⁰ and, in resolution WHA66.8 in May 2013, it adopted the comprehensive mental health action plan 2013–2020, which builds on the work of WHO's mental health gap action programme and notes that actions taken to promote mental health and prevent mental disorders are relevant for the prevention of epilepsy and other neurological disorders. Other resolutions are also pertinent to coordinated action on epilepsy include United Nations General Assembly resolution 66/2 adopting the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, the Health Assembly's resolution WHA66.10 which endorsed the global action plan for the prevention and control of noncommunicable diseases 2013–2020, resolutions 68/269 and WHA57.10 on road safety, resolution WHA66.12 on neglected tropical diseases, resolution WHA67.10 on newborn care and resolution WHA67.15 on violence.

14. In 1997, WHO and two international nongovernmental organizations, the International League Against Epilepsy and the International Bureau for Epilepsy, launched the *Global Campaign Against Epilepsy: Out of the Shadows* in order to raise awareness and strengthen efforts to improve care and reduce the impact of epilepsy. Under the auspices of the global campaign, demonstration projects have been undertaken in Argentina, Bolivia (Plurinational State of), Brazil, China, Georgia, Pakistan, Senegal, Timor-Leste and Zimbabwe. For example, the project in China was implemented in six provinces between 2000 and 2004 to test the feasibility of diagnosis and treatment of epilepsy at the primary health care level. The results showed that trained primary health care physicians could diagnose and treat people with epilepsy, and that the care model could significantly reduce the epilepsy treatment gap.⁴¹ This project has been extended to 18 provinces and covers a population of 75 million.

15. In 2005, WHO published a compilation of relevant information about resources for care of mental and neurological conditions in the world.⁴² The publication emphasized that globally the available resources for epilepsy care are insufficient for the large number of people needing such care and the known substantial burden associated with the disease. In addition, large inequities exist across regions and income groups of countries, with low-income countries having extremely meagre resources.

16. In 2008, WHO launched the WHO Mental Health Gap Action Programme, which includes epilepsy as a priority mental health and neurological condition. The Programme's objective is to expand services for mental, neurological and substance use disorders in low- and middle-income countries using an innovative and multifaceted approach. The Secretariat has issued normative

³⁹ Cameron A, Bansal A, Dua T, Hill SR, Moshe SL, Mantel-Teeuwisse AK et al. Mapping the availability, price, and affordability of antiepileptic drugs in 46 countries. *Epilepsia*, 2012; 53:962–969.

⁴⁰ See document WHA56/2003/REC/3, summary record of the fourth meeting of Committee A.

⁴¹ Epilepsy management at primary health level in rural China: WHO, International League Against Epilepsy, International Bureau for Epilepsy. Geneva: World Health Organization; 2009.

⁴² WHO, International Bureau for Epilepsy, International League Against Epilepsy. Atlas: epilepsy care in the world 2005. Geneva: World Health organization; 2005.

materials such as the Programme's intervention guide for mental, neurological and substance use disorders in non-specialized health settings and related training materials, which cover epilepsy care management.⁴³

17. The WHO Programme on Reducing the Epilepsy Treatment Gap builds on the experience with non-specialist primary health care providers to diagnose, treat and follow up people with epilepsy. It also mobilizes nongovernmental organizations and community groups among others to raise awareness about epilepsy and support people with epilepsy and their families, and supports health system strengthening to ensure sustainable access to antiepileptic medicines, reinforce referral systems, and enable better monitoring of epilepsy. Pilot initiatives have been initiated in Ghana, Mozambique, Myanmar and Viet Nam.⁴⁴

18. Regional conferences on public health aspects of epilepsy have been organized in all six WHO regions, with the participation of some 1300 delegates from more than 90 countries. Regional reports on epilepsy and declarations have also been issued by different WHO regions. The regional reports emphasize the need for action on public education, legislative reform, investment in research, support for organizations or associations on epilepsy, information exchange, and community-based control and prevention programmes.⁴⁵

19. In 2011, the Region of the Americas approved and has subsequently been implementing the Strategy and Plan of Action on Epilepsy for 2012–2021.⁴⁶ The strategy defines priority areas for epilepsy, including the need to promote programmes and legislation for the care of people with epilepsy and the protection of their human rights; establish networks of health services for people with epilepsy, with emphasis on primary health care and the provision of antiepileptic medicines; educate and sensitize the general population, including people with epilepsy and their families; and strengthen the ability to produce, assess and use information on epilepsy.

20. Also in 2011, the European Parliament approved the written declaration on epilepsy.⁴⁷ The declaration calls for the European Commission and Council to encourage research and innovation in the area of prevention and early diagnosis and treatment of epilepsy; prioritize epilepsy as a major disease that imposes a significant burden across Europe; encourage measures to ensure equal quality of life, including access to education, employment, transport and public health care for people with epilepsy, for instance by stimulating the exchange of best practice; and encourage effective health impact assessments on all major European and national policies. It calls on Member States of the European Union to introduce appropriate legislation to protect the rights of all people with epilepsy.

IMPROVING EPILEPSY CARE: WHAT IS NEEDED

21. Several actions can be taken at country level to make progress in dealing with the global public health issue of improving epilepsy care. These are outlined in paragraphs 22–30 below.

⁴³ mhGAP intervention guide for mental, neurological and substance use disorders in non-specialized health settings, available at http://www.who.int/mental_health/publications/mhGAP_intervention_guide/en/ (accessed 21 November 2014).

⁴⁴ http://www.who.int/mental_health/neurology/epilepsy/en/.

⁴⁵ For links to regional reports and declarations, see http://www.who.int/mental_health/publications/epilepsy_neurological_disorders/en/ (accessed 21 November 2014).

⁴⁶ See resolution CD51.R8 and document CD51/10: http://www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=24657&Itemid=270&lang=en (accessed 21 November 2014).

⁴⁷ European Parliament. Written declaration on epilepsy. Brussels, European Parliament, 0022/2011, 2011 (<http://www.ilae.org/Visitors/initiatives/documents/writtendeclaration.pdf>, accessed 21 November 2014).

22. Strengthen effective leadership and governance. National policies and legislation need to be formulated, strengthened and implemented in order to promote and protect rights of people with epilepsy and to prohibit discrimination in, for example, education, employment, marriage, reproduction, driving regulations and recreation.

23. Improve provision of epilepsy care. Policies on general health, mental health or noncommunicable diseases should include consideration of care for people with epilepsy. Budgets should be allocated that are commensurate with the human and other resources that have been identified as necessary to implement agreed-upon evidence-based plans and actions. Stakeholders from all relevant sectors, including people with epilepsy and their carers and family members, should be engaged in the development and implementation of policies, laws and services.

24. Integrate epilepsy management into primary health care. In order to help to reduce the epilepsy treatment gap, non-specialist health care providers should be trained and supported so that epilepsy can be diagnosed and treated in primary health care settings. A strong and functional referral system should be made available.

25. Increase access to medicines. Strategies should be formulated and implemented to make antiepileptic medicines more available, accessible and affordable. Strategic options are: to include essential antiepileptic medicines in national formularies; to strengthen supply chains and systems of selection, procurement and distribution; and to improve access to controlled medicines such as phenobarbital. It is estimated that extending the coverage of treatment with antiepileptic medicines to 50% of epilepsy cases would reduce the current epilepsy burden by between 13% and 40%.

26. Support strategies for prevention of epilepsy. Many of the causes of epilepsy in low- and middle-income countries are preventable, and the health and social sectors should be supported to assist in reducing the incidence of epilepsy. Effective implementation of relevant United Nations General Assembly and Health Assembly resolutions (see paragraph 13 above) could help to prevent many cases of epilepsy. Examples include promoting safe pregnancies and births, control of cysticercosis, prevention of head trauma, and prevention of stroke.

27. Increase public awareness and education. In order to help to reduce misconceptions and negative attitudes, and to influence more people with epilepsy to seek treatment, public education activities related to epilepsy should be strengthened, and community leaders, grassroots public health workers, and people with epilepsy and their families should be educated about the disease. The Secretariat should provide support to Member States in harnessing the potential contribution of traditional medicine to the health and well-being of people with epilepsy. These actions should help to reduce stigmatization of and discrimination against people with epilepsy.

28. Strengthen health information and surveillance systems. Data on epilepsy should be captured, collated, routinely reported, analysed and disaggregated by sex and age in order to measure progress in increasing access to services for people with epilepsy. National data systems and exchange of information between countries should also be reinforced, for instance collaboration on data collection.

29. Improve investment in epilepsy research and increase research capacity. Surveillance should be improved and comprehensive, accurate epidemiological estimates made of the burden of epilepsy, particularly in low- and middle-income countries. Informed and effective decision-making should be facilitated through the development of standardized and validated research tools. In addition to epidemiological research, priority should be given to research areas such as genetics; health system evaluation; diagnostics, prevention, treatment and rehabilitation; and scientific investigation of traditional medicine approaches to epilepsy treatment. The research capacity of

low- and middle- income countries should be built through expanded academic collaboration and establishing centres of excellence in such countries.

30. Collaborate with civil society and other partners. National epilepsy-related organizations should be established in order to improve care for people with epilepsy and to strengthen advocacy. These bodies could include professional societies, charitable foundations, epilepsy centres, and associations of patients and their families.

ACTION BY THE EXECUTIVE BOARD

31. The Board is invited to take note of the report and provide further guidance on the need for a coordinated action at the country level to address the health, social and public knowledge implications of the global burden of epilepsy.

RESOLUTION 13.5:

Executive Board Resolution EB136.R8

Global burden of epilepsy and the need for coordinated action at the country level to address its health, social and public knowledge implications

The Executive Board, having considered the report on the global burden of epilepsy and the need for coordinated action at the country level to address its health, social and public knowledge implications,⁴⁸ RECOMMENDS to the Sixty-eighth World Health Assembly, the adoption of the following resolution:

The Sixty-eighth World Health Assembly,

Considering resolution WHA66.8, in which the Health Assembly adopted the comprehensive mental health action plan 2013–2020, and resolution WHA67.22 on access to essential medicines;

Acknowledging United Nations General Assembly resolution 68/269 and resolution WHA57.10 on road safety and health, resolution WHA66.12 on neglected tropical diseases, resolution WHA67.10 on the newborn health action plan, resolution WHA67.15 on strengthening the role of the health system in addressing violence, in particular against women and girls, and against children, and the discussions on the control of neurocysticercosis and its association with epilepsy at the Fifty-sixth World Health Assembly;⁴⁹

Noting the Political Declaration of the High-level Meeting of the United Nations General Assembly on the Prevention and Control of Non-communicable Diseases,⁵⁰ at which Heads of State and Government recognized that mental and neurological disorders are an important cause of morbidity and contribute to the global noncommunicable disease burden, necessitating provision of equitable access to effective programmes and health-care interventions;

Considering the Millennium Development Goals, the outcome document of the United Nations Conference on Sustainable Development entitled “The future we want”,⁵¹ and the report of the Open Working Group on Sustainable Development Goals, established pursuant to United Nations

⁴⁸ Document EB136/13.

⁴⁹ See document WHA56/2003/REC/3, summary record of the fourth meeting of Committee A.

⁵⁰ United Nations General Assembly resolution 66/2.

⁵¹ United Nations General Assembly resolution 66/288.

General Assembly resolution 66/288, which proposes a Goal 3 (Ensure healthy lives and promote well-being for all at all ages) and target 3.4 (by 2030 reduce by one-third premature mortality from non-communicable diseases (NCDs) through prevention and treatment, and promote mental health and well-being);

Recognizing that epilepsy is one of the most common serious chronic neurological diseases, affecting 50 million people of all ages globally, and that people with epilepsy are often subjected to stigmatization and discrimination because of ignorance, misconceptions and negative attitudes surrounding the disease, and that they face serious difficulties in, for example, education, employment, marriage and reproduction;

Noting with concern that the magnitude of epilepsy affects people of all ages, gender, race and income levels, and further that poor populations and those living in vulnerable situations, in particular in low- and middle-income countries, bear a disproportionate burden, posing a threat to public health and economic and social development;

Cognizant that large differences exist in the level of epilepsy management in different countries, with, for example, the median number of neurologists in low-income countries standing at only 0.03/100 000 population, that the essential antiepileptic medicines are often unavailable, that the treatment gap is estimated to be over 75% in low-income countries and to be substantially wider in rural areas than in urban areas;

Noting that the majority of people with epilepsy can be free from seizures if appropriately treated with cost-effective, affordable antiepileptic medicines;

Recognizing in addition that certain causes of epilepsy can be prevented and that such preventive action can be promoted in the health sector and in sectors outside health;

Aware that in 1997, WHO and two international nongovernmental organizations, the International League Against Epilepsy and the International Bureau for Epilepsy, launched the Global Campaign against Epilepsy – “Out of the Shadows”, and that in 2008 WHO launched its mental health gap action programme, which provided a sound basis for WHO to further lead and coordinate global development work on epilepsy;

Aware also that practice in China and some other low-income countries has proved that country-level coordinated action may be very effective in controlling the disease and improving the quality of life of millions of people with epilepsy at little cost;

Recognizing the remarkable progress made recently in the technology of epilepsy management, from basic research to diagnosis and treatment;

Considering that international governmental organizations, nongovernmental organizations, academic societies and other bodies have recently enhanced their investment in epilepsy management and have undertaken a significant amount of work in collaboration with national governments, such as the International League Against Epilepsy and the International Bureau for Epilepsy, which have official relations with WHO and have been collaborating with WHO in epilepsy management for several decades;

Recognizing the role of WHO to demonstrate further leadership and coordination and take effective action for epilepsy management, in view of the large public health impact,

1. URGES Member States:⁵²

- (1) to strengthen effective leadership and governance, for policies on general health, mental health and noncommunicable diseases that include consideration of the specific needs of people with epilepsy, and make the financial, human and other resources available that have been identified, as necessary, to implement evidence-based plans and actions;
- (2) to introduce and implement, where necessary and in accordance with international human rights norms and standards, national health care plans of action for epilepsy management, aiming to overcome inequalities and inequities in health, social and other related services, paying special attention to people with epilepsy living in conditions of vulnerability, such as those living in poor and remote areas, including by strengthening public health care services, and training local human resources with proper techniques;
- (3) to integrate epilepsy management, including health and social care, particularly community-based services, within the context of universal health coverage, including community-based rehabilitation, into primary health care, where appropriate, in order to help to reduce the epilepsy treatment gap, by training non-specialist health care providers to provide them with basic knowledge for the management of epilepsy so that epilepsy can be diagnosed, treated and followed up as much as possible, in primary health care settings, as well as by empowering people with epilepsy and their carers for greater use of specified self and home care programmes, by ensuring a strong and functional referral system and by strengthening health information and surveillance systems to routinely collect, report, analyse and evaluate trends on epilepsy management;
- (4) to support the establishment and implementation of strategies for the management of epilepsy, particularly to improve accessibility to and promote affordability of safe, effective and quality-assured antiepileptic medicines and include essential antiepileptic medicines into national lists of essential medicines;
- (5) to ensure public awareness of and education about epilepsy, in particular in primary and secondary schools, in order to help to reduce the misconceptions, stigmatization and discrimination regarding people with epilepsy and their families that are widespread in many countries and regions;
- (6) to promote actions to prevent causes of epilepsy, using evidence-based interventions, within the health sector and in other sectors outside health;
- (7) to improve investment in epilepsy research and increase research capacity;
- (8) to engage with civil society and other partners in the actions referred to in subparagraphs 1(1) to 1(7) above;

2. INVITES international, regional, national and local partners from within the health sector and beyond to engage in, and support, the implementation of the actions set out in subparagraphs 1(1) to 1(8) above;

3. REQUESTS the Director-General:

- (1) to review and evaluate actions relevant to epilepsy that WHO has been leading, coordinating and supporting in order to identify, summarize and integrate the relevant best practices with a view to making this information widely available, especially in low- and middle-income countries;

⁵² And, where applicable, regional economic integration organizations.

- (2) to develop, in consultation with relevant stakeholders, on the basis of work requested in paragraph (1), a set of technical recommendations guiding Member States, in the development and implementation of epilepsy programmes and services, and to provide technical support to Member States in actions for epilepsy management, especially in low- and middle-income countries;
- (3) to report back to the Seventy-first World Health Assembly on progress in the implementation of this resolution.

14. Promoting health through the life course

14.2 Health in the post-2015 development agenda

Document A68/14 (Report by the Secretariat):

Health in the post-2015 development agenda

1. In resolution WHA67.14 the World Health Assembly, recognizing the importance of implementing relevant internationally agreed commitments, urged Member States to ensure that health is central to the post-2015 development agenda; to ensure that the post-2015 development agenda will accelerate and sustain progress towards the achievement of health-related Millennium Development Goals (MDGs); to incorporate into the post-2015 development agenda the need for action to reduce the preventable and avoidable burden of mortality, morbidity and disability related to noncommunicable diseases and injuries while also promoting mental health; to promote universal health coverage (UHC); and to emphasize the need for multisectoral actions to address social, environmental and economic determinants of health.
2. In that resolution the Health Assembly also requested the Director-General to continue active engagement with ongoing discussions on the post-2015 development agenda, in order to ensure the centrality of health in all relevant processes; and to continue to inform Member States and provide support, upon request, on issues and processes concerning the positioning of health in the post-2015 development agenda.
3. Against this background, the present report summarizes the process of crafting the post-2015 development agenda, including the course of action that will lead to the adoption of a new set of goals for sustainable development during 2015.

TOWARDS THE POST-2015 DEVELOPMENT AGENDA

4. The process up to April 2014 was summarized in a report to the Sixty-seventh World Health Assembly.⁵³ As part of a wide-ranging global consultation, the Open Working Group of the General Assembly on Sustainable Development Goals (OWG), consisting of representatives of Member States of the United Nations, in August 2014 proposed 17 sustainable development goals (SDGs) with 169 associated targets (Annex 1).⁵⁴ The proposed SDGs are supported by the three pillars of sustainability: economic development, environmental protection and social equity. In particular, they embrace the principles of the 1992 Rio Declaration on Environment and Development. Furthermore, they recognize that poverty eradication is one of the greatest challenges facing the world today and a prerequisite for sustainable development.
5. In its resolution 68/309 of 10 September 2014, the United Nations General Assembly decided that the proposal of the OWG shall be the main basis for integrating sustainable development goals into the post-2015 development agenda, while recognizing that other inputs will also be considered, in the intergovernmental negotiation process at the sixty-ninth session of the General Assembly.
6. In the scheme proposed by the OWG, health is positioned as one of the 17 SDGs, with the overarching goal to “Ensure healthy lives and promote well-being for all at all ages”. This overarching health goal has nine targets: three related to the MDGs, three on noncommunicable

⁵³ Document A67/20.

⁵⁴ See United Nations General Assembly document A/68/970 and Corr.1, annex.

diseases and injuries, and three that are cross-cutting or focused on systems, including UHC, universal access to sexual and reproductive health care services, and reduced hazards from air, water and soil pollution.⁵⁵

7. While the single health goal captures the key aspects of achieving good health, health is closely linked to many of the other 16 proposed goals. For example, health is a contributor to, and a beneficiary of, poverty reduction, hunger relief and improved nutrition, safer cities, lower inequality, sustainable consumption, affordable and clean energy, the management of toxic chemicals, clean water and sanitation, efforts to combat climate change, and the conservation of aquatic and terrestrial ecosystems. In addition, health statistics are key metrics of progress towards sustainable development because good health and well-being, in the fullest sense, depend on a wide range of economic, environmental and social improvements.

8. The dialogue on development was drawn together in the synthesis report, *The road to dignity by 2030*, which the UN Secretary-General presented to the General Assembly in December 2014.⁵⁶ The synthesis report presents a vision that Member States can take forward in negotiations leading to the United Nations summit for the adoption of the post-2015 development agenda in September 2015. At this summit, world leaders are expected to agree on an historic and far-reaching 15-year programme of work aimed at ending poverty and transforming lives while protecting the planet.

9. The synthesis report sets out the requirements for a realistic yet ambitious outcome from the special summit: an inspirational vision of the future, made plain in a declaration; a practical plan for that declaration, laid out in an integrated set of goals, targets and indicators; adequate means to implement the plan and a renewed global partnership for development; and a mechanism to ensure that promises become actions, with a framework to monitor and review implementation.

10. The synthesis report also identifies six essential elements to frame and reinforce the sustainable development agenda. These focus on: ending poverty and fighting inequalities; ensuring healthy lives; growing a strong, inclusive and transformative economy; promoting safe and peaceful societies and strong institutions; protecting our ecosystems for all societies and our children; and catalysing global solidarity for sustainable development.

11. In December 2014, the General Assembly outlined the negotiating process for the post-2015 development agenda, co-chaired by the Permanent Representatives of Ireland and Kenya. The first two sessions in this process took place by 25 February 2015. In the first, stocktaking session, held on 19–21 January 2015, Member States agreed on the need to clearly communicate what the post-2015 development agenda seeks to achieve in a way that is concise, compelling and understandable to the public. Public communication should be visionary and inspiring, focusing on people and the planet, with extreme poverty at the core. There was broad support for maintaining the 17 goals and associated targets proposed by the OWG. Member States agreed that the means of implementation – financing, capacity-building, technology transfer – should match the ambitions of the SDGs and targets. Member States also agreed that the September 2015 outcome will incorporate a political declaration, the SDGs and associated targets, the means of implementation, and a framework for monitoring and accountability.

12. The second session of intergovernmental negotiations, held on 17–20 February 2015, focused on the Declaration, including a “chapeau” to accompany the goals, targets, means of implementation and monitoring framework. Debate around the draft discussion document covered the following broad themes: the need to show how the three pillars of sustainable development are interdependent; managing the transition from MDGs to SDGs; framing the SDGs in a simple and

⁵⁵ See also document A68/13.

⁵⁶ United Nations General Assembly document A/69/700.

compelling way, for example in terms of “people, planet, partnership and prosperity”; the need for a strong representation of topics including inequality, gender, women, youth, resilience, migration and climate change; and similarly for the themes of transparency, universality, multidimensionality, sustainable production and consumption. From the health perspective, the Declaration should capture the main themes of the health goal, plus the role that health plays more generally in sustainable development. A first draft of the Declaration is expected by the end of April, and will be subject to negotiations in June and July.

13. The intergovernmental negotiating process will continue until the end of July 2015. At the session from 23 to 27 March, the focus was on indicators for the SDGs and targets. On 20–24 April, Member States will consider the means of implementation and the global partnership for sustainable development. A review of progress will be held on 18–22 May. The final three sessions on 22–25 June, 20–24 July and 27–31 July will conclude intergovernmental negotiations on the outcome document.

14. The question of how to finance the new sustainable development agenda is a key consideration for Member States and will be a central subject for discussion at the Third International Conference on Financing for Development, to be held in Addis Ababa, Ethiopia on 13–16 July. A major challenge is to align financing to achieve the SDGs at both global and national levels.

15. The United Nations Statistical Commission has been tasked with developing an indicator framework for monitoring progress towards the SDGs and targets. The Commission and its working mechanisms were requested to support this process by proposing indicators, and a provisional list was developed by February 2015. Because the 17 SDGs include 169 targets, and some targets have several components, such a process results in a large number of global indicators. In addition, there might be national, regional, and sectoral or thematic indicators. Several Member States have voiced concern about the large number of indicators resulting in an excessive national reporting burden, and have expressed a preference for a smaller and more manageable number. The Statistics Division of the United Nations Department of Economic and Social Affairs has subsequently announced its intention to aim for a shortlist of between 100 and 120 core indicators.

16. The process of choosing a shortlist of indicators inevitably means that some will be discarded. In the area of health, where several MDG-related targets and indicators are to be carried forward, care must be taken not to lose valuable new work done on noncommunicable diseases and injuries, on universal health coverage, and on the social and environmental determinants of health. World Health Assembly resolutions provide some guidance to aid choice, but these resolutions contain many targets and indicators related to health. The process of choosing key indicators is unlikely to be finalized before the March 2016 session of the Statistical Commission, although December 2015 has been mentioned as a target date for setting the core indicators.

ACTION BY THE HEALTH ASSEMBLY

17. The Health Assembly is invited to note the report.

ANNEX

SUSTAINABLE DEVELOPMENT GOALS (SDGS) PROPOSED BY THE OPEN WORKING GROUP OF THE GENERAL ASSEMBLY (OWG)

Goal 1 End poverty in all its forms everywhere

- Goal 2 End hunger, achieve food security and improved nutrition and promote sustainable agriculture
- Goal 3 Ensure healthy lives and promote well-being for all at all ages
- Goal 4 Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all
- Goal 5 Achieve gender equality and empower all women and girls
- Goal 6 Ensure availability and sustainable management of water and sanitation for all
- Goal 7 Ensure access to affordable, reliable, sustainable and modern energy for all
- Goal 8 Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all
- Goal 9 Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation
- Goal 10 Reduce inequality within and among countries
- Goal 11 Make cities and human settlements inclusive, safe, resilient and sustainable
- Goal 12 Ensure sustainable consumption and production patterns
- Goal 13 Take urgent action to combat climate change and its impacts
- Goal 14 Conserve and sustainably use the oceans, seas and marine resources for sustainable development
- Goal 15 Protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss
- Goal 16 Promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels
- Goal 17 Strengthen the means of implementation and revitalize the global partnership for sustainable development

14.5 Contributing to social and economic development: sustainable action across sectors to improve health and health equity (follow-up of the 8th Global Conference on Health Promotion)

Document A68/17 (Report of the Secretariat):

Contributing to social and economic development: sustainable action across sectors to improve health and health equity (follow-up of the 8th Global Conference on Health Promotion)

1. Resolution WHA67.12 requested the Director-General, inter alia, to prepare, for the consideration of the Sixty-eighth World Health Assembly, in consultation with Member States,⁵⁷ organizations of the United Nations system and other relevant stakeholders as appropriate, and within existing resources, a Framework for Country Action, for adaptation to different contexts, taking into account the Helsinki Statement on Health in All Policies,⁵⁸ aimed at supporting national efforts to improve health, and ensure health protection, health equity and health systems functioning, including through action across sectors on determinants of health and risk factors of noncommunicable diseases, based on best available knowledge and evidence.
2. In keeping with the request of the Director-General in this resolution, and in line with the interest expressed in this request by the United Nations General Assembly in its resolution A/RES/68/300,⁵⁹ the Secretariat developed a draft framework for country action across sectors for health and health equity through three rounds of informal consultations:
 - On 29 October 2014, the Secretariat published a first discussion paper for a web-based consultation.⁶⁰
 - On 16 February 2015, the Secretariat published a second discussion paper for a web-based consultation.⁶¹
 - On 5 and 6 March 2015, the Secretariat convened a technical reference group in Geneva to support the Secretariat in finalizing its work on the draft framework for country action.
4. The final draft framework for country action across sectors for health and health equity is annexed to this report.

⁵⁷ And, where applicable, regional economic integration organizations.

⁵⁸ Endorsed by the 8th Global Conference on Health Promotions, the Helsinki Statement on Health in All Policies: Framework for Country Action, is available at: <http://www.who.int/healthpromotion/frameworkforcountryaction/en/> (accessed 1 May 2015); see also the Health in All Policies: Framework for Country Action, at the same WHO website.

⁵⁹ United Nations General Assembly resolution A/RES/68/300, paragraph 10.

⁶⁰ The first discussion paper was posted until 31 December 2014. The consultation continued and comments on the first draft of the Framework were sought between 16 February and 3 March 2015. The first discussion paper is available at <http://www.who.int/nmh/events/action-framework-step1/en/>. Related links provide the contributions received from nine Member States, one United Nations organization, three nongovernmental organizations, and one private sector entity.

⁶¹ The second WHO discussion paper, of 16 February 2015, was posted until 3 March 2015 and is entitled, "First draft of the framework for country action across sectors for health and health equity". It is available at: <http://www.who.int/nmh/events/WHO-discussion-paper2.pdf> (accessed on 4 May 2015). Related links provide the contributions received from nine Member States, two United Nations organizations and intergovernmental organizations, and 11 nongovernmental organizations; there were no contributions from private sector entities.

ACTION BY THE HEALTH ASSEMBLY

5. The Health Assembly is invited to consider for approval the draft Framework for Country Action across Sectors for Health and Health Equity.

ANNEX

DRAFT FRAMEWORK FOR COUNTRY ACTION ACROSS SECTORS FOR HEALTH AND HEALTH EQUITY

SECTION 1: INTRODUCTION

What is the purpose of the framework?

1. The framework provides guidance to Member States on taking country-level action across sectors for improving health and health equity. Such action includes the support of the health sector to other sectors in developing and implementing policies, programmes and projects within their own remit, in a way that optimizes co-benefits (i.e. for all sectors involved).
2. The framework explains what action across sectors means, why such action is needed, the underlying values and principles, and how effective actions can be carried out across sectors at all levels of government. The framework clarifies the roles and responsibilities of different governmental and nongovernmental actors, and provides practical tools to facilitate the implementation of action across sectors.
3. The framework can be used to address specific health issues, or to establish a more comprehensive, systematic approach to ensuring action across sectors for health and health equity, with a focus on underlying determinants of health.

What is action across sectors?

4. Action across sectors refers to work undertaken by two or more government ministries or agencies to develop policies, programmes or projects. It includes both horizontal action between ministries or agencies, and action across different levels of government. Traditionally, the health sector has facilitated action across sectors for health and health equity, for example, through the “Health in All Policies” approach⁶² and the “whole of government” approach.⁶³
5. Substantial health gains can be made through explicit effort from sectors outside health, as outlined in paragraphs 7 to 12. Therefore, it is important for the health sector to support other sectors in developing and implementing policies, programmes and projects within their own remit

⁶² Health in All Policies is an approach to public policies across sectors that systematically takes into account the health implications of decisions, seeks synergy and avoids harmful health impacts. It aims to improve population health and health equity. It also improves the accountability of policy-makers for health impacts at all levels of policy-making, and emphasizes the consequences of public policies on health systems, and on determinants of health and well-being. See the Helsinki Statement on Health in All Policies, available at: <http://www.who.int/healthpromotion/frameworkforcountryaction/en/> (accessed 4 May 2015)

⁶³ The “whole of government” approach is one in which public service agencies work across portfolio boundaries, formally and informally, to achieve a shared goal and an integrated government response to particular issues. It aims to achieve policy coherence in order to improve effectiveness and efficiency. This approach is a response to departmentalism that focuses not only on policies but also on programme and project management. An example a 2004 publication by the Australian Public Service Commission: “Connecting government: Whole of government responses to Australia’s priority challenges”, available at: <http://www.apsc.gov.au/publications-and-media/archive/publications-archive/connecting-government> (accessed 4 May 2015).

that optimize co-benefits. Thus, in this framework, action across sectors in government or, more generally, in the public sphere, also refers to “multisectoral action”.⁶⁴

6. Engagement with non-State actors who play a critical role in promoting action across sectors is essential. This is also known as “multistakeholder action”.

Why is health action across sectors necessary?

7. Health action across sectors is necessary because many factors that are key to health outcomes lie beyond the reach and control of the health sector. Such factors include: the causes of, distribution of, and risk factors for, many diseases; inequitable access to care; and the social, economic and environmental determinants of health. Action across sectors is needed to ensure health protection and to optimize health systems functioning, both of which are essential for improving health and health equity.

8. Examples of how health can be affected by actions beyond the health sector include:

- decline in road deaths as a result of a range of measures on, for example, safer road design and motor vehicle safety;
- reduction in tobacco-related morbidity and mortality due to the implementation of tobacco control measures by different government sectors;
- reduction in cardiovascular disease and stroke due to a reduction in dietary salt intake;
- decline in mesothelioma as a result of regulations against the use of asbestos;
- decrease in mortality from diarrhoea because of improved access to clean water and sanitation;
- the increase in life expectancy due to additional years of education.

9. Action across sectors has proven to be an effective way to address specific health issues throughout the life course, most notably in tobacco control and in combating HIV/AIDS. It is also highly effective in health emergency situations, which usually require the rapid participation and cooperation of various sectors.

10. Action across sectors is particularly important in countries with weak infrastructures, an overemphasis on economic development at the expense of the environment, weak regulation and legislation for the prevention and control of noncommunicable diseases, and limited capacity of and access to health systems.

11. Health for all is a precondition for and an indicator of sustainable development. Action across sectors is needed in all countries to achieve a set of sustainable development goals beyond 2015, including a proposed goal to ensure healthy lives and promote well-being for all at all ages, and a proposed target to achieve universal health coverage.⁶⁵ Vice versa, achieving the proposed set of sustainable development goals by 2030 is critical for health and health equity, taking into account that most of the sustainable development goals are social, economic and environmental determinants of health, such as: poverty; hunger; food security and nutrition; inclusive and quality education; gender equity; water and sanitation; energy; inclusive and sustainable economic growth; employment and decent work; safe and sustainable cities; climate change; and peaceful and inclusive societies. Moreover, health is a contributing factor to the attainment of two other proposed sustainable development goals: equity and global partnership for sustainable

⁶⁴ The term “multisectoral action” refers to action between two or more sectors within the public sector and is generally interchangeable with “intersectoral action”.

⁶⁵ See United Nations General Assembly resolution A/RES/68/309 and document A/68/970.

development.⁶⁶ There are also links between health and the remaining four proposed sustainable development goals: industrialization and innovation; consumption and production patterns; use of the oceans, seas and marine resources; and the use of terrestrial ecosystems.

12. Addressing the social and environmental determinants of health across all sectors and for whole populations, irrespective of a country's stage of socioeconomic development, "is important to create inclusive, equitable, economically productive and healthy societies".⁶⁷

What forms does health action across sectors take?

13. Action across sectors can take multiple forms, including:

- the **health authority** initiates actions, with participation from one or more ministries or agencies, and focusing primarily on improving health and health equity (this is the most common form of action);
- the **head of government** initiates action with all ministries participating most of the time on a priority health concern, such as an outbreak or an emergency or longer-term health challenges such as noncommunicable diseases. It has been proven successful in responses to HIV/AIDS and maternal and child health issues as well as outbreaks, such as the recent Ebola outbreak;
- a **new structure** is established (or an existing government entity is used) to oversee and promote collaboration among different ministries, to address a priority public health concern (this form of action is common in international, national or local responses to HIV/AIDS);
- **authorities outside health** assume the lead agency role, as has occurred in the prevention of road deaths and injuries, where the road transport authorities have taken primary responsibility. There are many examples of this form of action; including actions by environmental protection agencies to address environmental hazards including air, noise and water pollution; and
- action is initiated at the **local government level**; it is increasingly common to find various sectors working together to address one or more public health and health equity issues through community-based or setting-based health promotion activities (e.g. healthy cities⁶⁸ and health-promoting schools).

SECTION 2: PROPOSED FRAMEWORK FOR COUNTRY ACTION ACROSS SECTORS FOR HEALTH AND HEALTH EQUITY

Core values and principles

14. The underlying values and principles on which the framework is based are as follows:

- **Right to health:** This is in line with the Constitution of the World Health Organization. The right to health applies equally to all stages of life.
- **Health equity:** Equity in health can be addressed when there is a focus on the causes of the disparities that persist. Vulnerable populations need to be given special attention.
- **Health protection:** Disease prevention and health promotion are key responsibilities of governments. Legislation, rules and regulations are important instruments to protect people from social, economic and environmental threats to health.

⁶⁶ For more information on sustainable development goals, see: <https://sustainabledevelopment.un.org/sdgsproposal> (accessed 4 May 2015).

⁶⁷ For more information on the United Nations Conference on Sustainable Development, The Future We Want, see: <http://www.uncsd2012.org/thefuturewewant.html> (accessed 4 May 2015).

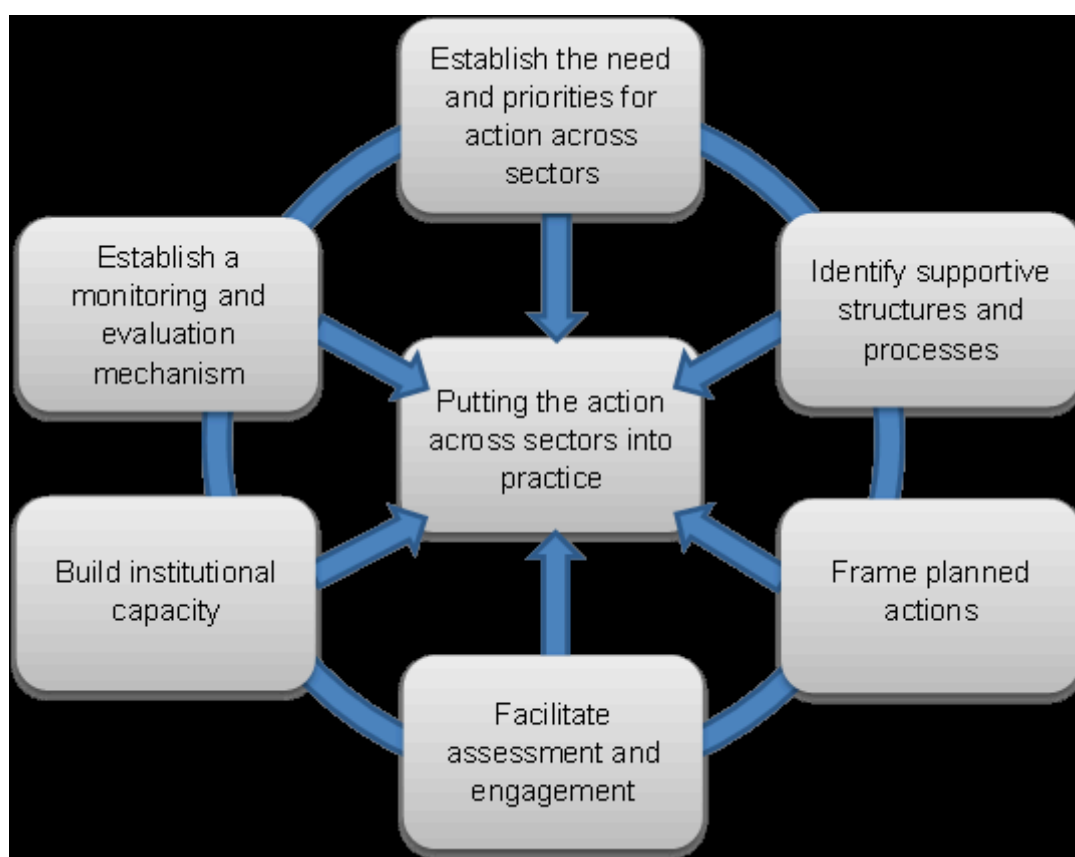
⁶⁸ For more information on types of healthy settings, see: http://www.who.int/healthy_settings/types/cities/en/ (accessed 4 May 2015).

- **Good governance:** Accepted principles of good governance include: legitimacy, grounded in the rights and obligations conferred by national and international law; accountability of governments towards their people; and participation of wider society in the development and implementation of government policies and programmes.
- **Sustainability:** It is important to ensure that policies aimed at meeting the needs of present generations do not compromise the needs of future generations.
- **Collaboration:** The protection and promotion of health and health equity requires collaboration and in many instances, joint action across various sectors and levels of government, non-State actors and the community.
- **Safeguard of public health interests:** To safeguard such interests, it is necessary to avoid undue influence by any form of conflict of interest, whether real, perceived or potential.

Proposed components for action

15. There are six key components that countries need to consider in implementing effective action across sectors, as shown in Figure 1. These components are not fixed in order or priority. Countries should adapt and adjust the components based on the country's specific social, economic and political contexts.

Figure 1. Key components of implementing health action across sectors



Source: Adapted from the Health in All Policy: Framework for Country Action, see: <http://www.who.int/healthpromotion/frameworkforcountryaction/en/>.

Key component 1: Establish the need and priorities for action across sectors

16. Establishing the need for action means determining what the specific needs are and how they might be addressed. Gaps in health and health equity must be identified, what works must be made

known, and other sectors must be supported in developing and implementing policies, programmes and projects within their own remit, which optimize co-benefits.

17. Listed below are some of the actions that can be taken to establish needs and priorities.⁶⁹

- *Ensure that there is high-level political will and commitment* – this requires advocacy, to raise awareness that achieving health and health equity is a key responsibility of all governments, that health is an outcome of all policies, and that health contributes to broader societal and policy goals, such as economic growth and sustainability.
- *Build a case for action across sectors* – increasing the awareness of decision-makers, civil society and the public about how policies from different sectors of government can affect health and health equity, demonstrating how the engagement of key non-State actors can enhance the results of taking action, bringing a focus on the benefits to other sectors by working with the health sector, and communicating the costs of inaction.
- *Use political mapping* – this can identify members and groups within government that would be supportive and influential in ensuring the commitment of other sectors.
- *Identify areas of common interest, and existing intersectoral structures and frameworks* that could be strengthened to improve the efficiency of work.
- *Prioritize actions* – this could be based, for example, on the significance of the issue for health or health equity, the alignment with government priorities, the existence of feasible and evidence-based solutions, available resources, and ethical criteria or those that are most amenable to intersectoral action.
- *Analyse information about the factors affecting health*. Some countries have adopted a health profile methodology to identify the main determinants of health and well-being in each municipality, helping to set local public health priorities and need for action across sectors.

Key component 2: Identify supportive structures and processes

18. In this context, a structure enables actors from different sectors to interact. It can be a collection of people designated for a function or purpose, such as a committee or an interagency network, a service provider, or a collection of interrelated services, such as a public health institute. A process outlines the interaction and communication, including power dynamics and influences, between actors.

19. Listed below are some of the actions that can be taken to identify structures and processes:

- *Strengthen the ministry of health* in terms of its capacity to identify and engage with different government sectors, WHO and other United Nations organizations and intergovernmental organizations, and non-State actors in actions initiated by the health sector. It is important to identify and initiate dialogue with motivated leaders, and with individuals who contribute to decision-making or policy implementation, within different sectors.
- *Identify the most appropriate facilitating agency* to manage, take forward and account for the action across sectors for a given topic or priority. Also, ensure that the agency has the necessary human resources to carry out the coordination work needed, examine existing collaboration frameworks across sectors, and explore the possibility of integrating health and equity aspects in those dialogues.
- *Create realistic and functional structures for communication and for working across sectors* or use existing structures, where available (examples are shown in Table 1), with clear roles and

⁶⁹ Examples of reducing tobacco demand in Turkey, as well as the WHO Urban Health Equity Assessment and Response Tool (Urban Heart) are available at <http://www.who.int/nmh/events/2015/case-studies-framework.pdf?ua=1> (accessed 13 May 2015).

responsibilities. These structures could be topic-specific or broad enough to tackle multiple issues. At the national level, experience from different countries indicates that structures work best when there is the direct involvement of the Head of State or Government.

- In countries with a decentralized government structure, *consider using the existing inter-territorial coordination mechanisms*, ensuring that regional and local entities are involved in the process.
- *Use legal frameworks*, including international treaties, presidential orders and memoranda of understanding to foster intersectoral collaboration.⁷⁰ At the national level, many countries have adopted laws and regulations affecting different sectors to decrease the use of tobacco by increasing taxes or banning smoking in public places.⁷¹
- *Improve accountability and explore available mechanisms for scrutiny* within the legislative process, such as oversight committees, public hearings, issue-based groups and coalitions, and public health reports to legislature.

Table 1. Examples of structures to foster collaborative work across sectors⁷²

| Structures | Description | Examples |
|--|--|--|
| Parliamentary commissions or groups | Composed of members of parliament with specific advocacy or an oversight role. | <ul style="list-style-type: none"> • Samoa Parliamentary Advocacy Group for Healthy Living |
| Merged or coordinating ministries | Ministries with a mandate that includes several sectors or areas of responsibility for intersectoral coordination. | <ul style="list-style-type: none"> • Ministry of Social Affairs and Health (Finland) • Ministry of Health and Family Welfare (India) • Department of Social Development (South Africa) |
| Interministerial/departmental committees | Composed of representatives from various governmental sectors. Usually horizontal (i.e. similar administrative levels – national, subnational, district), but sometimes vertical. Can include nongovernmental organizations, private sector and political parties; and can be permanent or time-limited, have generic tasks or be ad hoc and centred around a specific task. | <ul style="list-style-type: none"> • Advisory Board for Public Health (Finland) • Intersectoral Commission of Employment (Peru) • Health in All Policies Task Force (California, United States of America) • Governmental HIV and AIDS Committee (Estonia) • Intersectoral Commission for the Control of Production and Use of Pesticides, Fertilizers and Toxic Substances (Mexico) • Quebec Government network of departmental representatives to “promote awareness of the existing |

⁷⁰ Examples include the WHO Framework Convention on Tobacco Control and the Convention on the Rights of the Child.

⁷¹ Examples of legislation affecting different sectors to improve health include the 2012 Norwegian Public Health Act to Institutionalize Health in All Policies and the 2012 Public Health Product Tax in Hungary.

⁷² See submissions received by WHO through the web-based consultation on the first draft Framework, see: <http://www.who.int/nmh/events/WHO-discussion-paper2.pdf> (accessed 4 May 2015); also see the following publication: Leppo K, Ollila E, Peña S, Wismar M, Cook S, editors. Health in all policies: seizing opportunities, implementing policies. Helsinki: Ministry of Social Affairs and Health, Finland; 2013, page 11, also available at: <http://www.euro.who.int/en/about-us/partners/observatory/publications/studies/health-in-all-policies-seizing-opportunities,-implementing-policies> (accessed 13 May 2015).

| | | |
|----------------------------|--|---|
| | | <p>impact assessment tools in their respective ministries, and support the use of these tools” (Quebec, Canada)</p> <ul style="list-style-type: none"> • National Development Government Committee (Hungary) • Government HIV/AIDS Committee and Intersectoral task force on injury prevention (Estonia) |
| Health Commissions | Composed of representatives from various government sectors, nongovernmental organizations and private sector. Report to health minister. | <ul style="list-style-type: none"> • National NCD Commission (Barbados) |
| Support units | Units within ministry of health or other ministries with a mandate to foster intersectoral collaboration. | <ul style="list-style-type: none"> • Health in All Policies Unit (South Australia, Australia) |
| Local/community coalitions | Local organizations that promote collaboration among different sectors. | <ul style="list-style-type: none"> • Community Anti-Drug Coalitions of America (United States of America) • County Health Council coordinating Ebola response efforts in Margibi and Lofa (Liberia) |
| Networks | Flexible coordination mechanism composed of institutional partners. | <ul style="list-style-type: none"> • Canterbury Health in All Policies Partnership (Canterbury, New Zealand) • Network of department representatives to promote awareness of the existing impact assessment tools in their respective ministries, and support the use of these tools (Quebec, Canada) |
| Expert committees | Comprising experts from NGOs, academia, think tanks, the public or private sector often created ad hoc around a specific task. Their composition can have a political balance. | <ul style="list-style-type: none"> • Presidential Advisory Council for Pension Reform (Chile) |
| Public health institutes | Public institutes with capacity to monitor public health and its determinants, and to analyse policies and their potential health implications across sectors. | <ul style="list-style-type: none"> • See International Association of National Public Health Institutes. The Ministry of Health and Social Services of Quebec (Canada) has an agreement with the National Public Health Institute of Quebec, which is specifically devoted to the application of the legislated requirement for health impact assessment, see http://www.ncchpp.ca/133/Publications.ccnpps?id_article=124. |

Key component 3: Frame the planned action

20. Action plans can be stand-alone, or incorporated into existing action plans or strategic documents. The lead agency will initiate planning with the collaboration of the intersectoral established structure, whether it be a committee, a working group or another structure.

21. Listed below are some of the actions that can be taken to frame the planned action:⁷³

- *Identify and review the data available for a given issue* – this will include a legal and policy analysis, and a summary of available evidence-based interventions;
- *Identify existing action plans, policy documents and mandates* of the different sectors involved – to determine synergies and develop a common plan that ascertains community/systems changes to be sought and who will do what;
- *Define and agree on objectives, targets, indicators, population coverage, roles and responsible agencies and individuals, timelines, resources and a contingency plan;*
- *Ensure adequate human and financial resources* – although an increase in staff might not be necessary, changes in job practices might be required;
- *Develop a strategy to identify, prevent or counteract conflicts of interest;*
- *Develop a strategy to report the results and give adequate feedback to all sectors involved, and to the general public;*
- *Develop a monitoring and evaluation strategy with input from all sectors involved, including a health impact assessment.*

Key component 4: Facilitate assessment and engagement

22. Assessing health needs is important to identify unmet gaps in policy formulation or service provision. The information can then be used to determine priorities for action across sectors, and to plan specific policy or service improvements to meet these needs.

- A health needs assessment may involve: characterizing the epidemiology of health issues; understanding the patterns of and contributors to health inequities; identifying potential actions to improve health and health equity based on the best available evidence; canvassing the opinions of key groups and communities; and documenting the linkages between priority health needs, underlying determinants of health, existing policy levers and potential actions across sectors.
- It is also essential to assess the health impact of policies in order to ensure that the expected outcome of the policy is achieved.
- The agency responsible for conducting the assessment will depend on the type of assessment needed. In some cases, it may be preferable that an independent body be engaged for the task.

23. In general, the engagement of both State and non-State actors is essential throughout the entire process of policy making, from needs assessment, planning, implementation, to monitoring and evaluation. Creating awareness and facilitating the participation of stakeholders, through early involvement from the preparatory stages onwards, are critical to eventual success. Open and effective communication of the potential health and other implications with all sectors and stakeholders is essential to ensure a fuller understanding of both current and planned actions and policies in the wider community.

⁷³ Examples of the national good living plan in Ecuador are available at: <http://www.who.int/entity/nmh/events/2015/case-studies-framework.pdf?ua=1> (accessed 13 May 2015).

24. Historically, various stakeholder groups or sectors have co-existed within separate structures. It is increasingly recognized that an “action across sectors” approach would be more effective. Such an approach aims to move engagement across the continuum from co-existence through to collaboration.

25. Listed below are some of the actions that can be taken to facilitate engagement:⁷⁴

- *Use appropriate tools*, such as health and health equity impact assessment, health and health equity lens analysis, policy audits and budgetary reviews, to assess the health impact of policies.
- *Create an inclusive policy-making process* that includes key individuals, civil society groups, health care professional associations, community leaders and individuals, and patients who are likely to be affected by the existing or proposed policies. These people or groups should be invited to give their views on the benefits or adverse consequences of the policy, and their suggestions for improvement. Formal engagement tools can include health assemblies, citizen juries, town hall discussions, deliberative meetings or individual consultations. Internet-based tools such as discussion forums and social media are possible alternatives.
- *Identify individuals involved in decision-making* or policy implementation, and invite them to engage in the dialogue in order to understand their priorities and recommendations.
- *Specifically identify opportunities to engage with non-State actors*, including academia and professional associations, to seek assistance with assessment and engagement processes, and with the private sector, to facilitate shared understanding of the health agenda.

Key component 5: Establish a monitoring, evaluation and reporting mechanism

26. Mechanisms for monitoring, evaluation and reporting on progress provide evidence of what works and of best practices. It is recognized that each sector is probably already responding to its own key performance indicators and deliverables. Therefore, monitoring and evaluation indicators for intersectoral coordination, intervention and implementation would be additional requirements for stakeholders. Examples of suitable indicators can be drawn from those being developed by WHO for monitoring intersectoral influences on equity in health and universal health coverage, and in the Plan of Action on Health in All Policies (using WHO sustainable development goal indicators).

27. The tools mentioned previously for facilitating engagement (see paragraph 25) can also be used for monitoring and evaluation, and may include health impact and health equity impact assessments, health and health equity lens analysis, environmental impact assessments, policy audits and budgetary reviews.

28. Listed below are some of the actions that can be taken to establish mechanisms for monitoring, evaluation and reporting:⁷⁵

- Start planning for monitoring and evaluation early in the process and, where appropriate, develop an evaluation framework.
- Identify and agree on shared, meaningful indicators.
- Incorporate monitoring and evaluation throughout the action process (see Annex 1 of the Health in All Policies: Framework for Country Action).
- Establish the baseline, targets and indicators, as appropriate. For intersectoral action, these can be formal indicators and performance targets (on health status; on health inequities and their

⁷⁴ Examples of health impact assessments in Thailand are available at: <http://www.who.int/entity/nmh/events/2015/case-studies-framework.pdf?ua=1> (accessed 13 May 2015).

⁷⁵ An example of the PAHO Plan of Action on Health in All Policies is available at <http://iris.paho.org/xmlui/bitstream/handle/123456789/4629/CE154-17-e.pdf?sequence=1&isAllowed=y> (accessed 4 May 2015).

determinants; and on health action). Alternatively, a country can use a more flexible case-study approach based on its specific situation and needs (it is best to use existing governance-related monitoring and evaluation structures and frameworks where possible).

- Obtain data that can provide estimates for the different subpopulations, especially for vulnerable groups. Consider whether disaggregated data (including data on determinants of health) can be included.
- Carry out agreed monitoring and evaluation activities according to negotiated schedules.
- Ensure that reporting mechanisms are not too demanding for the participants, in order to avoid compromising the actual implementation.
- Measure co-benefits and provide evidence in support of future cooperation among sectors.
- Disseminate results and lessons learnt to all participating sectors, in order to provide feedback for future policy and strategy rounds.

Key component 6: Build capacity

29. Promoting and implementing action across sectors is likely to require the acquisition of new knowledge and skills by a wide range of institutions, professionals (health and non-health) and people in the wider community. Institutional capacity refers not only to the expertise of individual practitioners, but also to existing policy commitments, availability of funds, information and databases for planning and monitoring and evaluation, and organizational structure.

30. Capacity building is essential for all sectors involved and needs to be tailored and adapted to the specific country and sectoral contexts. There is a need for the different sectors to interact and exchange capacities during this process. It is also important that capacity building takes place at the same time in all sectors, given that collaborative action requires participation by all. Listed below are some actions that can be taken to facilitate capacity building:⁷⁶

- Encourage sectors to share and exchange skills and resources for capacity building.
- Promote the formation of communities of practice.⁷⁷
- Build capacity on research and innovation, for example with the use of new technologies for disease prevention and treatment.
- Build capacity on innovative financing or existing financing mechanisms to ensure long-term sustainability.
- Develop diplomacy and negotiation skills, which are invaluable to successful action across sectors. These skills are often acquired through specific training that focuses on action across sectors.⁷⁸

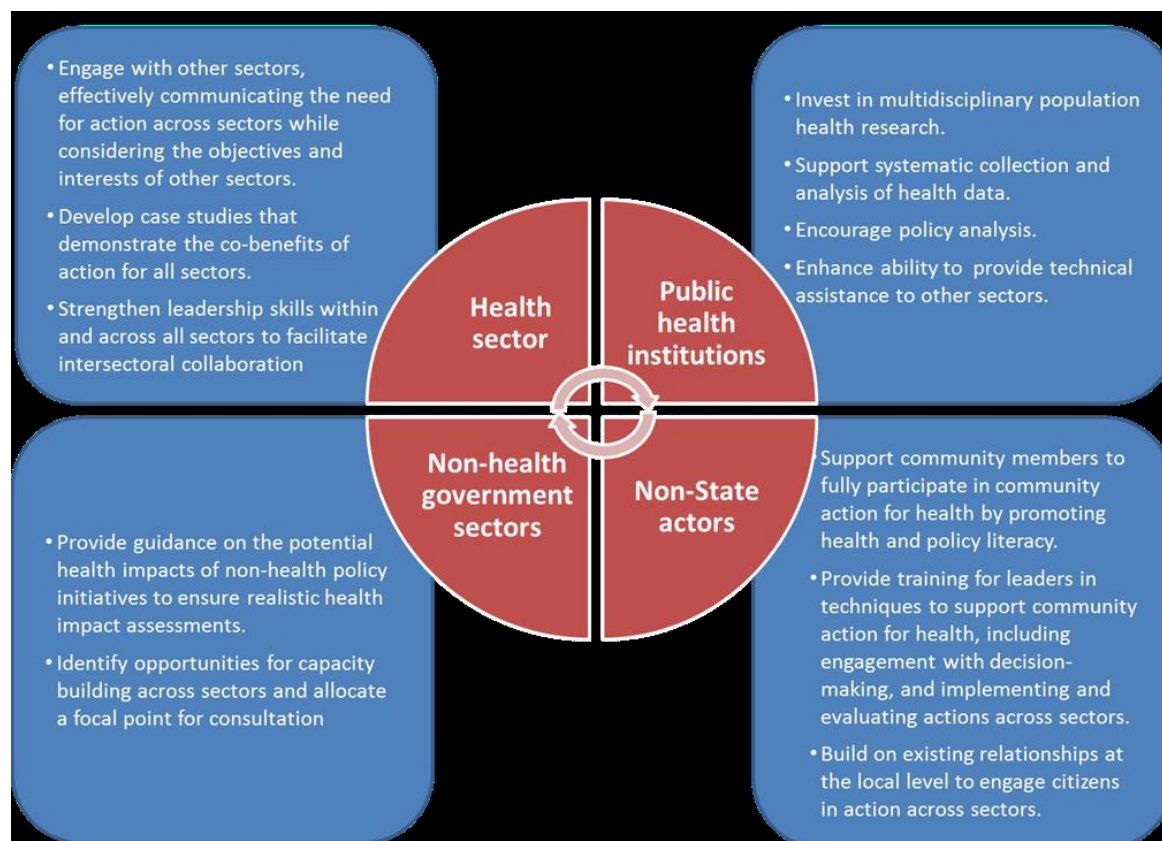
⁷⁶ For examples of operationalizing innovative funding for the treatment of HIV/AIDS, as well as the WHO Health in All Policies Training Manual, see: http://www.who.int/social_determinants/publications/health-policies-manual/en/ accessed on 4 May 2015); and see the Master Plan for Roll-out of Training in Working Across Sectors, at: <http://www.who.int/entity/nmh/events/2015/case-studies-framework.pdf?ua=1> (accessed 13 May 2015).

⁷⁷ The community of practice in the Australian state of South Australia has evolved over time, starting with informal collaborative relationships between policy-makers across sectors. These relationships have become progressively more formal and have developed into a network. They have been strengthened through skills workshops, sharing of experiences and outcomes, and sharing a mutual recognition of success in action across sectors, for example, including intersectoral representation of action across sectors at different forums. As the purpose, function and experience grow and develop, a community of practice emerges, which becomes an important supportive structure for facilitating the exchange of knowledge, information and lived experience among actors across different sectors and levels of government and community.

- Encourage sectors to put into place and implement strong accountability mechanisms.

31. Figure 2 gives a method for shared capacity building, showing some of the many readily available approaches that can be taken to build institutional capacity in different sectors.

Figure 2. Model for shared capacity building



Putting into practice action across sectors

32. The application of action across sectors requires conscientious effort and judicious use of evidence. To maximise the impact of application, theory-driven practices are essential and to put theory into practice, tools are necessary.

33. Such tools may include national strategies for action and mapping of government activities and opportunities. Governments may use legislation (including international treaties and presidential orders), establish new government units, or develop memoranda of understanding to improve intersectoral action. Other tools can also be used to incorporate action across sectors within legislative processes; for example, through oversight by committees with statutory responsibility for health, public hearings and consultations, issue-based groups and coalitions within legislatures, or public health reports to legislatures.

34. Listed below are some of the key issues for effective implementation:⁷⁹

⁷⁸ For example, the WHO Health in All Policies Training Manual outlines specific training activities on strategies and techniques for policy negotiation.

⁷⁹ Examples of salt-reduction campaigns in Bahrain, Kuwait and Qatar, as well as multisectoral engagement for road safety in Viet Nam are available at <http://www.who.int/entity/nmh/events/2015/case-studies-framework.pdf?ua=1> (accessed 13 May 2015).

- *Strategic application* – the need to address priority public health concerns and their underlying determinants according to a country’s situation when applying the framework.^{80,81}
- *Being alert to windows of opportunity* – crises, changes in government and other contextual factors may present opportunities to engage across sectors beyond the scope of planned action. Furthermore, once the health crisis has passed, efforts should be made to preserve and improve the structure and the coordination that was quickly put in place for it.
- *Putting plans into action, including the implementation of monitoring and evaluation plans* – the need to ensure that all the different sectors *understand* their roles and responsibilities (including the amount of resources that need to be invested and the implications of not performing the assigned activities) and also *fulfil* those roles and responsibilities.
- *Increasing collaboration* through different strategies – with different professional groups (for example, urban planners) to mobilize their contributions to health and health equity efforts, for example, collaboration with professional groups and offering training to build capacity, establishing intersectoral working groups, identifying a relevant catalyst (champion, political imperative, national strategy, civil action).
- *Providing for contingencies* – the need to manage contingencies that may occur. In this regard, efforts must be made to identify, assess and cope with threats and barriers to effective action across sectors. To put together a “Plan B” with different options is useful.
- *Considering a cross-sectoral co-financing approach* that has proven to be more cost-effective.⁸² Also considering sustainable funding sources, such as taxation of products (tobacco and alcohol are the most common), and *integrated budgets and accounting* through shared resources and financing.
- *Creating an organizational culture that supports implementation* through managing tools, such as practice guides, collaborative learning, and continuing education and training, using the WHO Health in All Policies Training Manual.

SECTION 3: ROLES AND RESPONSIBILITIES

Lead roles

35. For health action across sectors to be effective, a facilitating agency is needed that will actively coordinate and manage the process.

36. To effectively influence other sectors to undertake action for health, the facilitating agency must hold the authority to work with other sectors, the required expertise, and the necessary information on the health issues and their implications for other sectors. The facilitating agency should also have a good understanding of the priorities and decision-making methods of other sectors.

37. Whatever agency becomes the facilitator, the roles, responsibilities and accountability for all sectors of government must be established at the outset of the planning process, so that all are clear about their roles and responsibilities, and the benefits they may gain. This will avoid duplication of activity, and increase effective collaboration among the various actors.

Health sector

⁸⁰ Examples of such concerns include the rapidly-growing burden of noncommunicable diseases and of communicable diseases such as the Ebola virus disease, HIV/AIDS, malaria and tuberculosis; and the health impacts of environmental changes such as urbanization. The development of multisectoral plans on noncommunicable diseases prevention and control at the country level is a recent example.

⁸¹ The development of national multisectoral plans for the prevention and control of noncommunicable diseases is a recent example.

⁸² See <http://strive.lshtm.ac.uk/> (accessed 4 May 2015).

38. Although government as a whole bears the ultimate responsibility for the health of its citizens, health authorities at all levels (national, regional and local) have the mandate, legitimacy and expertise to initiate partnerships with other government sectors, in order to increase collaboration in the promotion of health and health equity. The health sector usually has a core advocacy function in promoting action across sectors and in articulating the mutual benefits of such an approach. Its role will shift depending on the form of action across sectors taking place, and the nature of the issue and the risk factors.

39. Possible roles for the health sector are to:

- identify and prioritize health issues;
- build knowledge and generate an evidence base for policy development and strategic planning;
- assess the effectiveness of action across sectors and the cost of inaction versus investment;
- initiate regular and continuous dialogue with other sectors and with the whole of society, and create structures for this dialogue if needed;
- understand the priorities and decision-making methods of other sectors;
- advocate for health protection and for social determinants of health to be addressed in public discourse and public policies; and
- promote synergy and negotiate trade-offs between sectors and among potential institutional partners.

Other government sectors

40. Action by sectors other than health, at national, regional and local level can substantially contribute to improved health and health equity, for example, through policies involving social protection, food security, education, poverty reduction, transportation, environment, finance, trade and commerce, and taxation and legislation on the marketing of certain products. Some sectors work more closely with the health sector than others, depending on two key factors: common interests and co-benefits.

41. Increasingly, with decentralized governance in countries, the role of mayors (or their equivalents) – and their contributions to promoting and facilitating action across sectors within and beyond the local government – must be examined and documented. The impact of action across sectors at the city level can be substantial through the healthy cities approach, which defines a healthy city as one that is continually creating and improving those physical and social environments, and expanding those community resources that enable people to mutually support each other in performing all the functions of life and in developing to their maximum potential.⁸³

WHO

42. In line with its expertise and experience in responding to health issues at the global, regional and national level, WHO should aim to:

- compile and promote evidence-based practices for action across sectors;
- promote action on universal health coverage and the social determinants of health;
- support policies for global health protection and health promotion;
- provide guidance and technical assistance for the implementation of policies across sectors on various levels of governance;

⁸³ *Health Promotion Glossary* is available at: www.who.int/healthpromotion/about/HPR%20Glossary%201998.pdf (accessed on 4 May 2015).

- provide a platform to advance multisectoral action by identifying and promoting sustained actions across sectors that can contribute to and support the implementation of the WHO Global NCD Action Plan 2013–2020 through the WHO Global Coordination Mechanism on the Prevention and Control of Noncommunicable Diseases; and
- work with and provide leadership for other United Nations organizations and other intergovernmental organizations, and encourage them to consider health objectives when implementing and monitoring major strategic initiatives.

Other United Nations organizations and other intergovernmental organizations

43. Many United Nations organizations and other intergovernmental organizations support action on social determinants for health in fields such as education, environment, refugees, gender and human rights. If health considerations were more explicitly included in these efforts, it would improve their potential impact on health and health equity. The integration of noncommunicable diseases into the roll-out processes of the United Nations Development Assistance Framework will support governments to integrate measures for the prevention and control of noncommunicable diseases into health planning at the country level, as well as national development and policies beyond the health sector.

44. The United Nations Interagency Task Force on the Prevention and Control of Noncommunicable Diseases is a recent example of action across sectors, working at the country level to prevent and control noncommunicable diseases.⁸⁴

Non-State actor engagement

45. An effective multisectoral response to improve health and health equity also requires participation from non-State actors. There is a growing body of experience with initiatives that have successfully mobilized non-State actors to improve health and health equity. Involvement of the private sector requires particular issues to be considered, such as the management of conflicts of interest, especially if the private sector entities involved are producing goods or services that may harm health.

46. Communities are in a key position to identify health issues and inequities, and to suggest suitable solutions at the local level. In addition to the valuable collective local wisdom, it is important to build community capacity by supporting the ability of community members to fully participate in community action for health. This may include promoting health and policy literacy, and training leaders in techniques to support and enable an informed community.

47. Nongovernmental organizations play a critical role in promoting health action across sectors due to their significant influence on State affairs. They can often provide data and evidence regarding health and health equity issues, which are important for identifying vulnerable populations and the need for action. Useful resources and technical expertise for the development of policies and plans may be provided by nongovernmental organizations. In addition, such bodies are usually led by passionate and committed individuals with great advocacy skills and the capacity to influence public opinion. Member States seeking to implement health action across sectors should seek to engage and include potentially relevant nongovernmental organizations as much as possible. International nongovernmental organizations also have a responsibility to ensure coherent policy in actions related to health and health determinants.

⁸⁴ More information is available at www.who.int/events/2015/action-across-sectors-framework and <http://www.who.int/entity/nmh/events/2015/case-studies-framework.pdf?ua=1> (accessed 13 May 2015).

48. The private sector is key to achieving specific goals, but can also contribute to a negative impact on health and its risk factors. Thus, understanding potential contributions and impact on health is the first step to determining appropriate engagement, while managing potential conflicts of interest.

49. The outcome document of the High-Level Meeting of the United Nations General Assembly on the Comprehensive Review and Assessment of the Progress Achieved in the Prevention and Control of NCDs⁸⁵ requested WHO to develop an approach that could be used to register and publish the contributions of non-State actors to the achievement of the nine global voluntary targets for noncommunicable diseases.

SECTION 4: MANAGING CONFLICT OF INTEREST

50. The engagement of Member States with non-State actors can bring important benefits to public health. There can be, however, risks to engagement with non-State actors, especially with the private sector. A clear risk is when there is conflict of interest between the non-State actor and the Member State.

51. Governments should conduct transparent due diligence and risk assessments before entering into engagement with non-State actors. As far as possible, they should ensure that financial resources for specific local or national coalitions devoted to health action across sectors, as well as any regulatory or norm-setting functions, are independent. When appropriate, Member States can obtain the support of the international community in the oversight and management of engagement, particularly with regard to international treaty obligations.

52. The Helsinki Statement on Health in All Policies urges governments to adopt conflict of interest measures to protect policies from distortion by commercial and vested interests and influence.

⁸⁵ United Nations General Assembly resolution A/RES/68/300.

14.6 Health and the environment: addressing the health impact of air pollution

Document A68/18 (Report by the Secretariat):

Health and the environment: addressing the health impact of air pollution

1. The Executive Board, in its consideration of health and the environment at its 135th session, decided to include the subject on the provisional agenda of the Board at its 136th session.⁸⁶ At that session the Board considered an earlier version of this report,⁸⁷ together with a draft resolution.⁸⁸ The Board then adopted decision EB136(14), in which Member States were encouraged to finalize their work on the draft resolution to enable it to be considered by the Sixty-eighth World Health Assembly. A preparatory process for the draft resolution, including informal consultations with Member States, is being held between January and May 2015. The present report describes the links between air pollution and health, and outlines some strategies for prevention, control and mitigation of the adverse effects of air pollution on health, including coordinated action between the health and other sectors.

EFFECTS OF EXPOSURE TO AIR POLLUTION ON HEALTH

2. Air pollution is one of the main avoidable causes of disease and death globally. About 4.3 million deaths each year, most in developing countries, are associated with exposure to household (indoor) air pollution.⁸⁹ A further 3.7 million deaths a year are attributed to ambient (outdoor) air pollution.⁹⁰

3. Even at relatively low levels air pollution poses risks to health, and because of the large number of people exposed it causes significant morbidity and mortality in all countries. However, although all populations are affected by air pollution, the distribution and burden of consequent ill-health are inequitable. The poor and disempowered, including slum dwellers and those living near busy roads or industrial sites, are often exposed to high levels of ambient air pollution, levels that appear to be worsening in many cities. Women and children in households that have to use polluting fuels and technologies for basic cooking, heating and lighting bear the brunt of exposure to indoor air pollution.

4. Most air pollutants are emitted as by-products of human activity, including heat and electricity production, energy-inefficient transport systems and poor urban development, industry, and burning waste and brush or forests.

5. Pollutants with the strongest evidence for public health concern are fine particulate matter⁹¹ and gases (mainly carbon monoxide, ozone, nitrogen oxides, sulfur dioxide and volatile organic compounds). Fine particulate matter, which is widespread both indoors and outdoors, damages the health of more people than any other air pollutant, through the deposition of particles in smaller airways and alveoli in the lungs and their penetration into the bloodstream. (Larger or more coarse particles, including dust and pollen are more restricted to the thoracic cavity and unable to penetrate the smaller airway systems.) Among the types of fine particulate matter, particular concern centres on elemental carbon and organic materials, transition metals and metal

⁸⁶ See document EB135/2014/REC/1, summary record of the second meeting, section 1.

⁸⁷ Document EB136/15.

⁸⁸ See summary record of the 136th session of the Executive Board, fifteenth meeting, section 1.

⁸⁹ WHO. Burden of disease from household air pollution for 2012, http://www.who.int/phe/health_topics/outdoorair/databases/HAP_BoD_results_March2014.pdf?ua=1 (accessed 1 December 2014).

⁹⁰ WHO. Burden of disease from ambient air pollution for 2012, http://www.who.int/phe/health_topics/outdoorair/databases/AAP_BoD_results_March2014.pdf?ua=1 (accessed 1 December 2014).

⁹¹ Commonly defined as particles with an aerodynamic diameter of less than 2.5 µm.

compounds; inorganic sulfates and nitrates; ammonia; sodium chloride; and mineral dust. Absorbed particles can damage inter alia lung function and the cardiovascular system, through oxidative stress, alteration of the electrical processes of the heart and systemic inflammation, leading to endothelial cell activation and dysfunction; altered blood pressure and heart rate, including heart rate variability; arrhythmia; and deregulated coagulation pathways; and ischaemia.

6. Exposure to air pollution, especially fine particulate matter, is a leading risk factor for noncommunicable diseases, in particular: ischaemia, myocardial infarction, stroke, chronic obstructive pulmonary disease and cancers. Of deaths due to outdoor air pollution 80% are attributed to heart disease and stroke and 20% to respiratory illnesses and cancers. For household pollution, acute respiratory diseases in children and chronic obstructive pulmonary disease are the most serious consequences, followed by heart disease and stroke. Indoor and outdoor air pollution together cause about one fifth of the global mortality from stroke and ischaemic heart disease, and more than one third of deaths from chronic obstructive pulmonary disease.

7. Air pollution and in particular its fine particulate component have recently been classified as a cause of lung cancer by IARC,⁹² which had already classified diesel combustion and the burning of coal (two main causes of household and ambient air pollution) as the source of carcinogens. Around 30% of all lung cancer deaths can be attributed to the joint effects of household and ambient air pollution.

8. More than half the deaths due to pneumonia in children aged under five years are attributed to household air pollution, making it a leading factor putting children's health at risk.

9. Cohort studies also have reported significant associations between air pollution and lung function development, respiratory infections and asthma in young children. There is also consistent evidence of the association between exposure to air pollution with birth outcomes, including low birth weight, preterm birth and small for gestational age births.⁹³

10. The impacts of both acute and long-term exposure to air pollution on health are substantial, but those resulting from long-term exposure are much greater than those observed for short-term exposure, suggesting that damage is due not just to exacerbation of underlying diseases but also to their progression. Numerous large follow-up studies that adjust for the effect of other factors such as tobacco smoking, diet or physical activity have consistently shown that long-term exposure to fine airborne particulates leads to increased incidence of premature mortality due to cardiovascular disease, chronic obstructive respiratory diseases as well as lung cancer.⁹⁴

STRATEGIES FOR REDUCING HEALTH IMPACTS OF AIR POLLUTION

11. Most sources of both ambient and household air pollution are directly influenced by the choice of energy technologies and fuels used, including the energy efficiencies of homes and transport systems. Therefore, the prevention of diseases related to air pollution depends on the implementation of specific sectoral policies that reduce air pollution at point of source (for instance, in energy and power generation, transport, urban planning, buildings, industry and agriculture). As most sources of air pollution coexist, the relative importance or proportional contribution of specific

⁹² Straif K, Cohen A, Samet J, eds. Air pollution and cancer. IARC Scientific Publication No. 161. Lyon, France; International Agency for Research on Cancer; <http://www.iarc.fr/en/publications/books/sp161/index.php> (accessed 2 December 2014).

⁹³ WHO Regional Office for Europe. Review of evidence on health aspects of air pollution – REVIHAAP Project: technical report. Copenhagen; Regional Office for Europe; 2013.

⁹⁴ WHO Regional Office for Europe. Review of evidence on health aspects of air pollution – REVIHAAP Project: technical report. Copenhagen; Regional Office for Europe; 2013.

sources in a particular setting needs to be identified in order to direct mitigation efforts appropriately for the greatest benefits to health.

12. The use of cross-sectoral approaches to health, such as health in all policies, can help to identify the appropriate policy responses for tackling the main sources of air pollution in specific sectors, as well as related opportunities for more joint action. In the context of social determinants of health, such approaches can also ensure appropriate consideration of relevant equity issues. The fact that policy options for tackling air pollution are specific to context and place – as are the health impacts of those decisions – provides further incentive for cooperation across sectors towards identifying and adopting local policies.

13. Integral to strategies to control the damaging effects of air pollution on health is the setting of clear health benchmarks, targets and reporting mechanisms for monitoring the effectiveness of air pollution control measures. WHO's air quality guidelines for both ambient⁹⁵ and indoor air quality⁹⁶ provide benchmarks, which are considered by most countries when setting goals for clean air. However, promoting successful prevention needs intermediary and process targets, for instance through sectoral policies known to reduce air pollution most harmful to health with new targets, for instance for adopting clean-energy sources for lighting in homes, rapid transit systems, and safe walking and cycling. Process-related targets may track the use of tools such as health impact assessments in decision-making on air pollution policy. The establishment of intermediary and process targets can also provide an incentive for intersectoral engagement.

14. Cities in particular are well placed to reduce air pollution and its associated health impacts, as they concentrate in one setting sources of pollution (transport, industry, buildings and even households – in some developing countries up to one third of outdoor air pollution comes from inefficient use of energy in households). Municipalities often have powers to influence policies and investments in more energy-efficient land use, transport, buildings and energy systems, and the health sector can contribute to identifying and communicating the healthier policy options for communities.

15. Emerging clean-energy technologies, including renewable energies such as solar and wind power, offer opportunities to reduce energy poverty while facilitating a shift to cleaner sources, particularly at the community and household levels. Business models are needed to support wide-scale and sustained adoption of such technologies, particularly in low- and middle-income settings.

16. The same technologies that produce large air pollution emissions also tend to contribute more to climate change, through both long-term (for example CO₂) and short-lived air pollutants, such as methane and black carbon. There are, therefore, synergies between reducing air pollution and mitigation of climate-changing emissions. For example, the same heating, lighting and cookstove technologies that reduce household emissions of black carbon also reduce overall levels of fine particulate matter and other health-damaging pollutants, leading to direct health benefits.

17. As reductions in exposure to air pollution can rapidly improve health, reduced disease incidence can be an indicator of the effectiveness of measures undertaken. For example, bans on the use of coal for domestic heating in Dublin were quickly followed by reductions in mortality; reductions in industrial and motor vehicle emissions due to economic restructuring after the reunification of Germany led to reductions in the incidence of respiratory diseases and improvements in lung function in children.

⁹⁵ WHO air quality guidelines for particulate matter, ozone, nitrogen dioxide and sulfur dioxide – global update 2005: summary of risk assessment. Geneva: World Health Organization; 2006 (document WHO/SDE/PHE/OEH/06.02).

⁹⁶ WHO indoor air quality guidelines: household fuel combustion. Geneva: World Health Organization; 2014.

18. At regional and global levels, and in particular in the context of discussions on the post-2015 sustainable development goals, reducing air pollution can be a health-relevant indicator in sustainable development policies, particularly with regard to sustainable transport, sustainable cities and clean energy.

THE ROLE OF THE HEALTH SECTOR AND MEMBER STATES IN ADDRESSING AIR POLLUTION AND HEALTH ISSUES

19. Preventing the ill-effects of air pollution depends on intersectoral action. The health sector needs to engage with a range of other sectors at national, regional and international levels in order to provide authoritative advice about those sectors' policy options that will yield the greatest benefits to health.

20. In supporting such engagement health ministries can play major roles, such as the following:

- (a) **Connecting health statistics to data on levels and sources of air pollution.** National statistics on morbidity, mortality and the use and costs of health care services are often not linked to data on air pollution or its sources (such as electricity production, transportation, heating and cooling of buildings, cooking and lighting). A targeted effort to analyse and communicate those linkages can bring together the relevant sectors, through sharing of information about interventions that simultaneously reduce air pollution and promote health.
- (b) **Strengthening monitoring of health outcomes related to air pollution.** Activities could include the development of associated indicators (namely impacts on health attributable to air pollution) and reinforcing links between monitoring systems used for air quality, health, weather and climate.
- (c) **Identifying expected risks to and benefits for health of policy interventions in the most polluting sectors, so as to identify interventions with the most health benefits.** Evidence from the use of existing tools, such as health impact assessments, can be used to support debate and decision-making. Reviews of existing national regulation and policies in polluting sectors can also be used to document their current health impacts.
- (d) **Engaging in health diplomacy at national, local and international levels.** Discussion with more polluting sectors could identify policies for reducing air pollution, lead to proposals for cooperation in order to identify those with greatest health benefits, and promote tracking of progress using health measures of performance.
- (e) **Identifying research priorities and supporting investigation of effective interventions in polluting sectors.** Such activity should focus on research to identify policies with most health benefits, including support for the establishment or strengthening of national institutions capable of conducting such research.
- (f) **Communicating widely sector policies that offer the most health benefits, and cooperating on communication strategies at global, national and local levels.** The aim would be to clarify and strengthen the health sector's contribution to the adoption of policies that bring the greatest improvements to health and to generate popular interest and demand for such policies.

FACILITATION OF MEMBER STATE ACTION ON AIR POLLUTION AND HEALTH BY THE SECRETARIAT

21. WHO's core role is to provide the health sector evidence, guidance and technical support and to facilitate its greater engagement with other sectors that are the primary polluters. Activities so far have included: the development of guidelines (for instance, on ambient air quality and household fuel combustion); global monitoring of solid fuel use by households, household air pollution and

ambient air pollution concentrations of particulate matter in over 1600 cities worldwide; and synthesis of knowledge on good practice (for example, health risks and benefits of transport, housing and energy policies). WHO also engages in health diplomacy and represents health interests in multisector forums such as the Climate and Clean Air Coalition to reduce Short-lived Climate Pollutants, the Global Alliance for Clean Cookstoves, and the United Nations Secretary-General's Sustainable Energy for All initiative. The underlying principle is to strengthen support to Member States, amplifying the health sector's ability to lead and influence change, mainly through activities such as:

- (a) **consolidation and sharing of evidence and lessons learnt** about the effectiveness of different sectors' policy measures and interventions to reduce air pollution and improve health outcomes;
- (b) **monitoring and reporting on national, regional and global trends**, including: the burden of disease attributable to outdoor and household air pollution, broken down by population group, and more systematic monitoring and reporting of reductions in air pollution and improvements in health associated with implementation of specific sustainable development policies in for example cities and/or the transport, energy, housing or agricultural sectors;
- (c) **provision of capacity building and technical support**, for example, in: assessing the burden of disease attributed to air pollution in a given context or setting; applying health in all policies or health impact assessments; issuing guidance for the identification and selection of air pollution policies most beneficial to health; and fostering health sector engagement in relevant wider intersectoral processes;
- (d) **exercising leadership in wider global efforts to tackle air pollution**, while maximizing synergies with programmes in related areas, such as climate change and sustainable energy, and forging appropriate links with existing global health initiatives;
- (e) **continued promotion of evidence-based guidelines** that inform norms and standards and thereby influence national, regional and global benchmarks and targets for indoor and outdoor air quality, and strategies and policies where evidence of pollution reductions and health benefits is most robust.

ACTION BY THE HEALTH ASSEMBLY

22. The Health Assembly is invited to note the report and to consider the draft resolution prepared by Member States, which is set out in document A68/18 Add.1.

Document A68/18 Add.1 (to follow)

15. Preparedness, surveillance and response

15.1 Antimicrobial resistance

Document A68/19 (Report by the Secretariat):

Antimicrobial resistance Summary report on progress made in implementing resolution WHA67.25 on antimicrobial resistance

1. The attached document EB136/19 was considered and noted by the Executive Board at its 136th session.⁹⁷

ACTION BY THE HEALTH ASSEMBLY

2. The Health Assembly is invited to note the report.

Document EB136/19 (Report by the Secretariat)

Antimicrobial resistance Summary report on progress made in implementing resolution WHA67.25 on antimicrobial resistance

1. In resolution WHA67.25 the Health Assembly requested the Director-General to develop a draft global action plan to combat antimicrobial resistance, including antibiotic resistance, and to report on progress in implementing the resolution. It also made additional requests, which are summarized below. The Director-General was requested:

- to ensure that all relevant parts of the Organization are actively engaged and coordinated in promoting work on containing antimicrobial resistance;
- to set aside adequate resources for the work of the Secretariat, in line with the Programme budget 2014–2015 and the Twelfth General Programme of Work, 2014–2019;
- to strengthen the tripartite collaboration between the UN Food and Agriculture Organization (FAO), World Organisation for Animal Health (OIE) and WHO for combating antimicrobial resistance;
- to explore with the United Nations Secretary-General options for a high-level initiative to increase political awareness, engagement and leadership on antimicrobial resistance.

2. This report responds to the Health Assembly's request for a summary of progress made in implementing the four aspects of the resolution referred to above. The accompanying document EB136/20 sets out the draft global action plan.

COORDINATING THE SECRETARIAT'S WORK

3. The Secretariat's work on antimicrobial resistance, which takes place across the Organization and involves all three organizational levels, is coordinated through the WHO Global Task Force on Antimicrobial Resistance. Through this body, all programmes and regional offices have contributed

⁹⁷ See summary records of the 136th session of the Executive Board, sixth meeting, section 4, and seventh meeting.

to the development of the draft global action plan and are working together to ensure that the work of the Secretariat is adequately reflected in the proposed programme budget 2016–2017.

4. In addition, in line with a request made in resolution WHA66.22 on Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, the Director-General is establishing a global health research and development observatory within the Secretariat in order to monitor and analyse relevant information on health research and development. As part of this work, a project has been initiated to incorporate information on research and development in respect of current and new antimicrobial medicines and diagnostics.

SETTING ASIDE ADEQUATE RESOURCES

5. The programme budget 2014–2015 was approved by the Health Assembly in resolution WHA66.2 in 2013, before the adoption of resolution WHA67.25; it does not, therefore, reflect the current priority given to antimicrobial resistance. Nevertheless, the Secretariat has estimated that, across the categories and programme areas and three levels of the Organization, there is a budgetary provision of about US\$ 15 million for work on antimicrobial resistance in the current biennium, in addition to the provision for established programmes on HIV, tuberculosis and malaria which include work to address antimicrobial resistance. However, it has not been possible to allocate all the staff and financial resources required, owing to the demands placed on the Organization in responding to the outbreak of Ebola virus disease in West Africa. In dealing with antimicrobial resistance, the Secretariat has therefore concentrated on its response to the requests made in resolution WHA67.25, in particular the development of a draft global action plan on antimicrobial resistance. The Secretariat has benefited from the support of the several Member States that have hosted consultations on antimicrobial resistance, which has mitigated the pressure on its resources.

6. The draft global action plan has been used as the basis for defining the work of the Secretariat on antimicrobial resistance for the biennium 2016–2017. An output that reflects the expected result of the Secretariat's work in this area has been defined for the proposed programme budget 2016–2017, including deliverables at each of the three levels of the Organization. The corresponding budget requirements will be submitted to the Sixty-eighth World Health Assembly for its consideration.

STRENGTHENING THE TRIPARTITE COLLABORATION OF FAO, OIE AND WHO

7. In 2010, FAO, OIE and WHO agreed a tripartite concept note on collaboration⁹⁸ that emphasizes stronger collaboration between the three organizations. They have identified antimicrobial resistance as one of the three flagship topics for collaboration under the tripartite arrangement. The areas of collaboration that have been strengthened in 2014 include collection of data on use of antimicrobial medicines in food-producing animals, integrated surveillance of antimicrobial resistance, capacity building through training workshops and national pilot projects, and development of joint advocacy material.

8. The FAO and OIE focal points for antimicrobial resistance have participated in all the meetings that WHO led or cosponsored on the development of the draft global action plan, including those of the Strategic and Technical Advisory Group on Antimicrobial Resistance. The focal points also participate in meetings of the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance, continuously providing essential and coordinated inputs. This cooperation is reflected in

⁹⁸ The FAO-OIE-WHO Collaboration: sharing responsibilities and coordinating global activities to address health risks at the animal-human-ecosystems interfaces – a tripartite concept note, 2010, available at http://www.who.int/influenza/resources/documents/tripartite_concept_note_hanoi_042011_en.pdf (accessed 20 November 2014).

the draft global action plan on antimicrobial resistance, in which several actions are attributed jointly to the three organizations within the tripartite collaboration.

EXPLORING OPTIONS FOR A HIGH-LEVEL INITIATIVE

9. The Director-General has written to the United Nations Secretary-General informing him of resolution WHA67.25 and in particular the Health Assembly's request for exploration of a high-level initiative, including a high-level meeting, to increase political awareness, engagement and leadership on antimicrobial resistance. In reply, the Secretary-General has assured the Director-General of his full support for the work of WHO and Member States on antimicrobial resistance. The consultations leading to the draft global action plan on antimicrobial resistance have identified some options particularly with regard to the needs of developing countries, and the need to establish partnership(s) to facilitate development of and access to new medicines and other interventions. These options are described in the draft global action plan.

10. In resolution WHA67.25, the Health Assembly also urged Member States to take action to combat antimicrobial resistance. The Secretariat has worked with Member States to collate information on the status of national action plans on antimicrobial resistance and on regulations and policies for the use of antimicrobial medicines. A report based on this information will be published before the Sixty-eighth World Health Assembly and will provide a baseline against which future progress at national and global levels can be monitored and reported.

ACTION BY THE EXECUTIVE BOARD

11. The Board is invited to note this report.

Document A68/20 (Report by the Secretariat)

Antimicrobial resistance

Draft global action plan on antimicrobial resistance

1. The Executive Board at its 136th session considered an earlier version of this report⁹⁹ and agreed the steps to be taken to revise the draft global action plan on antimicrobial resistance.¹⁰⁰ The Board's comments, input from discussions with FAO and OIE as well as advice from the Strategic and Technical Advisory Group on antimicrobial resistance have been taken into account in the following revised document.

INTRODUCTION

2. When microbes become resistant to medicines, the options for treating the diseases they cause are reduced. This resistance to antimicrobial medicines is happening in all parts of the world for a broad range of microorganisms with an increasing prevalence that threatens human and animal health. The direct consequences of infection with resistant microorganisms can be severe, including longer illnesses, increased mortality, prolonged stays in hospital, loss of protection for patients undergoing operations and other medical procedures, and increased costs. Antimicrobial resistance affects all areas of health, involves many sectors and has an impact on the whole of society.

3. The indirect impact of antimicrobial resistance, however, extends beyond increased health risks and has many public health consequences with wide implications, for instance on development.

⁹⁹ Document EB136/20.

¹⁰⁰ See summary records of the 136th session of the Executive Board, sixth meeting, section 4, and seventh meeting.

Antimicrobial resistance is a drain on the global economy with economic losses due to reduced productivity caused by sickness (of both human beings and animals) and higher costs of treatment. To counter it needs long-term investment, such as financial and technical support for developing countries and into development of new medicines, diagnostic tools, vaccines and other interventions, and in strengthening health systems to ensure more appropriate use of and access to antimicrobial agents.

4. The development of this draft global action plan on antimicrobial resistance, requested by the Health Assembly in resolution WHA67.25 in May 2014, reflects a global consensus that antimicrobial resistance poses a profound threat to human health. It reflects the input received to date from broad multisectoral and Member States' consultations.

5. The goal of the draft global action plan is to ensure, for as long as possible, continuity of successful treatment and prevention of infectious diseases with effective and safe medicines that are quality-assured, used in a responsible way, and accessible to all who need them. It is expected that countries will develop their own national action plans on antimicrobial resistance in line with the global plan.

6. To achieve this goal, the draft global action plan sets out five strategic objectives: (1) to improve awareness and understanding of antimicrobial resistance; (2) to strengthen knowledge through surveillance and research; (3) to reduce the incidence of infection; (4) to optimize the use of antimicrobial agents; and (5) to ensure sustainable investment in countering antimicrobial resistance. These objectives can be attained through the implementation of clearly identified actions by Member States, the Secretariat, and international and national partners across multiple sectors. The actions to optimize use of antimicrobial medicines and to renew investment in research and development of new products must be accompanied by actions to ensure affordable and equitable access by those who need them.

7. With this approach, the main goal of ensuring treatment and prevention of infectious diseases with quality assured, safe and effective medicines is achievable.

SCOPE

8. **Antibiotic resistance** develops when bacteria adapt and grow in the presence of antibiotics. The development of resistance is linked to how often antibiotics are used. Because many antibiotics belong to the same class of medicines, resistance to one specific antibiotic agent can lead to resistance to a whole related class. Resistance that develops in one organism or location can also spread rapidly and unpredictably, through for instance exchange of genetic material between different bacteria, and can affect antibiotic treatment of a wide range of infections and diseases. Drug-resistant bacteria can circulate in populations of human beings and animals, through food, water and the environment, and transmission is influenced by trade, travel and both human and animal migration. Resistant bacteria can be found in food animals and food products destined for consumption by humans.

9. Some of these features also apply to medicines that are used to treat viral, parasitic and fungal diseases; hence the broader term **antimicrobial resistance**.

10. The draft global action plan covers antibiotic resistance in most detail but also refers, where appropriate, to existing action plans for viral, parasitic and bacterial diseases, including HIV/AIDS,

malaria and tuberculosis.¹⁰¹ Many of the actions proposed in this plan are equally applicable to antifungal resistance in addition to resistance in those other microorganisms.

11. Antimicrobial resistance (and particularly antibiotic resistance) is spreading, and there are few prospects for the development of new classes of antibiotics in the short term. However, there is today considerable awareness of the need for, and political support for, action to combat antimicrobial resistance. Support is multisectoral, and there is increasing collaboration between the human health, animal health and agriculture sectors (including a tripartite collaboration agreed between FAO, OIE and WHO¹⁰²). The need for urgent action is consistent with a precautionary approach, and national and international multisectoral action and collaboration should not be impeded by gaps in knowledge.

12. This draft global action plan provides the framework for national action plans to combat antimicrobial resistance. It sets out the key actions that the various actors involved should take, using an incremental approach over the next 5–10 years to combat antimicrobial resistance. These actions are structured around the five strategic objectives set out in paragraphs 30–48.

THE CHALLENGE

13. Improvements in global health over recent decades are under threat because the microorganisms that cause many common human diseases and medical conditions – including tuberculosis, HIV/AIDS, malaria, sexually transmitted diseases, urinary tract infections, pneumonia, blood-stream infections and food poisoning – have become resistant to a wide range of antimicrobial medicines. Doctors must increasingly use “last-resort” medicines that are more costly, may have more side effects and are often unavailable or unaffordable in low- and middle-income countries. Some cases of tuberculosis and gonorrhoea are now resistant even to antibiotics of last resort.

14. Resistance develops more rapidly through the misuse and overuse of antimicrobial medicines. Antibiotic use for human health is reported to be increasing substantially. Surveys in a wide range of countries show that many patients believe that antibiotics will cure viral infections that cause coughs, colds and fever. Antibiotics are needed to treat sick animals but are also widely used in healthy animals to prevent disease and, in many countries, to promote growth through mass administration to herds. Antimicrobial agents are commonly used in plant agriculture and

¹⁰¹ World Health Organization global strategy for the surveillance and monitoring of HIV drug resistance. Geneva: World Health Organization; 2012 (http://www.who.int/hiv/pub/drugresistance/drug_resistance_strategy/en/, accessed 28 October 2014). Guidelines for surveillance of drug resistance in tuberculosis, fourth edition. Geneva: World Health Organization; 2009 (http://whqlibdoc.who.int/publications/2009/9789241598675_eng.pdf, accessed 28 October 2014). Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis. Geneva: World Health Organization; 2014 (http://apps.who.int/iris/bitstream/10665/130918/1/9789241548809_eng.pdf, accessed 28 October 2014). Global plan for artemisinin resistance containment. Geneva: World Health Organization; 2011 (<http://www.who.int/malaria/publications/atoz/9789241500838/en/>, accessed 28 October 2014). Emergency response to artemisinin resistance in the Greater Mekong subregion. Geneva: World Health Organization; 2013 (<http://www.who.int/malaria/publications/atoz/9789241505321/en/>, accessed 28 October 2014). Resolution WHA62.15. Prevention and control of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis. In: Sixty-second World Health Assembly, Geneva, 18–22 May 2009. Resolutions and decisions, annexes. Geneva: World Health Organization; 2009 (document WHA62/2009/REC/1):25–29; http://apps.who.int/gb/ebwha/pdf_files/WHA62-REC1/WHA62_REC1-en.pdf, accessed 28 October 2014).

¹⁰² The FAO-OIE-WHO Collaboration: sharing responsibilities and coordinating global activities to address health risks at the animal-human-ecosystems interfaces – a tripartite concept note, 2010, available at http://www.who.int/influenza/resources/documents/tripartite_concept_note_hanoi_042011_en.pdf (accessed 20 November 2014).

commercial fish and seafood farming. The potential impact of antimicrobials in the environment is also of concern to many.

15. Antimicrobial resistance can affect all **patients and families**. Some of the commonest childhood diseases in developing countries – malaria, pneumonia, other respiratory infections and dysentery – can no longer be cured with many older antibiotics or medicines. In lower-income countries, effective and accessible antibiotics are crucial for saving the lives of children with those diseases as well as other conditions such as bacterial blood infections. In all countries, some routine surgical operations and cancer chemotherapy will become less safe without effective antibiotics to protect against infections.

16. **Health-care workers** have a vital role in preserving the power of antimicrobial medicines. Inappropriate prescribing and dispensing can lead to their misuse and overuse if medical staff lack up-to-date information, cannot identify the type of infection, yield to patient pressure to prescribe antibiotics or benefit financially from supplying the medicines. Inadequate hygiene and infection prevention and control in hospitals help to spread infections. Hospital patients infected with methicillin-resistant *Staphylococcus aureus* have a higher risk of dying than those infected by a non-resistant form of the bacteria.

17. For **farmers, animal husbandry and the food industry**, the loss of effective antimicrobial agents to treat sick animals damages food production and family livelihoods. An additional risk for livestock workers is exposure to animals carrying resistant bacteria. For example, farmers working with cattle, pigs and poultry that are infected with methicillin-resistant *Staphylococcus aureus* have a much higher risk of also being colonized or infected with these bacteria. Food is one of the possible vehicles for transmission of resistant bacteria from animals to human beings and human consumption of food carrying antibiotic-resistant bacteria has led to acquisition of antibiotic-resistant infections. Other risks for infection with resistant organisms include exposure to crops treated with antimicrobial agents or contaminated by manure or slurry, and farmyard run-offs into groundwater.

18. Reducing antimicrobial resistance will require the **political will** to adopt new policies, including controlling the use of antimicrobial medicines in human health and animal and food production. In most countries, antibiotics can be purchased in markets, shops, pharmacies or over the Internet without prescription or involvement of a health professional or veterinarian. Poor quality medical and veterinary products are widespread, and often contain low concentrations of active ingredients, encouraging emergence of resistant microbes. Laws to ensure that medicines are of assured quality, safe, effective and accessible to those who need them need to be enacted and enforced.

19. The World Economic Forum has identified antibiotic resistance as a global risk beyond the capacity of any organization or nation to manage or mitigate alone,¹⁰³ but in general there is little awareness of the potential social, economic and financial impacts of drug resistance. In developed economies, these include higher health care costs and decreases in labour supply, productivity, household incomes, and national income and tax revenues. In the European Union alone, a subset of drug-resistant bacteria is responsible annually for some 25 000 deaths, with extra health care costs and lost productivity due to antimicrobial resistance amounting to at least €1500 million. Similar analyses are needed for low- and middle-income countries. Resistance to common veterinary antimicrobial medicines also causes food production losses, poor animal welfare and extra costs. Antimicrobial resistance is sapping the global economy and the full economic case needs to be made for long-term sustainable investment to tackle the problem, including the ensuring of access to financial and technical support for developing countries.

¹⁰³ Howell L, Ed. Global risks 2013: eighth edition. Geneva: World Economic Forum, 2013.

20. For the **pharmaceutical sector**, medicines that are no longer effective lose their value. Industry leaders are important partners in combating antimicrobial resistance, both by supporting the responsible use of medicines in order to prolong their effectiveness and through research and development of innovative medicines and other tools to combat resistance. No major new class of antibiotics has been discovered since 1987 and too few antibacterial agents are in development to meet the challenge of multidrug resistance. New concepts are needed for providing incentives for innovation and promoting cooperation between policy-makers, academia and the pharmaceutical industry to ensure that new technologies are available globally to prevent, diagnose and treat resistant infections. Public sector partnerships with the private sector are also important to help to ensure equitable access to quality-assured products and other related health technologies, through fair pricing and donations for poorest populations.

THE WAY FORWARD

21. Despite proposals and initiatives over many years to combat antimicrobial resistance, progress has been slow, in part because of, on the one hand, inadequate monitoring and reporting at national, regional and global levels, and, on the other, inadequate recognition by all stakeholders of the need for action in their respective areas.

22. At the national level, operational action plans to combat antimicrobial resistance are needed to support strategic frameworks.¹⁰⁴ All Member States are urged to have in place, within two years of the endorsement of the draft action plan by the Health Assembly, national action plans on antimicrobial resistance that are aligned with the global action plan and with standards and guidelines established by intergovernmental bodies such as the Codex Alimentarius Commission, FAO and OIE. These national action plans are needed to provide the basis for an assessment of the resource needs, and should take into account national and regional priorities. Partners and other stakeholders, including FAO, OIE, the World Bank, industry associations and foundations, should also put in place and implement action plans in their respective field of responsibility to counter antimicrobial resistance, and report progress as part of their reporting cycles. All action plans should reflect the following principles:

- (1) **Whole-of-society engagement including a one-health approach.** Antimicrobial resistance will affect everybody, regardless of where they live, their health, economic circumstances, lifestyle or behaviour. It will affect sectors beyond human health, such as animal health, agriculture, food security and economic development. Therefore, everybody – in all sectors and disciplines – should be engaged in the implementation of the action plan, and in particular in efforts to preserve the effectiveness of antimicrobial medicines through conservation and stewardship programmes.
- (2) **Prevention first.** Every infection prevented is one that needs no treatment. Prevention of infection can be cost-effective and implemented in all settings and sectors, even where resources are limited. Good sanitation, hygiene and other infection prevention measures that can slow the development and restrict the spread of difficult-to-treat antibiotic-resistant infections are a “best buy”.
- (3) **Access.** The aim to preserve the ability to treat serious infections requires both equitable access to, and appropriate use of, existing and new antimicrobial medicines. Effective implementation of national and global action plans to address antimicrobial resistance depends also on access, inter alia, to health facilities, health care professionals,

¹⁰⁴ The Secretariat has worked with Member States to collate information on the status of national action plans on antimicrobial resistance and on regulations and policies for use of antimicrobial medicines. A report based on these data, due to be published before the Sixty-eighth World Health Assembly, will provide a baseline against which future progress at national and global levels can be monitored and reported.

veterinarians, preventive technologies, diagnostic tools including those which are ‘point of care’, and to knowledge, education and information.

- (4) **Sustainability.** All countries should have a national action plan on antimicrobial resistance that includes and assessment of resource needs. The implementation of these plans will require long-term investment, for instance in surveillance, operational research, laboratories, human and animal health systems, competent regulatory capacities, and professional education and training, in both the human and animal health sectors. Political commitment and international collaboration are needed to promote the technical and financial investment necessary for effective development and implementation of national action plans.
- (5) **Incremental targets for implementation.** Member States are at very different stages in terms of developing and implementing national plans to combat antimicrobial resistance. To enable all countries to make the most progress towards implementing the global action plan on antimicrobial resistance, flexibility will be built into the monitoring and reporting arrangements in order to allow each country to determine the priority actions that it needs to take in order to attain each of the five strategic objectives and to implement the actions in a stepwise manner that meets both local needs and global priorities.

CONSULTATIVE PROCESS

23. In May 2014, the Sixty-seventh World Health Assembly adopted resolution WHA67.25 on antimicrobial resistance, in which it requested the Director-General, among other actions, to develop a draft global action plan to combat antimicrobial resistance, including antibiotic resistance, and to submit the draft to the Sixty-eighth World Health Assembly, through the Executive Board.

24. To initiate the preparation of a draft global action plan, the Secretariat used the recommendations of the Strategic and Technical Advisory Group on antimicrobial resistance,¹⁰⁵ existing national and regional action plans, WHO’s guidance and action plans on related subjects, as well as other available evidence and analysis.¹⁰⁶ The Secretariat regularly consulted FAO and OIE, for example through meetings as part of the tripartite collaboration and through their participation in other consultations, to ensure a one-health approach and consistency with Codex Alimentarius and OIE international standards and guidelines.

25. At its second meeting (Geneva, 14–16 April 2014),¹⁰⁷ the Strategic and Technical Advisory Group considered input from more than 30 additional participants, including representatives of intergovernmental organizations, civil society, public health and regulatory agencies, industry associations, professional organizations and patient groups. At a subsequent meeting (Geneva, 17 October 2014), the Advisory Group reviewed the text of the draft global action plan. The Strategic and Technical Advisory Group recently held its fourth meeting (Geneva, 24 and 25 February 2015) in order to provide advice to the Secretariat on finalization of the draft global action plan.

¹⁰⁵ Details of the Strategic and Technical Advisory Group on antimicrobial resistance and its recommendations are available at: <http://www.who.int/drugresistance/stag/en/> (accessed 18 November 2014).

¹⁰⁶ Details of national and regional action plans, WHO guidance and action plans for specific diseases and health topics including antimicrobial resistance, standards and guidelines established by intergovernmental organizations such as FAO and OIE, and other information taken into account will be documented in supplementary material that will be published on the relevant pages of the WHO website (<http://www.who.int/drugresistance/en/>, accessed 9 March 2015).

¹⁰⁷ The report of the meeting is available at: http://apps.who.int/iris/bitstream/10665/128675/1/WHO_HSE_PED_AIP_2014.4_eng.pdf?ua=1&ua=1 (accessed 18 November 2014).

26. During July and August 2014 the Secretariat held a web-based consultation for Member States and other relevant stakeholders, attracting 130 comments and contributions, including 54 from Member States, 40 from nongovernmental organizations and 16 from private-sector entities.

27. Between June and November 2014, Member States, stakeholders and the Secretariat convened additional high-level technical, political and interagency discussions to contribute to the action plan.¹⁰⁸ These included the Ministerial Conference on Antibiotic Resistance: joining forces for future health (The Hague, 25 and 26 June 2014); a meeting on the Global Health Security Agenda, including antimicrobial resistance (Jakarta, 20 and 21 August 2014); an informal Member States consultation to provide direct input on the draft plan (Geneva, 16 October 2014); a meeting on the responsible use of antibiotics (Oslo, 13 and 14 November 2014); and a meeting on global surveillance capacity, systems and standards (Stockholm, 2 and 3 December 2014).

STRATEGIC OBJECTIVES

28. The overall goal of the action plan is to ensure, for as long as possible, continuity of the ability to **treat and prevent infectious diseases with effective and safe medicines** that are quality-assured, used in a responsible way, and accessible to all who need them.

29. To achieve this overall goal, five strategic objectives have been identified. These are set out in paragraphs 30–48 with the corresponding actions for Member States, the Secretariat (including actions for FAO, OIE and WHO within the tripartite collaboration), and international organizations and other partners, in the table following paragraph 51. It is expected that countries will develop their own national action plans on antimicrobial resistance in line with the global plan.

Objective 1: Improve awareness and understanding of antimicrobial resistance through effective communication, education and training

30. Steps need to be taken immediately in order to raise awareness of antimicrobial resistance and promote behavioural change, through public communication programmes that target different audiences in human health, animal health and agricultural practice as well as consumers. Inclusion of the use of antimicrobial agents and resistance in school curricula will promote better understanding and awareness from an early age.

31. Making antimicrobial resistance a core component of professional education, training, certification, continuing education and development in the health and veterinary sectors and agricultural practice will help to ensure proper understanding and awareness among professionals.

Objective 2: Strengthen the knowledge and evidence base through surveillance and research

32. Actions and investments to tackle antimicrobial resistance should be supported by clear rationales of their benefit and cost-effectiveness. National governments, intergovernmental organizations, agencies, professional organizations, nongovernmental organizations, industry and academia have important roles in generating such knowledge and translating it into practice.

33. Particularly important gaps in knowledge that need to be filled include the following:

- the incidence, prevalence, range across pathogens and geographical patterns related to antimicrobial resistance are all information that is needed to be made accessible in a timely manner in order to guide the treatment of patients; to inform local, national and regional actions; and to monitor the effectiveness of interventions

¹⁰⁸ Information on these consultations is available at: <http://www.who.int/drugresistance/en/> (accessed 9 March 2015).

- understanding of how resistance develops and spreads, including how resistance circulates within and between humans and animals and through food, water and the environment, is important for the development of new tools, policies and regulations to counter antimicrobial resistance
- the ability rapidly to characterize newly emerged resistance in microorganisms and elucidate the underlying mechanisms; this knowledge is necessary to ensure that surveillance and diagnostic tools and methods remain current
- understanding of social science and behaviour, and other research needed to support the achievement of Objectives 1, 3 and 4, including studies to support effective antimicrobial stewardship programmes in human and animal health and agriculture
- research, including clinical studies conducted in accordance with relevant national and international governance arrangements, on treatments and prevention for common bacterial infections, especially in low resource settings
- basic research and translational studies to support the development of new treatments, diagnostic tools, vaccines and other interventions
- research to identify alternatives to nontherapeutic uses of antimicrobial agents in agriculture and aquaculture, including their use for growth promotion and crop protection
- economic research, including the development of models to assess the cost of antimicrobial resistance and the costs and benefits of this action plan.

34. WHO's global report on surveillance of antimicrobial resistance¹⁰⁹ also revealed many gaps in information on antimicrobial resistance in pathogens of major public health importance. International standards on harmonization of national antimicrobial resistance surveillance and monitoring programmes were adopted by OIE's members in 2012, but there are no internationally agreed standards for collection of data and reporting on antibacterial resistance in human health, and no harmonizing standards across medical, veterinary and agricultural sectors. There is also no global forum for the rapid sharing of information on antimicrobial resistance.

35. In 2013, some Member States of the European Union published a strategic research agenda on antimicrobial resistance through a joint programming initiative.¹¹⁰ This initiative, which also includes some countries outside the European Union, could provide an initial framework for further development of a global strategic research agenda.

Objective 3: Reduce the incidence of infection through effective sanitation, hygiene and infection prevention measures

36. Many of the most serious and difficult-to-treat antibiotic-resistant infections occur in health care facilities, not only because that is where patients with serious infections are admitted but also because of the intensive use therein of antibiotics. Although the development of resistance in such situations may be a natural consequence of necessary antimicrobial use, inadequate measures to prevent and control infection may contribute to the spread of microorganisms resistant to antimicrobial medicines.

37. Better hygiene and infection prevention measures are essential to limit the development and spread of antimicrobial-resistant infections and multidrug-resistant bacteria. Effective prevention of infections transmitted through sex or drug injection as well as better sanitation, hand washing, and food and water safety must also be core components of infectious disease prevention.

¹⁰⁹ Antimicrobial resistance: global report on surveillance 2014. Geneva: World Health Organization; 2014.

¹¹⁰ Strategic Research Agenda: Joint Programming Initiative on Antimicrobial Resistance. The Hague, JPIAMR, 2013.

38. Vaccination, where appropriate as an infection prevention measure, should be encouraged. Immunization can reduce antimicrobial resistance in three ways:

- existing vaccines can prevent infectious diseases whose treatment would require antimicrobial medicines
- existing vaccines can reduce the prevalence of primary viral infections, which are often inappropriately treated with antibiotics, and which can also give rise to secondary infections that require antibiotic treatment
- development and use of new or improved vaccines can prevent diseases that are becoming difficult to treat or are untreatable owing to antimicrobial resistance.

39. Much antibiotic use is linked to animal production. Antibiotics are sometimes used to prevent infections, to prevent the spread of diseases within a herd when infection occurs, and as a growth stimulant, and are often administered through feed and water. Sustainable husbandry practices, including the use of vaccines, can reduce infection rates and dependence on antibiotics as well as the risk that antibiotic-resistant organisms will develop and spread through the food chain.

Objective 4: Optimize the use of antimicrobial medicines in human and animal health

40. Evidence that antimicrobial resistance is driven by the volume of use of antimicrobial agents is compelling. High antibiotic use may reflect over-prescription, easy access through over-the-counter sales, and more recently sales via the Internet which are widespread in many countries. Despite measures taken by some Member States, antibiotic use in humans, animals and agriculture is still increasing globally. The projected increase in demand for animal food products may lead to yet further increases in antibiotic use.

41. Data on antibiotic use are collected and analysed in many high- and middle-income countries and OIE is developing a database on antibiotic use in animals. However, data are lacking on antibiotic use in human beings at the point of care and from lower-income countries.

42. More widespread recognition of antimicrobial medicines as a public good is needed in order to strengthen regulation of their distribution, quality and use, and encourage investment in research and development. In some cases, industry's spending on promoting products is greater than governmental investment in promoting rational use of antimicrobial medicines or providing objective information.

43. Decisions to prescribe antibiotics are rarely based on definitive diagnoses. Effective, rapid, low-cost diagnostic tools are needed for guiding optimal use of antibiotics in human and animal medicine, and such tools should be easily integrated into clinical, pharmacy and veterinary practices. Evidence-based prescribing and dispensing should be the standard of care.

44. Regulation of the use of antimicrobial agents is inadequate or poorly enforced in many areas, such as over-the-counter and Internet sales. Related weaknesses that contribute to development of antimicrobial resistance include poor patient and health care provider compliance, the prevalence of substandard medicines for both human and veterinary use, and inappropriate or unregulated use of antimicrobial agents in agriculture.

Objective 5: Develop the economic case for sustainable investment that takes account of the needs of all countries, and increase investment in new medicines, diagnostic tools, vaccines and other interventions

45. The economic case must reflect the need for capacity development, including training in low-resource settings, and the need for the evidence-based use of interventions across human and animal health care systems including medicines, diagnostic tools and vaccines.

46. Economic impact assessments are needed on the health and broader socioeconomic burden of antimicrobial resistance, and should compare the cost of doing nothing against the cost and benefit of action. Lack of such data hindered implementation of the 2001 Global Strategy for Containment of Antimicrobial Resistance.¹¹¹ The few studies on the economic cost of antimicrobial resistance are limited chiefly to developed countries.

47. Investment in the development of new antimicrobial medicines, as well as in diagnostic tools and vaccines, is needed urgently. Lack of such investment reflects, in part, fears that resistance will develop rapidly and that returns on investment will be limited because of restrictions in use. Thus research and development of new antibiotics is seen as a less attractive business investment than that of medicines for chronic diseases. Currently most major pharmaceutical companies have stopped research in this area, a situation described by WHO's Consultative Expert Working Group on Research and Development: Financing and Coordination¹¹² as "a serious market failure" and "a particular cause for concern". New processes are needed both to facilitate renewed investment in research and development of new antibiotics, and to ensure that use of new products is governed by a public health framework of stewardship that conserves the effectiveness and longevity of such products. The cost of investment in research and development may need to be de-linked from price and the volume of sales to facilitate equitable and affordable access to new medicines, diagnostic tools, vaccines and other results from research and development in all countries. Many forums have been created in recent years to discuss these issues.¹¹³

48. Antibiotics must also be supplemented by affordable, point-of-care diagnostic tools to inform health practitioners and veterinarians of the susceptibility of the pathogens to available antibiotics. The applicability and affordability of these techniques in low- and middle-income countries must be considered.

FRAMEWORK FOR ACTION ON ANTIMICROBIAL RESISTANCE

49. The framework presented below tabulates the actions that Member States, the Secretariat and international and national partners need to take in order to attain the goal and meet the objectives of the global plan.

50. All Member States are urged to have in place, within two years of the endorsement of the draft action plan by the Health Assembly, national action plans on antimicrobial resistance that are aligned with the global action plan and with standards and guidelines established by intergovernmental bodies such as the Codex Alimentarius Commission, FAO and OIE. These national action plans should provide the basis for an assessment of the resource needs, take into account national and regional priorities, and address relevant national and local governance arrangements. The Secretariat will facilitate this work by:

- supporting countries to develop, implement and monitor national plans
- leading and coordinating support to countries for assessment and implementation of investment needs, consistent with the principle of sustainability (subparagraph 22(4) above)

¹¹¹ Implementation workshop on the WHO global strategy for containment of antimicrobial resistance. Geneva: World Health Organization; 2003.

¹¹² Research and development to meet health needs in developing countries: strengthening global financing and coordination. Report of the consultative expert working group on research and development: financing and coordination. Geneva: World Health Organization; 2012.

¹¹³ Several existing initiatives were reviewed at WHO's Technical Consultation on Innovative Models for New Antibiotics' Development and Preservation (Geneva, 13 May 2014) (http://www.who.int/phi/implementation/consultation_inmadp/en/, accessed 20 November 2014).

- monitoring development and implementation of action plans by Member States and other partners
- publishing biennial progress reports, including an assessment of countries and organizations that have plans in place, their progress in implementation, and the effectiveness of action at regional and global levels; and including an assessment of progress made by FAO, OIE and WHO in implementing actions undertaken within the organizations' tripartite collaboration will also be included in these reports.

51. The Secretariat will also work with the Strategic and Technical Advisory Group on antimicrobial resistance, Members States, FAO and OIE, and other relevant partners to develop a framework for monitoring and evaluation, including the identification of measurable indicators of implementation and effectiveness of the global action plan. Examples of such indicators of effectiveness (impact) that could be applied for each of the strategic objectives are shown in the tabulated framework.

| Objective 1: Improve awareness and understanding of antimicrobial resistance through effective communication, education and training | | |
|---|--|--|
| Potential measures of effectiveness: extent of reduction in global human consumption of antibiotics (with allowance for the need for improved access in some settings), and reduction in the volume of antibiotic use in food production | | |
| Member State action | Secretariat action | International and national partners' action |
| <p>Increase national awareness of antimicrobial resistance through public communication programmes that target the different audiences in human health, animal health and agricultural practice, including participation in an annual world antibiotic awareness campaign.</p> <p>Establish antimicrobial resistance as a core component of professional education, training, certification and development for the health and veterinary sectors and agricultural practice.</p> <p>Include antimicrobial use and resistance in school curricula in order to promote better understanding and awareness, and provide the public media with accurate and relevant information so that public information and reporting reinforce key messages.</p> <p>Recognize antimicrobial resistance as a priority need for action across all government ministries through inclusion in</p> | <p>Develop and implement global communication programmes and campaigns, including an annual world antibiotic awareness campaign, building on existing regional and national campaigns and in partnership with other organizations (e.g. UNESCO and UNICEF). Provide core communication materials and tools (including those for social media and for assessing public awareness and understanding) that can be adapted and implemented by Member States and others.</p> <p>Develop, with FAO and OIE through the tripartite collaboration, core communication, education and training materials that can be adapted and implemented regionally and nationally, on subjects that include the need for responsible use of antibiotics, the importance of infection prevention in human and animal health and agricultural practice, and measures to control spread</p> | <p>Professional organizations and societies should establish antimicrobial resistance as a core component of education, training, examination, professional registration or certification, and professional development.</p> <p>OIE should continue to support its members in implementing OIE standards including veterinary professional standards and training, applying its Performance of Veterinary Services Pathway¹¹⁴ and updating of legislation.</p> <p>FAO should support awareness-raising on antimicrobial resistance and promote good animal production and hygiene practices among animal production and health workers, animal producers, and other stakeholders in the food and agriculture sectors.</p> <p>Intergovernmental organizations, including FAO, OIE and the World Bank, should raise awareness and</p> |

¹¹⁴ See: <http://www.oie.int/support-to-oie-members/pvs-evaluations/> (accessed 20 November 2014).

| | | |
|---|--|--|
| <p>national risk registers or other effective mechanisms for cross-government commitment.</p> <p>Promote and support establishment of multisectoral (one-health) coalitions to address antimicrobial resistance at local or national level, and participation in such coalitions at regional and global levels.</p> | <p>of resistant organisms through food and the environment. Provide support to Member States with the integration of education on antimicrobial resistance into professional training, education and registration.</p> <p>Publish regular reports on progress in implementing the global action plan and progress towards meeting impact targets, in order to maintain commitment to reducing antimicrobial resistance.</p> <p>Maintain antimicrobial resistance as a priority for discussion with Member States through the regional committees, the Executive Board and Health Assembly, and with other intergovernmental organizations, including the United Nations.</p> | <p>understanding of antimicrobial resistance and, in collaboration with WHO, should mirror the actions of the Secretariat within their constituencies.</p> <p>Other stakeholders – including civil society organizations, trade and industry bodies, employee organizations, foundations with an interest in science education, and the media – should help to promote public awareness and understanding of infection prevention and use of antimicrobial medicines across all sectors.</p> <p>WHO, FAO, OIE and other international stakeholders should encourage and support Member States in forging in-country as well as regional/global coalitions and alliances.</p> |
|---|--|--|

Objective 2: Strengthen the knowledge and evidence base through surveillance and research

Potential measure of effectiveness: extent of reduction in the prevalence of antimicrobial resistance, based on data collected through integrated programmes for surveillance of antimicrobial resistance in all countries

| Member State action | Secretariat action | International and national partners' action |
|--|--|---|
| <p>Develop a national surveillance system for antimicrobial resistance that:</p> <ul style="list-style-type: none"> includes a national reference centre with the ability systematically to collect and analyse data – including those on a core set of organisms and antimicrobial medicines from both health care facilities and the community – in order to inform national policies and decision-making; includes at least one reference laboratory capable of susceptibility testing to fulfil the core data requirements, using standardized tests for identification of resistant microorganisms and operating to agreed quality standards; | <p>Develop and implement a global programme for surveillance of antimicrobial resistance in human health, including surveillance and reporting standards and tools, case definitions, external quality assessment schemes, and a network of WHO Collaborating Centres to support surveillance of antimicrobial resistance and external quality assessment in each WHO region.</p> <p>Develop, in consultation with Member States and other multisectoral stakeholders, standards for the reporting, sharing and publication of data on antimicrobial resistance that take into account established practices for global disease surveillance and reporting, as well as legal and ethical</p> | <p>FAO, with WHO, should review and update regularly the FAO/WHO Codex Alimentarius Code of Practice to minimize and contain antimicrobial resistance and the Codex Alimentarius guidelines for risk analysis of foodborne antimicrobial resistance.</p> <p>The international research community and FAO should support studies to improve understanding of the impact of antimicrobial resistance on agriculture, animal production and food security, as well as the impacts of agricultural practices on development and spread of antimicrobial resistance, and to reduce non-therapeutic use of antimicrobial agents in agriculture through the development of sustainable</p> |

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| <ul style="list-style-type: none"> • strengthens surveillance in animal health and agriculture sectors by implementation of the recommendations of the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance for antimicrobial susceptibility testing of foodborne pathogens,¹¹⁵ the standards published in the OIE terrestrial and aquatic animal codes including the monitoring of resistance and antimicrobial use;^{116,117} the FAO/WHO Codex Alimentarius Code of Practice to Minimize and Contain Antimicrobial Resistance¹¹⁸ and the Codex Alimentarius Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance; • promotes participation in regional and global networks and sharing of information so that national, regional and global trends can be detected and monitored; • has the capacity to detect and report newly emerged resistance that may constitute a public health emergency of international concern, as required under the International Health Regulations (2005). <p>Collect and report data on use of antimicrobial agents in human and animal health and agriculture so that trends can be monitored and the impact of action plans assessed.</p> <p>Consider implementing an</p> | <p>requirements.</p> <p>Report regularly on global and regional trends in the prevalence of antimicrobial resistance in human health.</p> <p>Work with FAO and OIE, within the tripartite collaboration, to support integrated surveillance and reporting of antimicrobial resistance in human and animal health and agriculture, and develop measures of antimicrobial resistance in the food chain for use as indicators of risk to human health.</p> <p>Develop a framework for monitoring and reporting on antimicrobial consumption in human health, including standards for collection and reporting of data on use in different settings, building on the work of OECD.¹¹⁹</p> <p>With FAO and OIE, within the tripartite collaboration, collect, consolidate and publish information on the global consumption of antimicrobial medicines.</p> <p>Consult Member States and other multisectoral stakeholders for the development of a global public health research agenda for filling major gaps in knowledge on antimicrobial resistance, including methods to assess the health and economic burdens of antimicrobial resistance, cost-effectiveness of actions, mechanisms of development and spread of resistance, and research to underpin development of new interventions, diagnostic tools</p> | <p>husbandry practices.</p> <p>OIE should regularly update the terrestrial and aquatic animal codes (particularly with reference to antimicrobial resistance), revise the guideline on laboratory methods for bacterial antimicrobial susceptibility testing, and support the establishment of veterinary laboratory services through its Performance of Veterinary Services Pathway.</p> <p>Global health donors, international development bodies, and aid and technical agencies should support developing countries to build capacity to collect and analyse data on the prevalence of antimicrobial resistance and share or report such data.</p> <p>Research funding organizations and foundations should support implementation of the agreed global public health research agenda on antimicrobial resistance.</p> |
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¹¹⁵ Integrated surveillance on antimicrobial resistance: guidance from a WHO advisory group. Geneva: World Health Organization; 2013.

¹¹⁶ See document CAC/GL 77-2011 at: <http://www.codexalimentarius.org/standards/list-of-standards/en/> (accessed 20 November 2014).

¹¹⁷ See: <http://www.oie.int/en/our-scientific-expertise/veterinary-products/antimicrobials> (accessed 20 November 2014).

¹¹⁸ See: <http://www.codexalimentarius.org/committees-task-forces//?provide=committeeDetail&idList=6> (accessed 20 November 2014).

¹¹⁹ Prescribing in primary care. In: Health at a glance 2013: OECD Indicators. Paris: Organisation for Economic Co-operation and Development; 2013.

| <p>agreed global public health research agenda on antimicrobial resistance, including: research to promote responsible use of antimicrobial medicines; defining improved practices for preventing infection in human and animal health and agricultural practice; and encouraging development of novel diagnostic tools and antimicrobial medicines.</p> | <p>and vaccines. Monitor and report on implementation of the research agenda, for instance through the use of WHO's Global Health Research and Development Observatory.</p> <p>Work with partners to establish a sustainable repository for information on antimicrobial resistance and on the use and efficacy of antimicrobial medicines that is integrated with the global health research and development observatory and with a programme for independent evidence assessment and evaluation.</p> | |
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| <p>Objective 3: Reduce the incidence of infection through effective sanitation, hygiene and infection prevention measures</p> | | |
| <p>Potential measures of effectiveness: extent of reduction in the prevalence of preventable infections, and in particular the incidence of drug-resistant infections in health care settings</p> | | |
| Member State action | Secretariat action | International and national partners' action |
| <p>Member States may consider the following actions:</p> <ul style="list-style-type: none"> • take urgent action to implement and strengthen hygiene and infection prevention and control; • include training and education in hygiene and infection prevention and control as core (mandatory) content in training and education for health care and veterinary professionals and in their continuing professional development and accreditation or registration. • develop or strengthen national policies and standards of practice regarding infection prevention and control activities in health facilities and monitor implementation of and adherence to these national policies and standards. | <p>Facilitate the design and implementation of policies and tools to strengthen hygiene and infection prevention and control practices, particularly to counter antimicrobial resistance, and promote the engagement of civil society and patient groups in improving practices in hygiene and infection prevention and control.</p> <p>Ensure that policy recommendations for new and existing vaccines take into account the prospects for restricted treatment options because of antimicrobial resistance, and the additional benefits of reduced use of antimicrobial agents, including antibiotics.</p> <p>Work with partners and other organizations to facilitate the development and clinical evaluation of specific priority vaccines for the prevention of difficult-to-treat or untreatable infections.</p> | <p>Professional societies and accreditation bodies should support training and education on infection-prevention measures as a mandatory requirement in professional development, accreditation and registration.</p> <p>OIE should update its codes and manuals to take account of new developments in vaccines.</p> <p>FAO should continue to engage and support producers and stakeholders in the food and agriculture sectors in adopting good practices in animal husbandry and health aimed at reducing the use of antibiotics and the risk of development and spread of antimicrobial resistance.</p> |

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| <p>Include within national surveillance of antimicrobial resistance the collection and reporting of data on antimicrobial susceptibility of microorganisms causing health care-associated infections. Strengthen animal health and agricultural practices through implementation of the standards published in the OIE Terrestrial and Aquatic Animal Health Codes¹²⁰ and FAO/WHO Codex Alimentarius Code of Practice to minimize and Contain Antimicrobial Resistance.¹²¹</p> <p>Promote vaccination as a method of reducing infections in food animals.</p> | <p>Work with FAO and OIE, within the tripartite collaboration, to develop recommendations for the use of vaccines in food-producing animals, including recommendations for new vaccines, as a means to prevent foodborne diseases in humans and animals and reduce antimicrobial use.</p> | |
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Objective 4: Optimize the use of antimicrobial medicines in human and animal health

Potential measure of effectiveness: extent of reduction in global human consumption of antibiotics (with allowance for the need for improved access in some settings), the consumption of antibiotics used in food production (terrestrial and aquatic livestock, and other agricultural practices), and the use of medical and veterinary antimicrobial agents for applications other than human and animal health

| Member State action | Secretariat action | International and national partners' action |
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| <p>Develop and implement comprehensive action plans on antimicrobial resistance that incorporate the following elements:</p> <ul style="list-style-type: none"> • distribution, prescription, and dispensing of antimicrobials is carried out by accredited health or veterinary professionals under statutory body supervision or other suitably trained person authorized in accordance with national legislation; • marketing authorization is given only to antimicrobial agents that are quality assured, safe and efficacious; • development and implementation of national and institutional essential | <p>Strengthen and align, within the tripartite collaboration with FAO and OIE, the concepts of critically important antibiotics for human and animal health, and ensure that these concepts include use of new antibiotics so that a common position on restriction of antimicrobial medicines for human use can be established.</p> <p>Provide support to Member States in the development and enforcement of relevant regulations so that only, quality assured, safe and effective antimicrobial products reach users.</p> <p>Develop technical guidelines and standards to support access to, and evidence-based selection and responsible use of,</p> | <p>OIE should regularly update its Terrestrial and Aquatic Animal Health Codes, particularly with reference to antimicrobial resistance.</p> <p>FAO, in collaboration with WHO, should regularly review and update the FAO/WHO Codex Alimentarius Code of Practice to Minimize and Contain Antimicrobial Resistance to take into account not only residues in food but also the need for standards to minimize and control use of antimicrobial agents in agricultural practice.</p> <p>OIE, supported by FAO and WHO within the tripartite collaboration, should build and maintain a global database on the use of antimicrobial</p> |

¹²⁰ See: <http://www.oie.int/en/our-scientific-expertise/veterinary-products/antimicrobials> (accessed 20 November 2014).

¹²¹ See: <http://www.codexalimentarius.org/committees-task-forces//?provide=committeeDetail&idList=6> (accessed 29 October 2014).

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| <p>medicine lists guided by the WHO Model Lists of Essential Medicines, reimbursement lists and standard treatment guidelines to guide purchasing and prescribing of antimicrobial medicines, and regulation and control of promotional practices by industry;</p> <ul style="list-style-type: none"> laboratory capacity to identify pathogens and their antimicrobial susceptibility in order to guide optimal use of antimicrobial medicines in clinical practice; provision of stewardship programmes that monitor and promote optimization of antimicrobial use at national and local levels in accordance with international standards in order to ensure the correct choice of medicine at the right dose on the basis of evidence; identification and elimination of economic incentives in all sectors that encourage inappropriate use of antimicrobial agents, and introduction of incentives to optimize use; effective and enforceable regulation and governance for licensing, distribution, use and quality assurance of antimicrobial medicines in human and animal health, including a regulatory framework for preservation of new antibiotics; policies on use of antimicrobial agents in terrestrial and aquatic animals and agriculture, including: implementation of Codex Alimentarius and OIE international standards and guidelines as well as WHO/OIE guidance on the use of critically important antibiotics; phasing out of use of antibiotics for animal growth promotion and crop | <p>antimicrobial medicines, including follow-up to treatment failure.</p> <p>Provide leadership to strengthen medicines regulatory systems at national and regional levels, so that appropriate practices for optimizing use of antimicrobial medicines are supported by appropriate and enforceable regulation, and that promotional practices can be adequately regulated.</p> <p>Consult with Member States and pharmaceutical industry associations on innovative regulatory mechanisms for new antimicrobial medicines, for example considering them as a class of medicine that will require a different set of regulatory controls, and on new approaches to product labelling that focus on public health needs rather than marketing claims, in order to address the need for preservation of effectiveness and for global access.</p> <p>Develop standards and guidance (within the tripartite collaboration with FAO and OIE), based on best available evidence of harms, for the presence of antimicrobial agents and their residues in the environment, especially in water, wastewater and food (including aquatic and terrestrial animal feed).</p> | <p>medicines in animals.</p> <p>The research community in both the public and private sectors, including the pharmaceutical industry, should invest in the development of effective and low-cost tools for diagnosis of infectious diseases and antimicrobial susceptibility testing for use in human and animal health at points of care and dispensing (pharmacies).</p> <p>Donors, philanthropic and other nongovernmental organizations and civil society should ensure that their efforts to increase access to antimicrobial medicines are accompanied by measures to protect the continued efficacy of such medicines.</p> <p>Professional bodies and associations, including industry associations, health insurance providers and other payers, should develop a code of conduct for appropriate training in, education about, and marketing, purchasing, reimbursement and use of antimicrobial agents. This code should include commitment to comply with national and international regulations and standards, and to eliminate dependence on the pharmaceutical industry for information and education on medicines and, in some cases, income.</p> |
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| protection in the absence of risk analysis; and reduction in nontherapeutic use of antimicrobial medicines in animal health. | | |
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| Objective 5: Develop the economic case for sustainable investment that takes account of the needs of all countries, and increase investment in new medicines, diagnostic tools, vaccines and other interventions | | |
| Potential measures of effectiveness: extent of increase in sustainable investment in capacity to counter antimicrobial resistance for all countries, including investment in development of new medicines, diagnostics and other interventions | | |
| Member State action | Secretariat action | International and national partners' action |
| <p>Member States should consider assessing investment needs for implementation of their national action plans on antimicrobial resistance, and should develop plans to secure and apply the required financing.</p> <p>Member States are encouraged to participate in international collaborative research to support the development of new medicines, diagnostic tools and vaccines through:</p> <ul style="list-style-type: none"> • prioritization and support of basic scientific research on infectious diseases, and promoting partnerships between research institutions in developed and developing countries; • collaboration, based on fair and equitable benefit sharing as mutually agreed, in the investigation of natural sources of biodiversity and biorepositories as sources for the development of new antibiotics; • strengthening existing and creating new public–private partnerships for encouraging research and development of new antimicrobial agents and diagnostics; • piloting of innovative ideas for financing research and development and for the | <p>Work with the United Nations Secretary-General and bodies in the United Nations system to identify the best mechanism(s) to realize the investment needed to implement the global action plan on antimicrobial resistance, particularly with regard to the needs of developing countries.</p> <p>Work with the World Bank and with other development banks to develop and implement a template or models to estimate the investment needed to implement national action plans on antimicrobial resistance, and to collate and summarize these needs.</p> <p>Work with the World Bank and with FAO and OIE, within the tripartite collaboration, to assess the economic impact of antimicrobial resistance and of implementation of the action plan in animal health and agriculture.</p> <p>Explore with Member States, intergovernmental organizations, industry associations and other stakeholders, options for the establishment of a new partnership or partnerships:</p> <ul style="list-style-type: none"> • to coordinate the work of many unlinked initiatives aiming to renew investment in research and development of antibiotics (including | <p>Partners in the finance and economic sectors should define the economic case for national and global investment in combating antimicrobial resistance, including an assessment of the cost of implementing this action plan and the consequential cost of no action; this work could be led by the World Bank.</p> <p>FAO, OIE and other partners should support appropriate analyses to establish the case for investment and to inform the selection of interventions to improve animal husbandry, management, health, hygiene and biosecurity practices aimed at reducing antimicrobial use (and antimicrobial resistance) in different production settings.</p> |

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| <p>adoption of new market models to encourage investment and ensure access to new antimicrobial products.</p> | <p>follow-up initiatives from the Consultative Expert Working Group on Research and Development¹²²);</p> <ul style="list-style-type: none"> • to identify priorities for new treatments, diagnostics and vaccines on the basis of emergence and prevalence of serious or life-threatening infections caused by resistant pathogens; • to act as the vehicle(s) for securing and managing investment in new medicines, diagnostics, vaccines and other interventions; • to facilitate affordable and equitable access to existing and new medicines¹²³ and other products while ensuring their proper and optimal use; • to establish open collaborative models of research and development in a manner that will support access to the knowledge and products from such research, and provide incentives for investment. | |
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ACTION BY THE HEALTH ASSEMBLY

52. The Health Assembly is invited to consider and endorse this draft global action plan on antimicrobial resistance.

¹²² Research and development to meet health needs in developing countries: strengthening global financing and coordination. Report of the consultative expert working group on research and development: financing and coordination. Geneva: World Health Organization; 2012.

¹²³ Many of the actions that can support affordable and equitable access to medicines are set out in the Global strategy and plan of action on public health, innovation and intellectual property. Geneva: World Health Organization; 2011.

15.3 Implementation of the International Health Regulations (2005)

Document A68/22 (Report by the Director-General):

Implementation of the International Health Regulations (2005) Responding to public health emergencies

1. In response to resolution WHA61.2, in which it was decided that States Parties to the International Health Regulations (2005) and the Director-General shall report to the Health Assembly on the implementation of the Regulations annually, the present report provides an overview of the international response in 2014 and 2015 to public health events and emergencies, with a particular focus on the role of WHO and the International Health Regulations (2005) in preventing, detecting, reporting and responding to such events. This document is a companion to the report by the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation.¹²⁴ The Executive Board at its 136th session noted an earlier version of this report¹²⁵ and adopted resolution EB136.R5¹²⁶ on yellow fever risk mapping and recommended vaccination for travellers. This version of the report presents updated information.

KEY PUBLIC HEALTH EVENTS AND EMERGENCIES IN 2014–2015

2. In 2014 and 2015, WHO detected, tracked and responded to numerous public health risks and emergencies in close collaboration with countries, within the framework of the Regulations. From 1 January 2014 to 28 February 2015, a total of 321 “public health events” was recorded in WHO’s Event Management System.¹²⁷ Over the same period, WHO posted more than 400 updates and announcements on the event information site for National IHR Focal Points, relating to 79 public health events and regional updates. Most updates posted related to the Middle East respiratory syndrome coronavirus (MERS-CoV) event, the influenza A(H7N9) virus event in China and the outbreak of Ebola virus disease in West Africa.

3. In 2014, in line with the relevant provisions of the International Health Regulations (2005), the Director-General determined that events in West Africa concerning Ebola virus disease and the ongoing situation in relation to poliomyelitis constituted public health emergencies of international concern. The Director-General convened meetings of the IHR Emergency Committee on numerous occasions, as follows: eight times for MERS-CoV; five times for polio; and four times for Ebola virus disease. Temporary recommendations for Member States were issued under the Regulations on the international spread of wild poliovirus and regarding the Ebola virus disease outbreak; advice was provided by the Secretariat concerning MERS-CoV. With regard to the International Health Regulations (2005), 2014 and 2015 have been unprecedented years for public health emergencies of international concern.

Ebola virus disease

4. On 18 September 2014, the United Nations Security Council determined that the Ebola virus disease epidemics were a “threat to international peace and security” and unanimously adopted resolution 2177 (2014), which was cosponsored by 134 Member States. That is the highest number

¹²⁴ See document A68/22 Add.1.

¹²⁵ See document EB136/22 and summary records of the 136th session of the Executive Board, eighth meeting, section 1.

¹²⁶ See document EB136/2015/REC/1 for the resolution, and for the financial and administrative implications for the Secretariat of the adoption of the resolution.

¹²⁷ The Event Management System referred to is an internal monitoring system.

of cosponsors that a Security Council resolution has had, and is only the third time that the Security Council has taken such action on a public health crisis.

5. This led to the United Nations General Assembly unanimously adopting on 19 September 2014 resolution 69/1 on measures to contain and combat the recent Ebola outbreak in West Africa and, shortly thereafter, the establishment by the Secretary-General of the United Nations Mission for Ebola Emergency Response (UNMEER). The mission headquarters was set up in Accra, Ghana, and teams were established in Guinea, Liberia and Sierra Leone.

6. As the United Nations specialized agency for health and a central partner in UNMEER, WHO has been at the forefront of these efforts on an international scale, and has characterized the Ebola virus disease outbreak “the most severe, acute health emergency seen in modern times.”¹²⁸

7. WHO was first notified of Ebola virus disease cases in Guinea in March 2014 and immediately deployed support. An emergency committee on Ebola virus disease was convened under the International Health Regulations (2005) and met on four occasions: on 6–7 August, 16–21 September, 22 October 2014 and 20 January 2015. Following its first meeting, the Director-General determined that Ebola virus disease in West Africa constituted a public health emergency of international concern and issued temporary recommendations to support countries in their efforts to bring the epidemic under control and prevent international spread.

8. The outbreaks of Ebola virus disease in Senegal and Nigeria were declared over on 17 October 2014 and 19 October 2014, respectively. These results were due in large part to the rapid response of the two countries, including in terms of surveillance, response, measures at points of entry, and risk communication. The third meeting of the Emergency Committee on Ebola virus disease noted that the implementation of the recommended measures may have contributed to limiting any further international spread of the disease. At its fourth meeting, the Committee concluded that “getting to zero” Ebola cases remained the primary concern and guarded against complacency following a decrease in cases in the three most affected countries.

9. WHO and partner organizations agreed on a range of core actions to support countries unaffected by Ebola virus disease in strengthening their preparedness should cases of the disease be introduced. On the basis of existing national and international preparedness efforts, including previous work to develop core capacity requirements under the Regulations, a set of tools has been developed to support countries to intensify and accelerate their preparedness. Country visits have taken place in all regions to identify strengths in current national preparedness plans and to propose ways to address the gaps.

10. One of the key challenges of the ongoing Ebola virus disease epidemic is to ensure that the temporary recommendations issued by the Director-General under the International Health Regulations (2005) in respect of the Ebola virus disease are properly understood and implemented. Of particular concern is the recommendation urging Member States not to adopt unilateral travel and trade measures affecting countries experiencing intense transmission. In this connection, the Secretariat monitors travel and trade measures that vary from the above recommendations and communicates with Member States to confirm the exact nature and public health rationale for the measures. As at 19 February 2015, 505 reports had been recorded concerning such measures, involving a total of 69 countries. Where these measures were perceived as excessive, 42 verification requests were sent to the countries in question and 23 justifications for the measures were received. A further follow-up request for justification or update on measures implemented was sent to 40 countries. Three countries denied having closed their borders because of concerns relating to Ebola virus disease.

¹²⁸ See document EB136/26.

11. At the special session of the Executive Board in January 2015, members recognized that the Ebola outbreak demonstrated the urgency for all countries to have health systems capable of fully implementing the International Health Regulations (2005).¹²⁹

Middle East respiratory syndrome coronavirus

12. MERS-CoV was first identified in Saudi Arabia in 2012. The virus appears to be circulating widely throughout the Arabian Peninsula. Cases have been reported in a total of 23 countries, including some in North America, Asia and Europe. Globally, 1060 laboratory-confirmed cases of infection with MERS-CoV, including at least 394 related deaths, had been reported to WHO by 9 March 2015.¹³⁰

13. The grave concern surrounding this disease prompted the Director-General to convene an Emergency Committee on Middle East respiratory syndrome coronavirus. The Emergency Committee's first meeting took place on 9 July 2013,¹³¹ and has met on eight occasions in total. It has not advised the Director-General to declare the event a public health emergency of international concern, but has recommended that States Parties better understand the situation and take preventive measures, including in relation to pilgrims visiting the region.

14. The Emergency Committee noted at its eighth meeting on 4 February 2015 that, although significant efforts had been made to strengthen infection prevention and control measures, transmission in health care settings continued to occur. It noted also that, although the pattern of transmission appeared relatively unchanged, the overall situation and the possibility of international spread of the virus remained a concern.

15. The Secretariat continues to work with affected countries, as well as international technical partners and networks to coordinate the global health response, including providing updated information, conducting risk assessments and joint investigations with national authorities, convening scientific meetings, and developing guidance and training for health authorities and technical health agencies.

16. The Secretariat is continuing to provide regular updates to members and advisors of the Emergency Committee and the Committee will be reconvened, should circumstances require.

Poliomyelitis

17. The number of poliomyelitis cases has decreased by more than 99% since 1988 as a result of the global effort to eradicate the disease; however, the number of cases in 2013 increased by 82% over 2012, with eight countries reporting cases compared to five in 2012. On 5 May 2014, the Director-General convened an Emergency Committee under the International Health Regulations (2005) to review the situation. She declared that the international spread of wild poliovirus in 2014 constituted a public health emergency of international concern under the Regulations. She also issued temporary recommendations to reduce the international spread of wild poliovirus. The recommendations provide that those countries currently exporting wild poliovirus should ensure that all residents and long-term visitors (for more than four weeks) receive a dose of oral polio vaccine or inactivated poliovirus vaccine between four weeks and 12 months before international travel, and should also ensure that such travellers are provided with proof of vaccination. Other polio-affected countries not exporting wild poliovirus are encouraged to vaccinate residents and

¹²⁹ See resolution EBSS3.R1.

¹³⁰ For more information on MERS-CoV, see <http://www.who.int/csr/don/11-march-2015-mers-qatar/en/> (accessed 19 March 2015).

¹³¹ For more information on the Emergency Committee, see: http://www.who.int/ihr/ihr_ec_2013/en/ (accessed 4 March 2015).

long-term visitors before international travel.¹³² At its fourth meeting on 17 February 2015,¹³³ the Emergency Committee advised that the Director-General's temporary recommendations should apply to a third category of States: those no longer infected by wild poliovirus, but which remain vulnerable to its international spread.

18. Finally, the Director-General requested the Committee to reassess the situation within the next three months and provide advice on the important matter of whether the temporary recommendations should continue beyond the Sixty-eighth World Health Assembly or a standing recommendation under the Regulations would be needed in order to reduce more effectively the risk of international spread of poliovirus at that time.

Avian influenza A(H5N1) and A(H7N9) viruses

19. Influenza pandemics are recurring events that can have major health, economic and social consequences worldwide. With the growth of global travel, detecting the emergence of a new influenza virus and monitoring the activity of potential pandemic viruses, such as avian influenza A(H5N1) and A(H7N9) viruses, are crucial activities as influenza viruses can evolve rapidly, acquire efficient transmissibility and result in a pandemic, with little time to prepare a public health response.

20. Avian influenza A(H7N9) virus is a subtype of influenza viruses that normally infects birds but sometimes infects people. The first human infection was reported in China in March 2013 and was followed by a second and third epidemic wave in the winter months of 2014 and 2015 in the northern hemisphere. Since November 2014, a rapid increase in human infections with avian influenza A(H5N1) virus was reported in Egypt with 140 human cases reported between 1 November 2014 and 16 March 2015. Globally, an unprecedented number of outbreaks with avian influenza A(H5) viruses is being reported in birds with subtypes including H5N1, H5N2, H5N6 and H5N8, in Africa, Asia, Europe and North America. The avian influenza A(H5N1) and A(H7N9) viruses are the most obvious concern as they continue spreading in birds, reassorting with other avian influenza viruses that are endemic in various parts of the world, and causing infections in humans. The human population does not have immunity to these viruses, and they can cause severe disease and death in humans once infection occurs. Despite continuous zoonotic infections, these viruses so far do not have the ability to spread easily from human to human and the overall pandemic risk has not increased.

21. Under the International Health Regulations (2005), the Secretariat and Member States continue to monitor closely avian influenza A(H7N9) and A(H5N1) viruses and other influenza viruses of pandemic potential, conduct risk assessments, build preparedness and response capacities, and provide guidance to countries. WHO develops and adjusts appropriate interventions in collaboration with its partners, including animal health agencies and national veterinary authorities, in particular FAO and OIE through a variety of mechanisms to track and assess the risk of animal influenza viruses of public health concern.¹³⁴ Through the WHO Global Influenza Surveillance and Response System, candidate vaccine viruses of influenza with pandemic potential are available and updated, and antiviral susceptibility is being monitored. So far these viruses in general are sensitive to available antiviral medicines oseltamivir and zanamivir.

¹³² For more information on see <http://www.polioeradication.org/Infectedcountries/PolioEmergency.aspx#sthash.QuVm3bU5.dpuf> (accessed 5 March 2015).

¹³³ For more information on the temporary recommendations for polio see <http://www.who.int/media/centre/news/statements/2015/polio-27-february-2015/en/#> (accessed 5 March 2015).

¹³⁴ For more information on avian influenza, see: http://www.who.int/mediacentre/factsheets/avian_influenza/en/ (accessed 20 March 2015).

PROGRESS ON IMPLEMENTATION OF THE INTERNATIONAL HEALTH REGULATIONS (2005)

22. States Parties have continued to provide information to the Secretariat on the implementation of the International Health Regulations (2005) in relation to the national capacity requirements set out in Annex 1 of the Regulations. As at 31 March 2015, 160 States Parties from a total of 196 had reported on the implementation of the Regulations in 2014. The latest capacity scores, by WHO region, of States Parties that submitted a completed questionnaire are set out in the Annex.

23. Analysis of the self-reported information provided to the Secretariat by States Parties suggests that significant progress has been made in the following areas: establishment of a 24-hour presence of National IHR Focal Points; increased transparency in reporting events; more systematic use of early warning systems; better communication and collaboration between the animal and human health sectors (for example, sharing lessons learnt from the avian influenza A(H5N1) virus applied to the avian influenza A(H7N9) virus); coordinated collective efforts of countries and partners to build capacities; establishment of emergency response, coordination structures and improved international mechanisms to share information for rapid response.

24. All levels of the Organization have taken initiatives aimed at accelerating progress on implementation of the International Health Regulations (2005). These have been intensively reviewed at all the recent regional committee sessions, at which lessons learnt from outbreaks of Ebola virus disease and other public health events and emergencies relevant to the Regulations were discussed.

25. Following the discussions of the Executive Board at its 136th session and building on lessons learnt from the current situation of Ebola virus disease and the outcome of preparedness missions in the most at-risk countries in Africa, the Secretariat is currently considering options for strengthening the current system of self-assessment of IHR core capacities in order to incorporate an additional assessment mechanism to help countries to identify gaps, and develop and maintain core capacities. Options include systematic reviews of preparedness and response to significant public health events, voluntary external evaluations of the implementation of the Regulations in countries, and use of exercises to regularly test IHR capacities. The Secretariat will consult with Member States to further develop these options.

REVIEW COMMITTEE ON SECOND EXTENSIONS FOR ESTABLISHING NATIONAL PUBLIC HEALTH CAPACITIES AND ON IMPLEMENTATION OF THE INTERNATIONAL HEALTH REGULATIONS (2005)

26. Under Articles 5 and 13 of the International Health Regulations (2005), States Parties may request extensions to meet their core surveillance and response capacity requirements set out in Annex 1 of the Regulations. In total, 64 States Parties have informed the Secretariat that they have achieved these core capacities, 81 have requested extensions and 48 did not communicate their status or intentions. All extension requests for the period 2014–2016 were granted by the Director-General following the convening of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR (2005) Implementation (Geneva, 13 and 14 November 2014).¹³⁵

CONCLUSION

27. There is a wide consensus that the International Health Regulations (2005) have helped the international community to manage acute public health events and emergencies significantly better. Many States Parties have successfully assessed and strengthened the core national and local capacities called for in the Regulations. However, as illustrated by the Ebola virus disease outbreak, such capacities are not yet adequately established, resulting in catastrophic human, financial and

¹³⁵ See document EB136/22 Add.1.

economic consequences from the impact of the disease in the three countries with intense transmission. Considering the cost of the response, the need to invest now in capacities to better prevent, detect and respond rapidly to public health events has never been more evident.

28. The meeting of the Review Committee has recommended expanding the focus from mere compliance with the International Health Regulations (2005) to an emphasis at country level on the progressive realization of rights and obligations under the Regulations. The Committee further indicated that implementation of the Regulations, and public capacity strengthening in particular, should be seen as a continuous process, as opposed to one that comes to an end at any particular date, including 2016. These important shifts in perspective emphasize the integral relationship between the International Health Regulations (2005) and health systems, and the need for sustained investment.

ACTION BY THE HEALTH ASSEMBLY

29. The Health Assembly is invited to note the report.

Implementation of the International Health Regulations (2005)
Report of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation

1. The Executive Board at its 136th session noted the attached report EB136/22 Add.1¹³⁶ and adopted resolution EB136.R6.¹³⁷

ACTION BY THE HEALTH ASSEMBLY

2. The Health Assembly is invited to adopt the draft resolution recommended by the Executive Board in resolution EB136.R6.

Implementation of the International Health Regulations (2005)
Report of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation

1. The Director-General has the honour to transmit to the Executive Board the report of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation, which reflects its deliberations during the meeting in November 2014 (see Annex 1).

ACTION BY THE EXECUTIVE BOARD

2. The Executive Board is invited to consider this report. The Board is further requested to consider the draft resolution on the recommendations of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation prepared by the Secretariat (see Annex 2), as well as the report on financial and administrative implications for the Secretariat of the draft resolution (see Annex 3).

ANNEX 1

REPORT TO THE DIRECTOR-GENERAL OF THE REVIEW COMMITTEE ON SECOND EXTENSIONS FOR ESTABLISHING NATIONAL PUBLIC HEALTH CAPACITIES AND ON IHR IMPLEMENTATION
13–14 November 2014, Geneva, Switzerland

BACKGROUND

1. The International Health Regulations (2005) (the “IHR” or the “Regulations”) were adopted by the World Health Assembly in 2005.
2. This is the second IHR Review Committee to be convened. The first IHR Review Committee was convened in 2010 to assess the functioning of the Regulations; assess the ongoing global response to

¹³⁶ See summary records of the 136th session of the Executive Board, eighth meeting, section 1.

¹³⁷ See document EB136/2015/REC/1 for the resolution, and for the financial and administrative implications for the Secretariat of the adoption of the resolution.

the pandemic influenza A (H1N1) 2009 (including the role of WHO); and identify lessons learned for strengthening preparedness and response for future pandemics and public-health emergencies.¹³⁸

3. One of the most important provisions in the IHR is the obligation for all States Parties to establish core capacities to detect, assess, notify and report events, and to respond to public health risks and emergencies. The initial target date for establishment of these capacities was June 2012. At that time, 42 of 193 States Parties declared that they had met their core capacity requirements. As provided in the Regulations, 118 States Parties requested and were granted a two-year extension of the deadline up to June 2014.

4. Articles 5(2) and 13(2) of the Regulations provide that, in exceptional circumstances, and supported by a new implementation plan, States Parties may request a second extension, not to exceed two years. The decision to grant a further extension shall be made by the Director-General, taking into account the technical advice of a Review Committee.

5. At the time of this second Review Committee meeting, 64 States Parties had indicated that they met the minimum core capacity standards; 81 States Parties had requested an additional two-year extension of the implementation deadline; and 48 had not communicated their intentions to WHO.¹³⁹

6. The end of the second extension period will mark an important milestone in the implementation of the Regulations since they came into force in June 2007. This milestone will be a reminder that the work of developing, strengthening and maintaining the IHR's essential public health capacities is continuous and requires ongoing attention from all States Parties. The diversity and increasing frequency of events involving infectious disease and other hazards affecting public health are potent reminders that the IHR remain foundational to global health security.

APPOINTMENT OF THE REVIEW COMMITTEE

7. The Director-General appointed 13 members to the Review Committee from the IHR Roster of Experts in accordance with the IHR and the WHO Regulations for Expert Advisory Panels and Committees.

8. The purpose of the Review Committee was to: (1) advise the Director-General on requests from States Parties on second extensions (2014–2016) for establishing the core capacities to detect and respond to events as specified by Annex 1 of the IHR; and (2) advise the Director-General on how to better strengthen and assess IHR core capacities in the short- and long-term.

ORGANIZATION AND PROCESS OF THE MEETING

9. The meeting of the Committee took place at WHO headquarters in Geneva, 13–14 November 2014.

10. The Director-General thanked the Review Committee for its time and expertise, and noted that Ebola and other public health events continued to demonstrate the importance of having strong International Health Regulations. However, she mentioned that the world was still far from where it needs to be, with more States Parties having formally requested second extensions than had fully implemented IHR core capacities, and that advice on ways to improve the current situation was sought.

¹³⁸ See http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_10-en.pdf?ua=1.

¹³⁹ An additional three States became Parties to the IHR after June 2007 and have different time frames for implementation of core capacities.

11. The Acting Legal Counsel reviewed the procedural arrangements for the Review Committee. The Legal Counsel reminded the Committee that all members should act independently and provide their personal expertise as scientists and/or public health experts and that Committee members were expected to maintain confidentiality on the non-public information that was disclosed during the course of the meeting.

12. The Chair (Professor Didier Houssin), Vice-Chair (Dr Ximena Aguilera) and Rapporteur (Mr Andrew Forsyth) were elected. The Chair made a number of introductory remarks. The Review Committee adopted the proposed agenda.

13. The Chair noted that representatives of States Parties to the IHR, the United Nations (UN) and its specialized agencies and other international organizations were invited to attend the morning plenary session and to then return on the second day of the meeting at which time an oral summary of the Committee's deliberations would be presented.

14. The Director, Global Capacities, Alert and Response (Dr Isabelle Nuttall) made a background presentation on the IHR, including an overview of the Regulations, core capacity requirements, and associated time frames and extensions.

15. A number of States Parties and invited organizations made statements. All recognized the importance of IHR and the progress made so far. Some States Parties gave justifications for their request for extension related to the small size of their country, the circumstances of specific overseas territories or the natural disasters that affected their health systems. General comments included progress noted by countries in implementing the IHR, efforts to build surveillance systems and the importance of lessons learnt over recent years. A call for solidarity, with reference to article 44 of IHR, was clearly expressed by many States Parties, suggesting that twinning and networking would provide opportunities to assist. In their interventions, the international organizations noted the importance of a multisectoral approach and in particular the need to strengthen the collaboration with the animal health sector through, for example, a "One Health" approach. It was also noted that more attention should be paid to the occupational health requirements of front-line health care workers.

IHR IMPLEMENTATION

Progress and challenges

16. The Review Committee noted that considerable progress has been made in implementation of the IHR and reflected on the conclusions and recommendations of the report from the Review Committee on the functioning of the IHR and on pandemic influenza A (H1N1) 2009. The Committee noted that key achievements include: establishment and functionality of National IHR Focal Point entities (NFPs); increased transparency in reporting events, using early warning systems more systematically; better communication and collaboration between animal and human health sectors; coordinated collective efforts of countries and partners to build capacities (e.g. the Asia Pacific Strategy for Emerging Diseases (2010), Integrated Disease Surveillance and Response); establishment of emergency response coordination structures; and better international mechanisms to share information for rapid response. These achievements are the result of significant efforts made by States Parties, WHO, and donor programmes. Core capacities at central, intermediate and local levels are essential public health functions that are beneficial not only to the individual country, but to the global community.

17. Though progress had been made in many areas, the Review Committee emphasized that countries in every Region still face significant challenges to fully implement the IHR. Key impediments to IHR implementation include: insufficient authority/capacity of NFPs; the misconception that implementation of the IHR is the sole responsibility of ministries of health;

limited involvement/awareness of sectors other than human health; limited investment of national financial and human resources; high staff turnover; ongoing complex emergencies/conflict; the specific needs of small island states and States Parties with overseas territories; the focus on IHR extensions of the deadlines rather than on an expansion of capacities; a perception that implementation is a rigid, legal process with less emphasis on operational implications and learning from experience; and limited international solidarity to support the weakest countries in building capacities. States Parties' self-assessment of their implementation of the IHR is limited by the variable quality and reliability of information that is provided.

Requests for second extensions

18. The Review Committee was provided detailed country-level requests and implementation plans in advance of the meeting for their review. The Secretariat also provided aggregated analyses of the requests for second extensions; States Parties were grouped based on the completeness of the implementation plan which accompanied their second extension request and on their monitoring framework scores. The Review Committee heard the analysis and thoughts expressed by WHO regional offices representatives.

19. The Review Committee considered the variability between the different extension requests; e.g. the number of core capacities requested for extension, the reasons for doing so, and the completeness of proposed implementation plans. Some of the exceptional circumstances and obstacles to full implementation of the IHR cited by States Parties in their requests, included: the need for more time; financial, economic or public health issues (e.g., *"mass vaccination campaigns competing for resources, and various ongoing outbreaks"*); the lack of human resources; long-running emergencies (e.g., *"due to protracted emergencies caused by conflicts over three decades"*, *"significant gaps in infrastructure, human resources, human development, education and health continue to exist"*); internal or external political issues (e.g., *"unprecedented military and political crisis that has disrupted the socio-economic plan, the operation of the administration, and disorganized the healthcare system at all levels for the implementation of activities"*); and natural disasters.

Conclusion 1

20. The work to develop, strengthen and maintain the core capacities under the IHR should be viewed as a continuing process for all countries.

21. The current Ebola virus disease (EVD) outbreak has underscored the importance of having strong national and local capacities in place to rapidly detect, respond and take preventative measures to contain a serious public health threat. At the same time, it has highlighted the fragile nature of health systems in some countries, as well as the importance of a multi-sectoral approach. It is therefore of concern that only approximately one-third of States Parties have indicated that they have met the minimum core capacity requirements.

22. In formulating its advice to the Director-General, the Review Committee felt it was essential to consider the implementation status of all States Parties and not just those Parties that have requested a second extension. The Review Committee recommends the following for the Director-General's consideration:

Recommendation 1

23. States Parties that have indicated they have met the minimum core capacity requirements should be commended for their considerable efforts. *At the same time, they should be reminded that implementation of the IHR is a dynamic, ongoing process that must be continually assessed, maintained and strengthened as needed. These countries should be urged to continue their efforts to maintain and strengthen their core capacities, and to consider*

providing support to other States Parties that face technical, financial, political or other obstacles in establishing core capacities.

Recommendation 2

24. **All States Parties that have requested a second extension (or do so at a future date) should be granted the extension for 2014–2016.** *In granting this extension, the Director-General should note if the request was accompanied by an implementation plan and if so, whether or not the plan adequately addressed the criteria for the extensions noted by the Sixty-sixth World Health Assembly. In communicating with the State Party, the Director-General may also take into account other relevant information that relates to the core capacities for that country. The Director-General's communication with the State Party could also be used by WHO regional and country offices to engage with the State Party and where appropriate, serve as a basis for priority setting, establishing next steps, and resource mobilization. WHO (at headquarters, regional and country levels) should continue to support these countries, as needed, in their efforts to implement core capacities.*

Recommendation 3

25. **States Parties that have not communicated their intentions to WHO should be reminded of the importance of transparency** *in relation to both the letter and the spirit of the IHR. These States Parties likely represent a diverse group ranging from those that may have met the requirements for core capacities but not reported to that effect, to those that have made limited progress. WHO should make further attempts to contact these States Parties, offer assistance, and provide them with the opportunity to: request an extension if it is needed; or indicate that they have met the minimum requirements under IHR Annex 1 and that, therefore, no extension is necessary.*

Recommendation 4

26. **States Parties, stakeholders, and donor programmes should be encouraged to provide technical and financial assistance** *as needed. States Parties should be encouraged to use guidelines and tools that WHO has developed, or may in the future develop, to support implementation of the IHR.*

Short-term action to accelerate IHR implementation

27. The Committee discussed ways in which additional improvements could be made during the extension period. It was felt that not all NFPs are sufficiently empowered; they needed to be well positioned within the public health system with appropriate seniority and close to where decisions are taken, particularly during emergencies.

28. Laboratory services and surveillance systems should be better linked to improve integrated surveillance. A lesson learnt from EVD and other events is the value of having and using existing public health capacities and networks during emergencies. The diagnostic capacity of national and intermediate level laboratories should be enhanced by connecting them to surveillance networks including those connected to health centres and clinics, and through quality assurance, quality control programmes, and biological risk management.

29. There is a need to strengthen and build multisectoral surveillance capabilities at local and community levels, with trained staff working with clinicians, and to promote integration of surveillance systems for both communicable diseases and other hazards and to establish early warning alert and response systems where needed.

30. More can be done to strengthen data management as applied to both laboratories and epidemiological surveillance. The challenges in data management include: difficulties handling

multiple inputs from different sources; lack of reporting from some areas; lack of data management standards; and lack of linkages between data sets. Data collection at community level is weak in many outbreaks. Outbreak reviews at the local and national level should be encouraged and WHO should facilitate meta-evaluations of the last 20 major outbreaks to help provide evidence-based guidance.

31. One of the major challenges to IHR implementation is building up core capacities at points of entry, particularly in terms of surveillance, preparedness and response capacities. EVD has demonstrated the importance of adequate core capacity implementation at designated airports, ports and ground-crossings. Approaches or tools which integrate demography, migration, health burden, animal-human interface, transport hubs, volume of air traffic and the like into web-based applications, could assist risk assessment. Identification of high-risk international points of entry for the spread of diseases could facilitate prioritized capacity implementation at points of entry on a more scientific basis. In the context of EVD, exit screening can be used for security, and entry screening can be used as an opportunity for education, awareness raising and monitoring. It was emphasized that cross-border cooperation for the development of risk mapping, surveillance and coordinated responses to diseases and events is critical.

32. In the context of the current EVD epidemic, public health measures that have consequential implications for travel and trade raise complex and difficult issues that require very careful consideration; a review, possibly by an ad hoc technical group and/or formal evaluative analysis, is needed to identify lessons from recent experience, and assess from a public health perspective, and the wider social and economic effects, what works, what does not and why. At the technical and political level, additional measures taken by countries that vary from Temporary Recommendations made by the WHO Director-General in public health emergencies of international concern pose special challenges (e.g., in the context of EVD, blanket travel bans are measures which exceed the Temporary Recommendations). States Parties can apply such additional measures, but only under the conditions laid out in Article 43 of the Regulations. A State Party affected by an additional measure may request consultations with the implementing State Party in order to find a mutually acceptable solution (Article 43 paragraph 7 of the Regulations). WHO also can, and should, seek to obtain the public health rationale for additional measures, and share this with other countries. Where no rationale is forthcoming, this too may be disclosed for example, via the event information site.

33. The health and safety of frontline health care workers in outbreak situations or other public health events was considered to be critical. One key approach to their protection is training; recent outbreaks have shown that, where healthcare workers were well trained, fewer became infected. It is also important to build health workers' confidence and to ensure adequate numbers by providing appropriate support; e.g., through health insurance and regular salary payments. In the current Ebola epidemic, the Review Committee acknowledged the heroism shown by many frontline health care workers, often under the most difficult of circumstances, and in many cases, at the cost of their own lives.

Recommendation 5

34. The Committee recommends States Parties to:

- (a) *Review, and where appropriate, strengthen and empower NFPs to enable effective performance of key IHR functions, facilitate decision making and ensure high-level support for multi-sectoral communication and cooperation*
- (b) *Support the formation of multidisciplinary outbreak investigation and response teams, including animal health expertise where appropriate*

- (c) *Foster an operational approach in which cooperation between countries, results in practical and sustainable solutions to surveillance, laboratory, and other capacities in small islands and other small States*
- (d) *Use a risk assessment approach to prioritise public health threats, capacity gaps and to identify priority points of entry for designation and capacity building*
- (e) *Build the confidence of health care workers through policy measures that promote protection of and respect for health care workers' rights.*

Recommendation 6

35. The Committee also recommends to the Director-General to consider establishing technical working groups to:

- (a) *Strengthen data management capacities and practices; and*
- (b) *Review the lessons learned from current and past experience with public health measures that have had negative implications for travel, transport and trade.*

Longer-term commitment to the IHR to prevent the international spread of public health threats

36. The IHR (2005) have been tested repeatedly in recent years by the continued emergence and re-emergence of infectious disease, such as influenza, polio, MERS-CoV, and EVD, the majority of them zoonotic (i.e., infecting both humans and animals), underscoring the usefulness of a “One Health” approach. The possibility of harm from radiological and chemical hazards is also of concern, contributing to an increasingly complex world in which the global community will continue to face an array of diverse threats to its health and well-being. It is critical, therefore, that the IHR are seen, and used, as an essential tool in contributing to global health security.

37. States Parties envisioned a long life for the IHR (2005): “By not limiting the application of the IHR (2005) to specific diseases, it is intended that the Regulations will maintain their relevance and applicability for many years to come even in the face of the continued evolution of diseases and the factors determining their emergence and transmission.”¹⁴⁰

38. Against this backdrop, the Review Committee considered the longer-term development of and commitment to the IHR core capacities. The Review Committee noted that the principles and key themes of the IHR provide an important foundation upon which to construct a long-term approach:

- The IHR recognize the interdependence between countries with respect to both threats to public health and the respective capacities of countries to manage those threats.
- The IHR provide a risk-based framework that recognizes the different nature of various threats and of the measures needed to address them.
- Proportionality is an important consideration that can be applied to capacity building (e.g. capacities of small developing island States will never match those of large countries) as well as to response measures, which should be commensurate with and restricted to public health risks.
- Implementation of the Regulations should be “... guided by the goal of their universal application for the protection of all people of the world from the international spread of disease”¹⁴¹

¹⁴⁰ See Foreword to the International Health Regulations (2005), Second Edition.

¹⁴¹ See Article 3, paragraph 3, of the IHR.

Methodologies for the shorter- and longer-term development of IHR capacities

39. To move countries towards greater IHR functionality, it is essential to have better information on the robustness of States Parties' core capacities. States Parties currently report on their progress in implementing the Regulations through a self-assessment approach that is facilitated by WHO data collection instruments and supporting tools. The Review Committee discussed the advantages and challenges to approaches that would build upon a basic "checklist" approach to methodologies that can better assess quality and functional performance. Options discussed included assisted self-assessments, voluntary independent evaluations, peer reviews and certifications.

40. Systematic reviews of States Parties' or regions' responses to disease outbreaks and other public health events is another way of assessing capacities in a more integrated and arguably useful fashion. It was noted that there are no processes or systems currently in place to institutionalize collection and dissemination of observations and "lessons learned".

Conclusion 2

41. Implementation of the IHR should now advance beyond simple "implementation checklists" to a more action-oriented approach to periodic evaluation of functional capacities.

42. The Review Committee noted that implementation of the "theoretical construct" of the IHR has now been tested against the realities of public health threats and the varying capacities and resources of States Parties to address them. In light of this experience, implementation of the IHR should now advance beyond simple "implementation checklists" so there is a more action-oriented approach to periodic evaluation of functional capacities. This will require a carefully prepared "roadmap" including regional engagement with States Parties for improvement.

Recommendation 7

43. The Review Committee recommends that the Director-General consider a variety of approaches for the shorter- and longer-term assessment and development of IHR core capacities as follows:

States Parties should urgently: (i) strengthen the current self-assessment system (e.g., if not already done, the annual self-assessment reports and planning processes should be enhanced through multi-sectoral and multi-stakeholder discussions); and (ii) implement in-depth reviews of significant disease outbreaks and public health events. This should promote a more science or evidence-based approach to assessing effective core capacities under "real-life" situations. Simultaneously, the Secretariat should promote a series of regional formal evaluations or meta-evaluations of the outbreak reviews, managed by the regional offices, to facilitate cross-region learning and to distil lessons learnt for future IHR programming.

In parallel, and with a longer term vision, the Secretariat should develop through regional consultative mechanisms options to move from exclusive self-evaluation to approaches that combine self-evaluation, peer review and voluntary external evaluations involving a combination of domestic and independent experts. These additional approaches should consider, amongst other things, strategic and operational aspects of the IHR, such as the need for high level political commitment, and whole of government/multi-sectoral engagement. Any new monitoring and evaluation scheme should be developed with the active involvement of WHO regional offices and subsequently proposed to all States Parties through the WHO governing bodies' process.

44. This performance oriented information needs to be supplemented by information of an advocacy nature that demonstrates to States Parties, especially potential donors, the value of providing additional support to IHR post 2016. One example of this potential advocacy material would be economic analysis of the costs of international public health events, such as, SARS, Avian

Influenza, MERS CoV, Ebola Viral Disease etc. and the benefits of maintaining and enhancing core IHR capacities.

Recommendation 8

45. ***A comprehensive, time-phased, prioritized plan for continued implementation and maintenance of the IHR to guide longer-term capacity development for the IHR should be developed based on the outcomes of the consultative process, analytic reviews and analyses mentioned above. Such a plan should be both realistic and with aspirational components, taking into account the wide disparities in States Parties' capacities and resources. Consideration should be given to delineating the basic core capacities that should be in place for all countries.***

Resource requirements

46. The development and maintenance of core capacities require extensive and sustained financial and personnel resources for States Parties. Of particular concern, as noted by the IHR Emergency Committee for EVD, is the fragile nature of health systems and other relevant sectors needed for a multisectoral response in some countries "with significant deficits in human, financial and material resources, resulting in a compromised ability to mount an adequate ... outbreak control response."¹⁴²

47. In some cases, States Parties alone cannot supply the resources to develop and maintain core capacities, as well as mount a surge response for potential public health emergencies of international concern. The private sector has an important supporting role. The Review Committee emphasized that it is in the interest of the private sector to contribute resources for public health preparedness and response. Infectious and other public health events can have considerable direct and indirect economic ramifications for the private sector (e.g., commerce, travel, tourism, entertainment, sports), as well as the directly affected countries.

48. Well-resourced countries and intergovernmental and non-governmental entities have made significant contributions (e.g., financial, technical, supplies/materials, and personnel) in response to the EVD outbreak. Mobilization of these resources, however, has taken considerable time and effort. In this connection, it was noted that the Review Committee on the Functioning of the IHR (2005) in relation to Pandemic (H1N1) 2009 made two relevant recommendations: (1) the establishment of a more extensive global, public health reserve work force; and (2) the creation of a contingency fund for public health emergencies.¹⁴³ Progress in implementing these recommendations has been limited to the creation of the African Public Health Emergency Fund. Urgent support by States Parties, including through WHO governing bodies, is required.

49. The Committee re-emphasized the findings of the Review Committee on the Functioning of the IHR and on Pandemic Influenza A (H1N1) in May 2011, namely that "WHO's capacity to prepare and respond in a sustained way to any public health emergency is severely limited by chronic funding shortfalls, compounded by restrictions on the use of funds from Member States, partners and donors."¹⁴⁴

Recommendation 9

50. ***The Review Committee recommends that the Director-General encourage dialogue among States Parties and public and private partners, including large NGOs, to improve cooperation and assistance:***

¹⁴² Statement on the 1st meeting of the IHR Emergency Committee on the 2014 Ebola outbreak in West Africa, available at <http://www.who.int/mediacentre/news/statements/2014/ebola-20140808/en/>.

¹⁴³ See http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_10-en.pdf?ua=1.

¹⁴⁴ Ibid.

- (a) *Obtain support for the sustained development and maintenance of national capacities over the long-term, with particular attention to countries requesting extensions/countries with significant capacity gaps;*
- (b) *Create a response fund, as recommended by the first Review Committee, for use in public health emergencies of international concern that can be readily available for future events; and*
- (c) *Create a more extensive global, public-health reserve work force that can be mobilized as part of a sustained response to a public health emergency of international concern.*

Recommendation 10

51. ***The Review Committee encourages the States Parties to support WHO through financial and staffing resources in preparation for, and during, public health emergencies of international concern.***

ANNEX 2

DRAFT RESOLUTION ON THE RECOMMENDATIONS OF THE REVIEW COMMITTEE ON SECOND EXTENSIONS FOR ESTABLISHING NATIONAL PUBLIC HEALTH CAPACITIES AND ON IHR IMPLEMENTATION

The Executive Board, having considered the report of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR implementation,¹⁴⁵ RECOMMENDS to the Sixty-eighth World Health Assembly the adoption of the following resolution:

The Sixty-eighth World Health Assembly,

PP1 Having considered the report of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR implementation;

PP2 Reminding Member States of their rights and obligations under the International Health Regulations (2005) and their responsibility to the international community;

PP3 Recalling the final report of the Review Committee on the Functioning of the International Health Regulations (2005) and on Pandemic Influenza A (H1N1) 2009 transmitted by the Director-General to the Sixty-fourth World Health Assembly;¹⁴⁶

PP4 Recognizing the establishment of a Review Committee as required under Articles 5 and 13 of the International Health Regulations (2005) and as provided for in Chapter III of Part IX of the said Regulations;

PP5 Commending the successful conclusion of the work of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR implementation, the leadership of its chair, the dedication of its distinguished members, and the submission of its report to the Director-General for transmittal to the Sixty-eighth World Health Assembly,

(OP1) 1. URGES Member States to support the implementation of the recommendations contained in the report of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation;

¹⁴⁵ Document EB136/22 Add.1.

¹⁴⁶ Document A64/10.

(OP2) 2. REQUESTS the Director-General:

- (1) to present an update to the Sixty-ninth World Health Assembly, through the Executive Board, on progress made in taking forward the recommendations of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation;
- (2) to provide technical support to Member States in implementing the recommendations of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation.

RESOLUTIONS 15.3:

Executive Board Resolution EB136.R5

Yellow fever risk mapping and recommended vaccination for travellers

The Executive Board, having considered the report on Implementation of the International Health Regulations (2005),¹⁴⁷ RECOMMENDS to the Sixty-eighth World Health Assembly the adoption of the following resolution:

The Sixty-eighth World Health Assembly,

Recalling the adoption by the Sixty-seventh World Health Assembly of the updated Annex 7 of the International Health Regulations (2005),¹⁴⁸ recommending that a single dose of yellow fever vaccine is sufficient to confer sustained immunity and life-long protection against yellow fever disease, that a booster dose of yellow fever vaccine is not needed, and that the validity of a certificate of vaccination against yellow fever shall extend for the life of the person vaccinated;

Highlighting the fact that States Parties may immediately apply these changes even though Annex 7 of the International Health Regulations (2005), as amended, is expected to enter into force in June 2016, in accordance with Article 59 of the Regulations;

Noting that, for the purposes of Annex 7 of the International Health Regulations (2005), vaccination against yellow fever may be required of any traveller leaving an area where the Organization has determined that a risk of yellow fever transmission is present,

1. URGES Members States:

- (1) during the interim period until June 2016, to inform WHO if they voluntarily accept to extend the validity of a certificate of vaccination against yellow fever for the life of the person;
- (2) to comply with the WHO recommendation for the definition of areas at risk of yellow fever and of the yellow fever vaccination recommendations for travellers;

2. REQUESTS the Director-General:

- (1) to publish, and update in real time, an online list of countries accepting a certificate of vaccination against yellow fever for the life of the person vaccinated;

¹⁴⁷ See document EB136/22.

¹⁴⁸ See resolution WHA67.13 and WHA67/2014/REC/1, Annex 5.

- (2) to establish a formal scientific and technical advisory group on geographical yellow fever risk mapping, with the participation of countries with areas at risk of yellow fever, to: (i) maintain up-to-date yellow fever risk mapping; and (ii) provide guidance on yellow fever vaccination for travellers in ways that facilitate international travel.

Executive Board Resolution EB136.R6

The recommendations of the review committee on second extensions for establishing national public health capacities and on IHR implementation

The Executive Board, having considered the report of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR implementation,¹⁴⁹ RECOMMENDS to the Sixty-eighth World Health Assembly the adoption of the following resolution:

The Sixty-eighth World Health Assembly,

Having considered the report of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR implementation;

Reminding Member States of their rights and obligations under the International Health Regulations (2005) and their responsibility to the international community;

Recalling the final report of the Review Committee on the Functioning of the International Health Regulations (2005) and on Pandemic Influenza A (H1N1) 2009 transmitted by the Director-General to the Sixty-fourth World Health Assembly;¹⁵⁰

Recognizing the establishment of a Review Committee as required under Articles 5 and 13 of the International Health Regulations (2005) and as provided for in Chapter III of Part IX of the said Regulations;

Commending the successful conclusion of the work of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR implementation, the leadership of its chair, the dedication of its distinguished members, and the submission of its report to the Director-General for transmittal to the Sixty-eighth World Health Assembly,

1. URGES Member States to support the implementation of the recommendations contained in the report of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation;
2. REQUESTS the Director-General:
 - (1) to present an update to the Sixty-ninth World Health Assembly, through the Executive Board, on progress made in taking forward the recommendations of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation;
 - (2) to provide technical support to Member States in implementing the recommendations of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation.

¹⁴⁹ Document EB136/22 Add.1.

¹⁵⁰ Document A64/10.

15.4 WHO response in severe, large-scale emergencies

Document A68/23 (Report of the Director-General):

WHO response in severe, large-scale emergencies

1. Pursuant to the request by the Executive Board in resolution EBSS3.R1, adopted at the special session on Ebola, the Director-General submits this report on all WHO Grade 3 and United Nations Inter-Agency Standing Committee Level 3 emergencies where WHO has taken action between May 2014 and April 2015.
2. During the period under review, WHO responded to 40 emergencies (see Annex) including an unprecedented six concurrent emergencies evaluated as Grade 3, the most severe level based on WHO's Emergency Response Framework.¹⁵¹ Since May 2014, WHO has declared three new Grade 3 emergencies: the complex humanitarian crisis in Iraq (graded in August 2014), the Ebola virus disease outbreak in West Africa (graded in July 2014) and the earthquake in Nepal (graded in April 2015). The other three Grade 3 emergencies are those in the Syrian Arab Republic, Central African Republic and South Sudan, each of which is an on-going conflict graded in 2013.
3. The six Grade 3 emergencies involve 11 countries, with commensurate scale and complexity of operations. The crisis in the Syrian Arab Republic also affects Jordan, Lebanon and Turkey, and the Ebola virus disease outbreak includes Guinea, Liberia and Sierra Leone.¹⁵² With the exception of the Ebola virus disease outbreak and the Nepal earthquake, all the Grade 3 emergencies are also Inter-Agency Standing Committee system-wide Level 3 emergencies.
4. Although Grade 3 emergencies are the most high profile and demanding, they should not obscure the other serious on-going emergencies. Since 1 May 2014 WHO has responded to 31 acute graded emergencies (including the six at Grade 3), in addition to nine protracted crises (e.g., those in Afghanistan, Democratic Republic of the Congo, Myanmar and Somalia). Some countries have had more than one emergency (e.g., Philippines) and some have experienced both acute and protracted crises during that period (e.g., Pakistan). Health needs are almost always among the most pressing for populations directly affected by emergencies. Over the past 18 months, for example, communities have ranked health services as their highest priority during assessments in Central African Republic, Philippines and Syrian Arab Republic.
5. According to the United Nations Office for the Coordination of Humanitarian Affairs, the global scale of humanitarian need is currently the highest on record. There are 77.9 million people requiring humanitarian assistance worldwide; about 172 million people are affected by conflict. In addition, close to 200 million people are affected annually by natural and technological disasters, resulting in almost 110 000 deaths. As of 20 April 2015, total humanitarian appeals amounted to US\$ 18 700 million, of which only 15% was funded (8% within the health sector). The competing demands for humanitarian financial assistance have never been greater.

¹⁵¹ The Emergency Response Framework outlines three separate grades of emergency that convey the extent of organizational support required for the emergency response: 1, 2, and 3. A Grade 1 emergency requires minimal WHO response; Grade 2 requires moderate WHO response; and Grade 3 requires substantial WHO response. The relevant members of the Organization's Global Emergency Management Team determine the emergency grade after consideration of scale, urgency, complexity and context. Once an emergency is graded, WHO's response is monitored according to well-defined, time-bound performance standards.

¹⁵² Cases of Ebola virus disease were also documented in Mali, Nigeria, Senegal, Spain, the United Kingdom of Great Britain and Northern Ireland and the United States of America. These countries were not covered by the Grade 3 declaration.

WHO'S ACTIONS IN EMERGENCY RESPONSE

Syrian Arab Republic

6. The conflict in the Syrian Arab Republic has entered its fifth year, directly affecting 12.2 million people, of whom 7.6 million are internally displaced and 3.8 million are refugees. Five countries (Egypt, Iraq, Jordan, Lebanon and Turkey) have generously absorbed large numbers of refugees, placing huge burdens on their own national social services and local communities.

7. The conflict has had a major impact on access to health care, with the near collapse of the Syrian health system and a significant change in the country's public health profile (increased trauma, outbreaks of poliomyelitis and measles, mental health problems and complications of communicable diseases). Most technical and operational support to the WHO Country Office is delivered through the Emergency Support Team established in Amman, Jordan, in January 2013. The Emergency Support Team works with the affected countries to ensure an approach that covers the whole of the Syrian Arab Republic as well as a coordinated regional health approach.

8. WHO increased its operational capacity in the Syrian Arab Republic to 66 staff, and has a decentralized network of 27 medical focal points across all governorates, including those in remote and opposition-controlled areas. WHO has sub-offices in Aleppo, Hassake and Homs and plans to establish a presence in Daraa. WHO also has active partnerships with 56 local nongovernmental organizations to improve access and establish sustainable modalities for delivery of health services.

9. In 2014, WHO distributed 13.5 million medical treatments in the Syrian Arab Republic, 22% of which were distributed through partner nongovernmental organizations and 32% of which went to hard-to-reach and opposition-controlled areas, including in Aleppo, Daraa, Deir ez-Zor, Hassake, Idleb, Raqqa and Rural Damascus. This figure is more than twice the amount distributed in 2013. In addition, 10 rounds of polio vaccination were administered to 2.9 million children under 5 years old in 2014; 1.1 million children were vaccinated against measles in June 2014. The number of Disease Early Warning System sentinel sites increased from 441 to 650 in 2014, a third of these in opposition-controlled areas.

10. The crisis has also overburdened health systems in neighbouring countries. WHO worked with host governments and health sector partners to assess, monitor and address key public health risks and health sector burden related to the 3.8 million Syrian refugees and affected host communities in Egypt, Iraq, Jordan, Lebanon and Turkey.

11. Despite the expansion of WHO's response, gaps remain owing to increasing health needs, difficulty in accessing services, limited operational capacity of partners and limited funding. The health sectors within the Syrian Arab Republic and in neighbouring countries require a total of US\$ 687.2 million (and WHO needs US\$ 131.6 million) in 2015 to continue providing life-saving medicines, medical supplies and equipment to a growing number of increasingly vulnerable people; strengthen trauma management; expand delivery of immunization services; provide mental health and physical rehabilitation services; strengthen overall support to health services in neighbouring countries; and support a regional approach to communicable disease surveillance and response.

Central African Republic

12. The crisis in the Central African Republic has displaced more than one million people since December 2013. Today there are more than 430 000 internally displaced persons and more than 1.47 million people in urgent need of humanitarian health support. About 60% of health care facilities are now functional, but 80% of those depend on support from partners.

13. WHO expanded its country presence by bringing in 55 staff in successive phases and repurposing 31 country office staff members to respond to the crisis. There are currently 69 staff members in Bangui and the three subnational offices (Bambari, Bandoro and Bouar).

14. WHO leads the Health Cluster of 64 health partners to coordinate the provision of emergency health services to people most in need. Free health care was delivered to the most vulnerable and supplies provided to care for 800 000 people; 345 508 children were vaccinated against measles and poliomyelitis; and a disease early warning surveillance and response system was established covering 82% of displaced people. Despite these efforts, health coverage remained limited. Challenges to providing emergency and basic health services remain insecurity and related lack of access and high operational costs, lack of resources, limited number of operational partners and collapse of the national essential medicines supply system.

15. The health cluster requires US\$ 63 million in 2015, US\$ 15 million of which WHO needs in order to provide urgent support to the affected population. As at 20 April 2015 the funding gap was 100%.

South Sudan

16. The crisis in South Sudan has resulted in 4.1 million people needing humanitarian assistance in 2015, of whom the Health Cluster is targeting 3.4 million, including 706 000 children aged under 5 years and 840 000 women of child-bearing age. There has been major disruption to health care delivery due to attacks on facilities, health workers and patients, shortages of medicines and lack of personnel.

17. Since the start of the crisis, WHO has been operational in all 10 states, and expanded its presence particularly in the five conflict-affected states of Central Equatoria, Jonglei, Lakes, Unity and Upper Nile; 138 staff members have supported the emergency response. WHO leads the Health Cluster with 36 health partners operating in the conflict-affected states.

18. In 2014, WHO delivered life-saving medicines for treatment of 959 000 people, supported emergency primary health care services in the Protection of Civilians sites, supported emergency vaccination campaigns against poliomyelitis and measles, oral cholera vaccination in major sites for internally displaced persons, responded to a cholera epidemic in five states and to outbreaks of hepatitis E, measles and visceral leishmaniasis, deployed surgical teams to manage trauma cases in Bentiu, Bor, Juba and Malakal, and strategically prepositioned essential medicines and life-saving supplies as part of contingency planning.

19. The risk of communicable disease outbreaks remains high in 2015. WHO and its health partners face numerous challenges in sustaining health services owing to insecurity, limited logistic and technical capacities, limited operational partners and lack of funding and staffing.

20. About US\$ 90 million is required for the Health Cluster emergency response in 2015, of which US\$ 16.7 million is required for WHO. WHO's funding gap as at 20 April 2015 was 83.6%.

Iraq

21. The current crisis has led to massive population displacement, with an increase from 1.8 million in late 2014-early 2015 to a total of 2.2 million internally displaced persons as of March 2015. Combined with 250 000 Syrian refugees in the northern governorates and the needs of host communities, the total humanitarian caseload is now 5.2 million people.

22. WHO expanded its humanitarian health response and strengthened its capacity, reaching 81 technical and operational staff including 25 international staff members. WHO established hubs and/or focal points in 10 governorates, and leads the Health Cluster of 45 health partners.

23. WHO provided essential medicines and medical supplies for a total of 1.6 million beneficiaries throughout the country (August 2014–February 2015), and supported the provision of primary health care services (819 546 consultations between August 2014 and January 2015) to internally displaced persons and refugees in Dohuk, Sulaymaniah and Erbil. To improve access to care for both internally displaced persons and host communities, WHO supported Dohuk and Sulaymaniah governorates with 10 mobile medical units each. More than 300 000 people were covered and more than 53 000 people reached with various medical interventions.

24. WHO supported the central Ministry of Health, the Kurdistan Regional Ministry of Health, and Directorates of Health by strengthening planning and management capacity and providing technical expertise in health assessments, disease surveillance and information management.

25. A major challenge to humanitarian response is insecurity, and a significant part of the country is inaccessible with limited or no access to health services. The limited number of operational partners and lack of financial resources are also problematic.

26. In 2015, WHO requires US\$ 120.3 million to respond to the health needs of more than five million beneficiaries (2.2 million internally displaced persons and 3.5 million people in host communities). WHO's funding gap as at 20 April 2015 was 100%.

Ebola virus outbreak, West Africa

27. The first confirmed case of Ebola virus disease in West Africa was documented on 21 March 2014 in the Forestière region of Guinea, although cases may have occurred as early as December 2013. Since then the outbreak has spread to involve nine countries, including Guinea, Liberia, Mali, Nigeria, Senegal, Sierra Leone, Spain, the United Kingdom of Great Britain and Northern Ireland and the United States of America. As at 17 April 2015 there have been 25 834 confirmed cases and 10 702 deaths in the three main affected countries of Guinea, Liberia and Sierra Leone.

28. Milestones in emergency response have included WHO's declaration on 25 March 2014 of the outbreak as a Grade 2 emergency; its upgrade to a Grade 3 emergency on 25 July 2014; the declaration on 8 August 2014 of a Public Health Emergency of International Concern; and the establishment of the United Nations Mission for Ebola Emergency Relief on 17 September 2014.

29. In response to a worsening of the outbreak, the international community expanded its response substantially during the second half of 2014. In support of this, the United Nations Secretary-General established the United Nations Mission for Ebola Emergency Response. Under this unique United Nations mission, WHO provided technical leadership while working with partners to develop a phased response strategy. The first phase emphasized isolating and treating patients, burying the dead in a safe and dignified manner, and promoting behavioural change. The second phase has emphasized case finding, contact tracing and community engagement.

30. In response to the Ebola virus disease outbreak in West Africa, WHO has established the largest emergency operation in its history. As at 16 April 2015, more than 700 staff members were deployed across more than 60 field sites in the three main affected countries of Guinea, Liberia, and Sierra Leone, with a further 37 in Mali. In total, more than 2100 technical experts have been deployed by WHO, including 678 experts from partners in the Global Outbreak Alert and Response Network. In addition, the United States Centers for Disease Control and Prevention have directly deployed experts in surveillance, contact tracing, data management, laboratory testing and health education, and have supported assessments of Ebola preparedness in non-affected border countries.

31. WHO has worked closely with a wide range of governmental, local and international partners. Key operational partners include the International Organization for Migration and sister United

Nations specialized agencies, funds and programmes (e.g., WFP, UNICEF, UNFP and UNDP), the African Union, the Government of Cuba and its medical brigades, nongovernmental organizations (e.g. Médecins Sans Frontières, International Medical Corps, International Rescue Committee and Save the Children) and the International Federation of the Red Cross and Red Crescent Societies.

32. Drawing on its own expertise, and strong linkages with governments, foreign medical teams, the Global Outbreak Alert and Response Network and other technical networks, such as the Emerging and Dangerous Pathogens Laboratory Network and Global Infection Prevention and Control Network, WHO has played a major role in expanding critical capacities for clinical, public health, infection control and laboratory services across the three main countries. Consistent with its normative role, WHO has provided or produced 45 technical guidance documents, covering a broad range of public health and clinical topics. More than 4000 staff members and consultants have been trained on Ebola virus disease, and a further 1400 people have accessed online training provided by the Organization.

33. WHO has also facilitated the review and consideration of numerous vaccines, medicines, therapies and diagnostic tools for the treatment and detection of Ebola virus disease. Accelerated review procedures have allowed the fast tracking of several of these therapeutics and diagnostics.

34. WHO has undertaken extensive work in all regions to support Member States in preparing for possible cases of Ebola virus disease, including technical support missions to 15 priority countries in the African Region, assistance with operational plans for these countries, monitoring preparedness capacities, and disseminating technical guidance.

35. WHO is playing a leading role in supporting the three main affected countries to reactivate health facilities safely and plan for health system recovery. WHO convened a partner meeting on building resilient health systems in Ebola-affected countries (Geneva, 10–11 December 2014); played a vital role in the Ebola recovery assessments led by the European Union, UNDP and the World Bank; and has contributed to the health system recovery plans that have recently been presented to partners.

36. Although significant progress has been made in recent months, the outbreak has revealed that in many respects WHO's own emergency structures, systems, capacities and culture will need to be addressed during the proposed reform of WHO emergency capacities in order for it to be adequately prepared for a crisis of this scale and complexity.

Nepal

37. On 25 April 2015 an earthquake of magnitude 7.8 struck Nepal, with the epicentre in Lamjung District, 70 kilometres north-west of Kathmandu. As at 28 April 2015, preliminary information indicated 4358 deaths, 8174 injuries and more than eight million people affected. Projections from the Ministry of Health and Population suggested that there may be as many as 10 000 deaths and 60 000 injuries. Thirty nine of 75 districts have been affected, with 11 priority districts requiring the most assistance. Continuing hazards have included aftershocks, avalanches and landslides.

38. Damage to hospitals and health facilities has been variable. In Kathmandu, all five main hospitals remained functional in spite of sustaining some damage, in part owing to retrofitting undertaken as part of national preparedness plans. However, up to 90% of the health facilities in Ramechhap, Nuwakot, Sindhupalchowk and Gorkha have been severely damaged.

39. The urgent response priorities included rescue; recovery; and provision of emergency trauma and medical care, shelter, water and sanitation and food aid. The Government of Nepal has a well-established Strategy for Disaster Risk Reduction Management, with health components, including

preparedness planning, developed by the Ministry of Health and Population with support from WHO. In the days following the earthquake, WHO assisted the Ministry in implementing the Strategy, including the activation of a dedicated and equipped Health Emergency Operations Centre. WHO staff members were immediately deployed to assist the Ministry with rapid assessments of the health impact, health needs and impact on health facilities of the earthquake.

40. The Government has requested urgent international medical assistance, and it is essential that such support is well coordinated and, particularly when working in remote districts, largely self-sufficient. WHO is supporting the Government in registering foreign medical teams, classifying them according to their capacities and guiding their field deployment to the areas of greatest need. By the end of April 2015, 63 foreign medical teams had arrived in the country, and another 39 had been asked to refrain from deployment until specifically requested, following on-going needs assessments. The Health Cluster has also been activated, with WHO co-chairing with the health ministry. Members of the Cluster include development partners who have repurposed their programmes to assist the relief effort and the newly arrived foreign medical teams. Cluster Members are required to support the Government's priorities and response plans.

41. Within 72 hours of the earthquake, WHO had brought in 15 staff members from country offices, the Regional Office for South-East Asia and headquarters to support the response. These included experts in emergency management, public health, epidemiology, logistics, water and sanitation, and communications. Over 30 more were on standby, ready for deployment once requested. WHO also immediately mobilized essential medicines and supplies to meet the needs of 120 000 people for three months, surgical supplies to meet the needs of 1200 patients, trauma kits for 500 patients, interagency diarrhoeal disease kits for 2100 cases and nine medical tents.

42. At the time of writing, WHO was continuing to expand its operations and expected to open more field sites in the priority districts. Key activities included conducting assessments, establishing disease surveillance, coordinating partners and providing technical guidance, for example on management of dead bodies. Crucial disease control measures were being implemented and a public health risk assessment developed. WHO also expected to provide psychosocial and reproductive health support and continuity of care for patients with chronic illness.

43. A US\$ 75 million flash appeal was launched on 29 April 2015, US\$ 6 million of which was for WHO's operations. A United Nations Central Emergency Response Funds allocation of US\$ 15 million was also expected, of which WHO requested US\$ 2 million.

Other acute/graded emergencies and protracted crises

44. In addition to the six concurrent Grade 3 emergencies, WHO responded to the health needs of affected populations in 25 other acute/graded emergencies and nine protracted crises during the reporting period. Eleven of the acute/graded emergencies occurred between 1 January and 20 April 2015 alone.

45. The acute/graded events included 11 Grade 2 emergencies, due to conflict (Cameroon, Niger, Nigeria, Ukraine and Yemen), outbreaks (Middle East respiratory syndrome in the Middle East and avian influenza (H7N9) in China), floods (Madagascar, Malawi and Mozambique) and a cyclone (Vanuatu); and 13 Grade 1 emergencies. Some countries were affected repeatedly by several separate events.

46. In Grade 1 and Grade 2 emergencies, as in all acute/graded emergencies, WHO's response strategy and deliverables were consistent with its Emergency Response Framework, supporting governments and working with health partners to ensure coverage and quality of emergency health services.

47. Nine countries face protracted emergencies: Afghanistan, Democratic Republic of the Congo, Mali, Myanmar, Pakistan, Philippines, Somalia, Sudan and Yemen. Two have had acute-on-chronic escalations of conflict (Philippines and Yemen).

48. Protracted emergencies require special attention, as they are all associated with persistently high levels of mortality and morbidity, are prone to acute-on-chronic exacerbations (including outbreaks, escalations of conflict and natural disasters), are increasingly difficult to mobilize human and financial resources for, and are all expected to continue for the foreseeable future. Five of these countries are among the 10 with the highest child mortality rates globally. Constraints to WHO's emergency response in these countries include chronic underfunding, lack of human resources, problems of access due to insecurity, limited number of operational partners, logistics difficulties and, in some cases, complicated administrative and clearance processes.

CONCLUSION

49. All six Grade 3 emergencies and the nine protracted crises that WHO is currently responding to will continue to require the Organization to play a major operational role for the foreseeable future. Only the Ebola outbreak is likely to end within the next 12 months. All will eventually require major recovery operations. When considered together with the high number of infectious disease events, natural disasters and new conflicts, it is clear that there is no real "peace time" for WHO and its emergency partners.

50. For each crisis, WHO's emergency response was mounted according to the Organization's Emergency Response Framework, to deliver on performance standards structured around four critical functions: leadership, information, technical expertise, and core services (e.g., logistics, human resources, resource mobilization and supply distribution). In each of the six Grade 3 emergencies and many of the other crises, WHO has also been required to fill gaps in health services through direct management of health facilities and mobile clinics, subcontracting local nongovernmental organizations, distributing essential medicines and supplies, and recruiting clinical staff for government facilities.

51. In all Grade 3 emergencies, WHO applied three essential policies: *the surge policy* ensured WHO country office staff members were appropriately repurposed and experienced emergency personnel were deployed; the *health emergency leader policy* allowed experts to be deployed to support WHO Representatives in leading the response; and the *no-regrets policy* supported predictable levels of staffing and funds at the onset of all emergencies, including access to WHO's Rapid Response Account.

52. WHO drew on its Rapid Response Account on several occasions in 2014 and 2015, for instance for a bridging loan to secure the continuity of operations in protracted crises. Rapid Response Account reserve funds amount to about US\$ 1 million, established with one-off grants from humanitarian donors over the past 10 years. Rapid Response Account loans are disbursed based on a standard operating procedure and are released within a few hours, but need to be refunded by WHO country offices once they receive funding from appeals. Given the number of emergencies and insufficient funding of emergency response, the Rapid Response Account is not always reimbursed and therefore funding from this account is limited to small amounts of between US\$ 80 000 and US\$ 200 000 (with exceptions on a case-by-case basis) for each new emergency.

53. As at 20 April 2015, WHO funding against appeals for the five Grade 3 emergencies was worryingly low.¹⁵³ Major challenges to WHO's emergency response include insufficient core funding

¹⁵³ Central African Republic: 0% of US\$ 15 million; Iraq 0% of US\$ 120.3 million; South Sudan: 16.4% of US\$ 16.8 million; Syrian Arab Republic: 11.1% of US\$ 131.6 million; and the Ebola virus disease outbreak:

and human resource capacity to ensure a predictable response, lack of rapid response funding, insecurity, increasing field costs (due to security, logistics and subnational presence), and inefficient internal administrative, financial and human resource processes. An internal report in December 2014 concluded that WHO needed an estimated 1587 staff globally dedicated to Category 5 emergency operations across all hazards; currently, there are only 530 (i.e., only 33.4% of required human resource capacity).

54. In the past 12 months, WHO and its partners have been called upon to provide assistance in a range of demanding and often insecure environments. The six on-going Grade 3 emergencies have been especially challenging, given their scale, complexity and operational difficulties. WHO's own performance in recent emergencies – like that of many of its partners – has been mixed. WHO staff members have frequently performed beyond expectations, but each of these emergencies has demonstrated deficiencies in WHO's emergency structures, systems, capacities and culture. These issues should be addressed to ensure that WHO can effectively provide the global leadership, support to Member States' capacity-building, technical guidance, and predictable, timely and effective response to emergencies that the world expects.

55. But response is only part of the answer. WHO, through building Member States' capacity under the International Health Regulations (2005) and emergency risk management programmes, has the duty to support countries in preventing and mitigating the health consequences of emergencies. The Organization also has a responsibility to lead – through policy development and technical guidance, coordination of partnerships such as the Global Outbreak Alert and Response Network and the Global Health Cluster, advocacy, and provision of health intelligence and analysis to guide emergency programmes. It is these interconnected areas of building capacities of Member States, delivering effective response, and leading the emergency health community that should form the basis of a holistic emergency programme for the Organization in the future.

ACTION BY THE HEALTH ASSEMBLY

56. The Health Assembly is invited to note this report.

ANNEX

LIST OF ACUTE/GRADED AND PROTRACTED EMERGENCIES IN THE REPORTING PERIOD (MAY 2014–APRIL 2015)

| Country, territory or area/emergency | Date of recent grading | Type of crisis | Grade |
|---|-------------------------------|-----------------------|--------------|
| Bosnia and Herzegovina | 21/05/2014 | Floods | 1 |
| Cabo Verde | 02/12/2014 | Volcanic eruption | 1 |
| Cameroon | 01/04/2015 | Conflict/civil strife | 2 |
| Central African Republic | 13/12/2013 | Conflict/civil strife | 3 |
| Croatia | 21/05/2014 | Floods | 1 |
| Global (Middle East Respiratory Syndrome) | 02/05/2013 | Public health event | 2 |
| Global (Avian influenza (H7N9)) | ? | Public health event | 2 |
| Iraq | 12/08/2014 | Conflict/civil strife | 3 |
| Libya | 04/12/2014 | Conflict/civil strife | 1 |
| Madagascar | 19/03/2015 | Floods | 1 |
| Malawi | 20/01/2015 | Floods | 2 |
| Mali | 04/02/2015 | Conflict/civil strife | 2 |

63.6% of US\$ 349.7 million. A United Nations flash appeal in response to the Nepal earthquake was due to be launched on 29 April 2015.

| | | | |
|---|------------------------|--------------------------------|-------|
| Micronesia (Federated States of) | 02/04/2015 | Storm | 1 |
| Mozambique | 28/01/2015 | Floods | 2 |
| Nepal | 27/04/2015 | Earthquake | 3 |
| Niger | 01/04/2015 | Conflict/civil strife | 2 |
| Nigeria | 01/04/2015 | Conflict/civil strife | 2 |
| Occupied Palestinian territory | 10/11/2014 | Conflict/civil strife | 1 |
| Pakistan | 20/06/2014 | Displacement | 1 |
| Pakistan | 11/09/2014 | Floods | 1 |
| Philippines | 08/12/2014 | Storm (Typhoon Hagupit (Ruby)) | 1 |
| Philippines | 10/03/2015 | Conflict/civil strife | 1 |
| Country, territory or area/emergency | Date of recent grading | Type of crisis | Grade |
| Serbia | 21/05/2014 | Floods | 1 |
| South Sudan | 12/02/2015 | Conflict/civil strife | 3 |
| Syrian Arab Republic (Egypt, Jordan, Lebanon, Turkey) | 03/01/2015 | Conflict/civil strife | 3 |
| Tuvalu | 16/03/2015 | Storm | 1 |
| Ukraine | 12/02/2015 | Conflict/civil strife | 2 |
| Vanuatu | 16/03/2015 | Storm | 2 |
| Ebola virus disease (Guinea, Liberia, Sierra Leone) | 26/07/2014 | Public health event | 3 |
| West Bank and Gaza Strip | 10/11/2014 | Conflict/civil strife | 1 |
| Yemen | 02/04/2015 | Conflict/civil strife | 2 |
| Afghanistan | N/A | Protracted | N/A |
| Democratic Republic of the Congo | N/A | Protracted | N/A |
| Mali | N/A | Protracted | N/A |
| Myanmar | N/A | Protracted | N/A |
| Pakistan | N/A | Protracted | N/A |
| Philippines | N/A | Protracted | N/A |
| Somalia | N/A | Protracted | N/A |
| Sudan | N/A | Protracted | N/A |
| Yemen | N/A | Protracted | N/A |

16. Communicable diseases

16.1 2014 Ebola virus disease outbreak and follow-up to the Special Session of the Executive Board on Ebola

Document A68/24 (Report by the Secretariat):

2014 Ebola virus disease outbreak: current context and challenges; stopping the epidemic; and preparedness in non-affected countries and regions

1. This report provides an update on the Ebola virus disease outbreak in West Africa and response during 2015.¹⁵⁴ It sets out the progression of the outbreak since January 2015 and outlines the steps taken in response, work on preparedness, research and development, and early recovery of health systems in the affected countries. The report concludes with an overview of the next steps for the response, especially in light of the staged decommissioning of the United Nations Mission for Emergency Ebola Response (UNMEER).

CONTEXT OF THE EBOLA OUTBREAK DURING 2015

2. Early 2015 saw a significant but variable decline in week-to-week case incidence of Ebola across Guinea, Liberia and Sierra Leone. At the end of April 2015, the geographic spread of transmission of Ebola virus disease had contracted and was mostly localized to six western prefectures of lower Guinea and four north-western districts of Sierra Leone. The response to the outbreak then shifted to a second phase built on the traditional public health interventions, however, challenges persist in fully implementing the standard of response required to interrupt residual transmission chains.

3. In Liberia, no new cases had been reported for three consecutive weeks, until a new case was identified on 20 March 2015. On 9 May 2015, 42 days after the burial of the last confirmed case, the outbreak was declared over in Liberia. The number of weekly cases in Guinea ranged from 74 at the beginning of this year to nine at the lowest in the last week of April. In Sierra Leone, the highest number of cases was 248 during the first week of 2015 but that number had dropped to nine cases per week at the end of April.

4. A substantial reduction in the number of districts with active transmission across the three countries has been off-set by persistently high transmission in the western areas of Sierra Leone and in and around Freetown, and in the lower region of Guinea and in and around Conakry. In the week to 26 April 2015, 76% of all confirmed cases were in Forecariah, a prefecture of Guinea, and the bordering district of Kambia in Sierra Leone.

5. While responders continue to focus on ending transmission, the number of Ebola survivors is now higher than in any previous Ebola outbreak. The survivors, an already traumatized population, face substantial medical and psychosocial issues. The longer-term health complications of Ebola survival are being studied to develop guidelines for survivor treatment and care, and to minimize the ongoing impact of the disease.

6. Possible instances of sexual transmission have been reported from male survivors of Ebola virus disease to their partners. Although sexual transmission of Ebola is still to be confirmed, if verified, this route of infection presents another difficult challenge to sustain the interruption of transmission

¹⁵⁴ See document EBSS3/2 for the context and challenges of the outbreak, and response and preparedness activities conducted up to the end of 2014.

and the end of the outbreak. A research agenda is being implemented to better understand and manage the risks of sexual transmission. Interim guidance for management of the risks associated with sexual transmission of the disease among survivors recommends an extended period of screening for all survivors, complemented by essential counselling on safe sexual practices.

RESPONSE

7. By the end of 2014, WHO had established the largest emergency operation in its history in response to the Ebola crisis. As of 2 May 2015, over 800 deployees were in place across more than 60 field sites in Guinea, Liberia and Sierra Leone, with a further 37 staff in Mali. In early 2015, the Ebola response, led by UNMEER, shifted from its first to its second phase. Its first phase emphasized isolating and treating patients, safe and dignified burials, and promoting behaviour change. Phase two emphasized the critical importance of community engagement, contact tracing and case finding.

8. Logistical and programmatic challenges were anticipated during the rainy season, particularly in geographically remote areas. Operations during the first months of 2015 were concentrated, therefore, on limiting the transmission of Ebola to a contiguous band of coastal districts and directing additional resources to achieve this. Efforts are now targeted towards further limiting transmission to the border area between Guinea and Sierra Leone and maintaining vigilance in all other areas. WHO also has an ongoing programme of work across government and agencies to detail and address the programmatic and operational risks.

9. Heightened awareness and understanding of Ebola among many affected communities has enabled local ownership of the response. However, resistance in a small number of communities continues to be a challenge: deaths from Ebola continue to be identified in the community in Guinea and Sierra Leone, and new confirmed cases are recorded among people who cannot be linked to known chains of transmission. Improved anthropological analysis, detailed case investigation, active surveillance and community engagement in these areas is required to ensure that all remaining chains of transmission can be tracked and ultimately brought to an end.

10. Member States and local and international partners continue to provide critical financial and human support to the Ebola response.¹⁵⁵ With the support of governments and strong linkages with foreign medical teams, humanitarian agencies, the Global Outbreak Alert and Response Network and technical networks, such as the Emerging and Dangerous Pathogens Laboratory Network and Global Infection Prevention and Control Network, critical capacities for epidemiology, clinical, infection control and laboratory services across the three most affected countries have been expanded.

Preparedness activities

11. Despite the decrease in the overall incidence of Ebola cases, there is still a risk of introduction of the disease to other countries. WHO has undertaken extensive work in all regions to assist Member States to strengthen preparedness for possible Ebola cases. WHO continues to support countries with the aim of ensuring they are ready to safely and effectively detect, investigate and report potential Ebola cases, and to mount a rapid and effective response. On the basis of existing national and international preparedness efforts, including previous work to develop core capacities under the

¹⁵⁵ Key operational partners for WHO include: nongovernmental and humanitarian organizations (e.g., Médecins Sans Frontières, International Medical Corps, International Rescue Committee, International Committee of the Red Cross, Save the Children); as well as numerous other partners, including: the Government of Cuba and its medical brigades, United Nations agencies, funds and programmes (including: WFP, United Nations Office for the Coordination of Humanitarian Affairs, UNICEF, UNFPA, UNAIDS, and UNDP); and the African Union, Economic Community of West African States, International Federation of Red Cross and Red Crescent Societies, International Organization for Migration.

International Health Regulations (2005), a set of tools has been developed to support countries to intensify and accelerate their preparedness.

12. Based on geographical proximity to affected countries, trading dynamics, population movement and relative strength of the national health system, 14 countries in the African region were identified¹⁵⁶ and are receiving accelerated preparedness support. All priority countries are implementing budgeted national Ebola preparedness and response plans, have tested their systems through simulations and have taken measures to strengthen their capacities and capabilities to respond. Progress is shared publicly on the WHO Ebola Preparedness Dashboard.¹⁵⁷ The target is for countries to have achieved a score of at least 50% in the first six months of 2015. As of April 2015, 29% of priority countries had achieved this target, compared to 7% in December 2014.

13. The roll-out of preparedness support to countries is ongoing and directly linked to strengthening the International Health Regulations (2005) and ensuring that the core capacities to manage health emergencies due to multiple hazards are part of resilient health systems. The results and lessons learnt from Ebola preparedness are feeding into a common framework for action to strengthen global health security and multi-hazard risk management through the implementation of sustained preparedness activities in vulnerable countries.

International Health Regulations (2005)¹⁵⁸

The Emergency Committee regarding Ebola

14. In 2015, the Emergency Committee regarding Ebola convened under the International Health Regulations (2005) has met twice, on 20 January 2015 and 9 April 2015. The Committee has maintained its August 2014 perspective that the outbreak constitutes a public health emergency of international concern. In January 2015, the Committee concluded that “getting to zero” Ebola cases remains the primary concern, and warned against complacency. The meeting in April 2015 called for the lifting of additional national measures that interfered with international trade and transport.

15. The Committee highlighted that additional health measures, such as quarantine of returning travellers, refusal of entry, cancellation of flights and border closure, significantly interfere with international travel and transport and have a negative impact on both the response and recovery efforts.

16. In keeping with implementation of the Committee’s recommendations, WHO works with Member States to confirm the exact nature and public health rationale for any additional measures, and to ensure that the temporary recommendations issued by the Director-General under the International Health Regulations (2005) are well understood. At 1 April 2015, there were 570 reports of such measures, involving 69 countries; 47 verification requests had been sent where measures were perceived as excessive, and 23 justifications for the measures concerned had been received.

Establishment of a review committee

17. Further to the request,¹⁵⁹ the Director-General has prepared options for establishing a Review Committee under the International Health Regulations (2005) to examine the role of the International Health Regulations (2005) in the Ebola outbreak and response, with the following objectives:

¹⁵⁶ The 14 countries in Africa identified as priority countries are Benin, Burkina Faso, Cameroon, Central African Republic, Côte d’Ivoire, Guinea-Bissau, Ethiopia, Gambia, Ghana, Mali, Mauritania, Niger, Senegal and Togo.

¹⁵⁷ Available at <http://apps.who.int/ebola/preparedness/map> (accessed 8 May 2015).

¹⁵⁸ See document A68/22.

¹⁵⁹ See resolution EBSS3.R1, paragraph 53.

- (a) to assess the effectiveness of the International Health Regulations (2005) with regard to the prevention, preparedness and response to the Ebola outbreak, with a particular focus on notification and related incentives, temporary recommendations and additional measures, levels of emergency and declaring a public health emergency of international concern and building and validation of core capacities;
- (b) to assess what was implemented and what was not from the previous Review Committee in 2011¹⁶⁰ and related impact on the effectiveness of the International Health Regulations (2005) in relation to the current Ebola outbreak;
- (c) to recommend steps to improve the functioning, transparency, effectiveness and efficiency of the International Health Regulations (2005) and to strengthen preparedness and response for future emergencies with health consequences, with proposed timelines for any such steps.

18. The review will be conducted in accordance with Chapter III of Part IX of the International Health Regulations (2005) and WHO's Regulations for Expert Advisory Panels and Committees.¹⁶¹ The Director-General will appoint members of the Review Committee from the International Health Regulations Expert Roster,¹⁶² taking into account a number of elements, including: equitable geographical representation; gender balance; a balance of experts from developed and developing countries; representation of a diversity of scientific opinion, approaches and practical experience in various parts of the world; and an appropriate interdisciplinary balance.

19. The Review Committee will be provided with all relevant documents and the conclusions of the interim assessment conducted by the panel of independent experts.¹⁶³ An extensive review of the implementation of the recommendations of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009¹⁶⁴ will be conducted as part of the review.

20. The Review Committee will be supported by technical experts and the Secretariat, as appropriate, in relevant aspects of public health, the International Health Regulations (2005) and emergency response.

21. The Director-General will convene the first session of the Review Committee after the Sixty-eighth World Health Assembly, and present the Committee's preliminary findings to the 138th session of the Executive Board in January 2016. For the consideration of the Health Assembly, it is proposed that a final report be presented to the Sixty-ninth World Health Assembly in May 2016.

Research and development

22. With the research and development community, WHO has facilitated the review and consideration of numerous vaccines, drugs, therapies, and diagnostics for the treatment and detection of Ebola virus disease. WHO has convened many consultations to review emerging data and to discuss the way forward. Accelerated review procedures have allowed the fast-tracking of several of the vaccines and diagnostics.

¹⁶⁰ See document A64/10.

¹⁶¹ See Regulations for Expert Advisory Panels and Committees, Basic documents, Forty-eighth edition. Geneva: World Health Organization; 2014, pp. 121–130, also at: <http://apps.who.int/gb/bd/> (accessed 8 May 2015).

¹⁶² More information on the Expert Roster is available at: http://www.who.int/ihr/procedures/ihr_committees/en/ (accessed 8 May 2015).

¹⁶³ See document A68/25.

¹⁶⁴ See document A64/10, Annex.

23. The first rapid antigen test to diagnose Ebola was listed in February 2015 under the WHO Emergency Assessment and Use – a new procedure introduced to ensure acceptable quality, safety and performance standards for new medical products during an epidemic. Several other new tests are currently being assessed, including four head-to-head trials for rapid diagnostic tests taking place in Sierra Leone.

24. Clinical trials are under way in Guinea and Sierra Leone for convalescent blood and plasma therapies, and data from earlier plasma trials in Liberia are being analysed. The ZMapp and TKM-Ebola treatments are showing the most promise in preclinical animal studies.

25. Phase 3 efficacy studies of an Ebola vaccine – VSV-EBOV – commenced in Guinea on 23 March 2015 and in Sierra Leone on 9 April 2015. In Guinea the trial is led by a consortium of the Government, Canada, Norway, WHO, Médecins Sans Frontières, and other partners, following a “ring vaccination” design. In Sierra Leone the study is led by the Ministry of Health and sponsored by the Centers for Disease Control and Prevention (United States of America) and is based on individual randomization within clusters vaccinated sequentially. Phase 2 of a larger vaccine efficacy study is under way in Liberia in a collaborative effort between the Government of Liberia and the National Institutes of Health (United States of America), with each of three groups being administered either rVSV-ZEBOV, ChAd3-ZEBOV, or a placebo. A Phase 2 trial for the ChAd3-ZEBOV vaccine is planned in a number of African countries; Phase 1 trials for two other candidate vaccines have been completed.

26. WHO will be working on a blueprint for research and development in epidemics or health emergency situations where there are no, or insufficient, preventive and curative solutions. In the vaccines area, for example, this could include proactive establishment of “target product profiles” to guide development and the definition of accelerated regulatory pathways. Medicines activities could focus on development of robust preclinical models to better anticipate new drug development.

Building resilient health systems in Ebola-affected countries

27. The current Ebola outbreak has cemented the notion that resilience must be the foundation of every district health system. The WHO Framework for Health Sector Response, Recovery and Resilience from Ebola is focused on these three interdependent work areas.

28. WHO is playing a leading role in supporting the affected countries to safely reactivate health facilities and plan for health system recovery, working with national health authorities, nongovernment organizations, technical experts, and other partners to support early recovery efforts as a step towards long-term health systems development. Immediate early recovery needs include enhanced infection prevention and control and patient safety; increased capacity of the health workforce; strengthened surveillance; and the safe reactivation of essential health services.

29. In close collaboration with national governments, WHO has initiated the conversation on long-term health systems rebuilding and development. In addition, it has supported national authorities’ development of costed health system recovery plans. WHO continues to provide support to the affected countries in implementing such plans.

30. WHO will continue to work with each of the three most affected countries to support the implementation of national plans, and will focus on the health system constraints that existed prior to the epidemic, which contributed to the trajectory of the epidemic. Novel catalytic approaches to capacity development will be explored, for example, twinning partnerships. Lessons on safe reactivation of health services will be consolidated and shared.

LOOKING FORWARD

31. UNMEER responsibilities, functions and assets are being transitioned to national authorities and United Nations specialized agencies, funds and programmes in each country. UNMEER has concluded its operation in Mali and is working towards closure of its offices in Liberia by the end of May 2015, in Sierra Leone by the end of July 2015, and in Guinea by the end of August 2015. As UNMEER's role in the affected countries gradually declines, WHO's technical leadership and coordination of the response will take greater prominence.

32. The next step in the response is crucial, building on the progress, capacities and lessons to date. To accelerate the decline in cases, and to bring the outbreak to an ultimate end, efforts need to be redoubled across all major lines of action, with special emphasis on anthropological analysis, detailed case investigation, active surveillance and community engagement. These efforts will be guided by the 2015 WHO Strategic Response Plan: West Africa Ebola Outbreak.¹⁶⁵

33. Complacency among affected or at-risk communities remains a significant risk for the response, as does "Ebola fatigue" among donors and communities. The elimination of Ebola is necessary to ensure the reactivation of essential services and the future recovery of the affected countries. Accordingly, WHO will maintain field capacity into 2016. Continued international support will be central to ensuring the end of the outbreak.

ACTION BY THE HEALTH ASSEMBLY

34. The Health Assembly is invited to note this report, to consider the draft decision contained in document A68/51, and to endorse the establishment of a review committee under the International Health Regulations (2005), whose purpose is to examine the role of the International Health Regulations (2005) in the Ebola outbreak and response.

Document A68/25 (Report by the Secretariat):

2014 Ebola virus disease outbreak and follow-up to the Special Session of the Executive Board on Ebola

Ebola Interim Assessment Panel

In line with resolution EBSS3.R1, the Director-General has the honour to transmit to the Sixty-eighth World Health Assembly the first report of Ebola Interim Assessment Panel (see Annex).

ANNEX

EBOLA INTERIM ASSESSMENT PANEL

First Report of the Panel

1. During the special session of the Executive Board on Ebola in January 2015, Member States adopted a resolution calling for an interim assessment, by a panel of outside independent experts, on all aspects of WHO's response in the Ebola outbreak.¹⁶⁶ In response to the resolution, the Director-General established a panel to undertake this work in early March 2015. Since this time, the Panel has reviewed significant numbers of reports and met with key people within and outside

¹⁶⁵ See 2015 WHO Strategic Response Plan: West Africa Ebola Outbreak, at: <http://www.who.int/csr/resources/publications/ebola/ebola-strategic-plan/en/> (accessed 8 May 2015).

¹⁶⁶ Resolution EBSS3.R1.

WHO, including senior WHO staff, representatives of the United Nations Mission for Ebola Emergency Response, international nongovernmental organizations and Member States. By the time the Health Assembly meets, the Panel will also have carried out visits to the severely affected countries and to the Regional Office for Africa. This report has been prepared in advance of the visits, and does not yet encompass the information gained by the Panel in the countries themselves or at the regional level. The final report will incorporate lessons learnt, including what has and has not worked in the field.

2. The Panel is committed to adhering closely to its mandate and terms of reference,¹⁶⁷ beginning with an assessment of the roles and responsibilities of WHO at the three levels of the Organization. However, it should be underscored that the Organization consists not only of the Secretariat, but also the Member States. Member States are responsible for their own actions and statements, especially with respect to their obligations under the International Health Regulations (2005). They have key decision-making roles in relation to WHO priorities, resources and the Secretariat's mandate. Many of these responsibilities go beyond the remit of Ministers of Health; other government ministries and Heads of State also bear responsibilities, especially in times of crisis. The Panel therefore welcomes the establishment of the United Nations Secretary-General's High-level Panel on the Global Response to Health Crises to examine these broader issues.

3. The Panel considers this a defining moment for the work of WHO. Together, the WHO leadership and the Member States need to take determined action to address the challenges at hand. "Business as usual" or "more of the same" is not an option. Although there may be responsibility on the part of individuals for the way in which the response to the Ebola outbreak has been handled, it is necessary to identify and correct the structural causes of any shortcomings. In doing so, it must be recognized that there is an increasingly complex nexus of health, humanitarian and security crises that requires the United Nations system to find new approaches that go beyond institutional silos.

4. The Panel is acutely aware that the Ebola crisis began and continues in local communities. These communities have been indelibly marked by fear and sorrow and by great sacrifice. The toll on their own health workers has been extraordinarily high, and local people are also integral to ensuring safe and dignified burials, staffing treatment centres, and performing contact tracing. Many international workers, including WHO staff at all three levels of the Organization, have likewise put themselves at great risk for the good of the global community. The panel acknowledges with deep gratitude their work and generosity of spirit, and that of the huge number of people working in their own countries to bring this crisis to an end.

PRELIMINARY OBSERVATIONS

5. The Ebola Virus Disease outbreak, which began in 2013 in West Africa, is the largest and most complex Ebola outbreak on record. Widespread and intense transmission has devastated families and communities, compromised essential civic and health services, weakened economies and isolated affected populations. The outbreak also put enormous strain on national and international response capacities, including WHO's outbreak and emergency response structures. The Panel is extremely concerned about the grave health, social and economic costs of the Ebola outbreak. In light of the unpredictable nature of outbreaks and other health crises, and the mounting ecological changes that may trigger them, improving WHO's response to events such as these is critical. Systems and measures that are put in place need to be able to deal with extreme complexity, especially in relation to outbreaks in fragile States with weak institutions.

6. The Panel is cognizant of the many other public health and humanitarian crises that were competing for the attention of WHO and the broader United Nations system during this period. For

¹⁶⁷ See Appendix.

WHO, these included outbreaks of Middle East respiratory syndrome coronavirus (MERS-CoV), poliomyelitis, and avian influenza H5N1 and H7N9 virus infection. For WHO and the broader United Nations and humanitarian system, Level 3 humanitarian emergencies during 2014 included the crises in the Central African Republic, Iraq, South Sudan and Syrian Arab Republic. The Panel recognizes that once the full extent of the risk was understood and resources were mobilized, it was possible to better control the Ebola outbreak, and that the worst-case scenarios concerning projected numbers of cases did not come to pass.

7. This outbreak was particularly challenging because of the characteristics of the virus and because health care systems and public health infrastructure in all three affected countries were extremely fragile, suffering – among other things – from structural weaknesses, inadequate surveillance and few laboratories. Additional complications included underlying mistrust within the communities, highly mobile populations, porous borders, and the urban context of the epidemic. It was within this setting that an Ebola outbreak was able to become a large-scale emergency. All the organizations involved faced new challenges related to the scope and the nature of their respective roles.

8. There were serious gaps in the early months of the outbreak in terms of engaging with the local communities. Traditional cultural practices, including funeral and burial customs, contributed to virus transmission, yet culturally sensitive messages and community engagement were not prioritized. Essentially, bleak public messaging emphasized that no treatment was available and reduced communities' willingness to engage; medical anthropologists should have been better utilized to develop this messaging. It must also be realized that the fact that communities were already in a post-conflict situation manifested itself in high levels of distrust in authority. Owing to an extent to a lack of involvement on the part of the broader humanitarian systems, the nongovernmental organization resources, such as community development workers and volunteers, many from the countries and communities themselves, were not mobilized in the early stages. Given WHO's extensive experience with outbreaks, health promotion and social mobilization, it is surprising that it took until August or September 2014 to recognize that Ebola transmission would be brought under control only when surveillance, community mobilization and the delivery of appropriate health care to affected communities were all put in place simultaneously.

9. It is still unclear to the Panel why early warnings, approximately from May through to July 2014, did not result in an effective and adequate response. Although WHO drew attention to the "unprecedented outbreak" at a press conference in April 2014, this was not followed by international mobilization and a consistent communication strategy. The countries most affected, other WHO Member States, the WHO Secretariat, and the wider global community were all "behind the curve" of the rapid spread of the Ebola virus. Many of the nongovernmental organizations that were on the ground in the affected countries, running development or humanitarian programmes, were faced with having to respond to a situation for which they were not well prepared; they lacked normative guidance and no adequate coordination mechanisms existed. The Panel is continuing to explore reasons for this delay, including political, cultural, organizational and financial factors.

10. The International Health Regulations (2005) constitute the primary international framework for strengthening global health security. However, in the Ebola outbreak, there were issues about the timely sharing of information, resulting from multiple factors, including clearance at many levels. Anxiety about the consequences of notification in the countries affected was high and subsequently justified by the response of other countries, airlines and business leaders. Under the International Health Regulations (2005), a Public Health Emergency of International Concern was announced only on 8 August 2014. The declaration served to mobilize resources for the response, but also resulted in significant numbers of countries implementing measures additional to those recommended by WHO. These measures interfered with international travel and trade. As a result, the countries affected faced not only severe economic consequences but also barriers in receiving necessary

personnel and supplies. In these complex circumstances, lines of communication between WHO and decision-makers beyond the ministries of health, such as heads of state and government, become ever more critical.

11. It is well understood that WHO leads the health cluster in major humanitarian crises. It is unclear, however, how a public health emergency fits into the wider humanitarian system and at what point an outbreak becomes a humanitarian emergency that requires a broader United Nations-wide response which would include coordination with the many nongovernmental organization actors on the ground. One of the difficulties is that the risk assessment of public health emergencies and so-called humanitarian emergencies differs, because of uncertainty in assessing the likelihood of disease spread. In a humanitarian emergency, staffing and other resource needs can often be more directly assessed. Notwithstanding these challenges, given the need to bring together WHO and the broader United Nations system in the Ebola response, it is important to consider how these systems should interrelate; the Panel will revisit this matter in its final report.

12. Although WHO has considerable numbers of policies and procedures in place, notably the International Health Regulations (2005) and the Emergency Response Framework, these were activated late because of the judgments declaring the Public Health Emergency of International Concern and the Grade 3 emergency. These delays were related to many factors, including the following: a late understanding of the context and nature of this Ebola outbreak, which was different from previous outbreaks; unreliable reporting on the spread; problems with information flow within WHO; and difficult negotiations with countries. All these factors need to be addressed. Leadership by the Director-General, organizational alignment and clarity of decision making are paramount.

13. The very same issues made it difficult for WHO to communicate as the authoritative body on the crisis. Although an emergency media team was put in place to manage WHO's messaging and content, the communication strategy was not able to counteract the very critical reporting on the work of the Organization. This problem was reinforced by the delayed declaration of the Public Health Emergency of International Concern, misleading Twitter messages and leaked documents. It is still unclear why WHO was not able to engage in a high-level media response with greater command over the narrative.

14. There is a strong, if not complete, consensus that WHO does not have a robust emergency operations capacity or culture. Further, in this emergency, before August 2014 WHO did not appropriately seek support from other United Nations agencies and humanitarian actors in the United Nations Inter-Agency Standing Committee system. At an earlier stage these resources could have been made available and known systems put in place; these might have averted the crisis that led to the need to establish the United Nations Mission for Ebola Emergency Response.

15. In September 2014, the United Nations Secretary-General's leadership, through the establishment of the United Nations Mission, was essential in galvanizing the global community into a response, particularly in generating political and financial commitment by donor countries, as well as in prompting the deployment of military personnel by some countries. However, the Panel plans further analysis to determine whether a similar mechanism would be the appropriate model for managing future large-scale health emergencies, as it functioned by cutting across existing mechanisms, rather than engaging the United Nations cluster system. It is clear that governance processes in the United Nations system need to be appropriate for different crisis situations.

16. Overall, WHO needs to improve its ability to engage in partnerships in its emergency preparedness response. There have been signs throughout the crisis that WHO's ability to partner with the United Nations, the private sector and other non-State actors has not been strong. These relationships cannot be established during crises, but need to be developed when building

preparedness. At the same time, it is important to keep in mind that such preparedness has to be built in relation to all emergencies with health consequences.

PRELIMINARY RECOMMENDATIONS

17. Health is primarily the sovereign responsibility of countries, but the means to fulfil this responsibility are increasingly global. International collective action is therefore required. Such collective action has several main goals: to protect people's health, to prevent the international spread of health risks, and to ensure a robust response to global health threats when they occur. International collective action is essential for the effective and efficient governance of the global health system.

18. Each global health crisis has shown the tragic consequences, including those in the social and economic spheres, of the failure of countries to invest in global public goods for health. Those failures are then mirrored as weaknesses in WHO, as the Organization suffers from a lack of political and financial commitment by its Member States despite the global health risks they face. The Ebola outbreak might have looked very different had the same political will and significant resources that were spent in responding to it been made available to Member States and the WHO Secretariat over the past five years in order to support three key areas of action: ensuring global health preparedness at country level in implementing the International Health Regulations (2005); supporting countries to establish or strengthen primary health care systems; and developing diagnostics, vaccines, and medicines for neglected tropical diseases.

19. Now is the historic political moment for world leaders to give WHO new relevance and empower it to lead in global health. A strengthened, well-funded WHO can support all countries as they prepare to meet the challenges of increasing global interdependence and shared vulnerability. In response, the Secretariat needs to take serious steps to earn this leadership role in relation to outbreaks and emergency response and to regain the trust of the international community.

20. At present, WHO does not have the operational capacity or culture to deliver a full emergency public health response. A number of options have been suggested by different organizations and individuals: (i) a new agency should be established for health emergencies; (ii) the emergency part of the health response should be led by another United Nations agency; or (iii) investments should be made so that the operational capacity of WHO for emergency response is fully in place.

21. The panel recommends that the third option should be pursued with vigour. Establishing a new agency would take time to put in place and substantial new resources would be required to establish its basic administrative systems, and operational response capacity. A new agency would, in any case, have to rely on and coordinate with WHO for public health and technical resources, creating an unnecessary interface. Similarly, if another United Nations agency were expected to develop health operational capacity, it too would need to coordinate in depth with WHO, especially with respect to the International Health Regulations (2005). All this suggests that, as WHO already has the mandate to deliver on operational response, it would be a far more effective and efficient use of resources to make WHO fit for purpose. This will require the resources and political will of the Member States.

22. The Panel puts this recommendation to the Health Assembly now so that the overarching strategic direction is clear and that change can be driven forward quickly. If Member States agree to this strategic direction, then matters such as the Global Health Emergency Workforce and the proposed Contingency Fund can immediately move to implementation, so that the world is better placed to respond to significant public health emergencies.

23. A WHO that is capable of adequately responding to public health emergencies requires deep and substantial organizational change. The reaffirmation of WHO's mandate in these emergencies

should not be given lightly. This will require accountability and monitoring. Below we set out the key implications.

Organizational culture

24. When an emergency occurs, there must be an ability to shift into a command and control structure with rapid decision-making. It will require adapting and adjusting resource allocation, methods of work and information practices. Member States also have to be flexible, recognizing that some ongoing work of the Organization may be delayed or postponed in an emergency. In WHO's own capacity in large-scale emergencies, the biggest skill gap continues to be found in the area of crisis coordination and leadership, and this needs to be addressed. Wherever possible, however, in-country coordination should be led by the governments of the affected countries themselves; this should include taking into account their own assessment of needs.

25. Complete commitment is needed from Member States and WHO's leadership about what emergency response requires. All WHO staff must be aware of the implications of emergency response, and those likely to be deployed must be thoroughly trained, including through simulation exercises. As previously recommended,¹⁶⁸ the Organization should establish "an internal, trained, multidisciplinary staff group who will be automatically released from their duties for an unspecified duration, with a relief rotation after a designated interval."

Changes to systems, structures and processes

26. It will be critical to have a single, unified entity within WHO for emergency response. The outbreak and humanitarian/emergency response activities should be merged. This should be supported by new, streamlined systems and processes in administration, human resources management, and procurement that would allow rapid action and deployment.

27. The Panel understands that an appropriate structure for an emergency operations capacity is being developed and costed, and the Panel would be pleased to review it. It should be stressed that the core capacity at all three levels of the Organization does not need to be huge but it does need to be sufficient. First, in an emergency, many of the WHO deployments will come from its internal staff and the Global Outbreak Alert and Response Network (GOARN), standby partners, and the Global Health Cluster or, in the case of health care delivery, through the agreed availability of foreign medical teams and, in the future, through the Global Emergency Health Workforce. In addition, WHO does not need to build up an emergency capacity entirely separate from the other United Nations agencies. For example, while the Organization needs internal logistical skills and experience, these are more likely to be for specification rather than for direct material handling. WHO should have standing agreements with other agencies, certainly with WFP, to provide practical logistical capacity in relation to purchasing and transport. It might also consider an agreement with UNICEF for community engagement on public health. Similarly, there may be other areas where capacity does not need to be built separately; these should be fully explored. WHO should continue to use its technical competence in promoting normative guidance for policy and practices to be used by all actors.

28. The Panel recommends that this new structure should be put into place as quickly as possible, and work should be reported to the Executive Board in 2016. The necessary resources should be provided from increased Member States core contributions. The Secretariat's capacities for surveillance and technical support as required under the International Health Regulations (2005) also need to be urgently reviewed, and the relevant departments need to be supported by an adequate base budget.

¹⁶⁸ Document A64/10.

International Health Regulations

29. A second area of concern is the direct responsibilities of Member States themselves. This begins with preparedness. The International Health Regulations (2005) set out a number of core surveillance and response capacity requirements. Although the International Health Regulations (2005) entered into force in 2007, not all Member States have these core capacity requirements in place. As of January 2015, 64 States Parties have informed the Secretariat that they have achieved these core capacities; 81 States Parties have requested second extensions through 2016; and 48 States Parties did not communicate their status or intentions. In addition, there are serious concerns about the reliability of the self-assessments that Member States complete on their implementation of the national capacity requirements. This leaves these countries at high risk, and increases the risk for the international community.

30. WHO should propose a thorough but prioritized and costed plan to develop the core public health capacities for all countries in respect of the International Health Regulations (2005). This plan should be put to donor agencies, Member States and other stakeholders for funding. To propose this plan WHO will need reliable information about the current situation in each country. This requires some form of peer review or other external validation. At present only self-assessment is used. It is in the countries' own interest to have a thorough and objective analysis; the Panel recommends that ways to do this be explored. Although the focus is on public health systems, health care systems across all countries need to be in place. This again requires significant funding by Member States and possibly new types of financing mechanisms. The Panel would support this being a strong part of the post-2015 development agenda and the financing of global public goods.

31. It should be noted that the direct responsibilities of Member States under the International Health Regulations (2005) cover the individual governments' own responsibilities in acknowledging a public health emergency, but also require countries not directly affected to behave with appropriate responsibility towards the international community. At present there are significant disincentives for a government to be transparent about a public health emergency. During the Ebola outbreak, more than 40 countries implemented additional measures that significantly interfered with international traffic, outside the scope of the temporary recommendations issued by the Director-General on the advice of the Emergency Committee. The International Health Regulations (2005) impose restrictions on such measures, but this proved difficult to enforce as very few countries informed WHO of these additional measures, and, when requested to justify their measures, few did so. While the Panel recognizes that each Member State is a sovereign country with as its first priority the health of its own citizens, in our globalized world, where the health of one State is so interconnected with that of others, governments nevertheless also have a responsibility to act as global citizens. Accordingly, it is important to examine this weakness of the International Health Regulations (2005).

32. The Panel requests that the full IHR Review Committee assessment of the Ebola crisis should examine again the responsibilities of States Parties in notification and in other relevant matters, including border closures, trade and transport. Where possible, incentives need to be found for countries to declare public health emergencies. The Panel also emphasizes the importance of considering indemnification options, in order to address the severe economic penalties that affected countries may experience. Fear of travel and trade restrictions is a serious deterrent to reporting outbreaks, and addressing these concerns will improve transparency and encourage early reporting. There may also need to be some form of sanctions when countries take measures beyond those deemed necessary for public health; such precedents exist in the practices of WTO. If the current situation continues, WHO has little ability to enforce Member States' obligations under the International Health Regulations (2005).

33. At present, there is only one level of declaration – Public Health Emergency of International Concern (PHEIC) or not PHEIC. The Panel suggests that the IHR Review Committee consider whether

there should be different levels of alert, as this would make it possible to alert and engage the wider international community at an earlier stage.

Financing

34. At present only 25% of WHO's biennial programme budget comes from assessed contributions. The remainder comes from voluntary funds that are largely restricted for purposes specified by donors. There are no core funds for emergency response as such, although every year a considerable amount of money is spent as donor contributions for emergencies. WHO is put at a severe disadvantage by the fact that the core funds are so limited and do not allow an appropriate base for response. On a related note, the resources that underpin the Secretariat's capacity to monitor the International Health Regulations (2005), and provide related technical support, have been reduced to a level that the Panel believes is now inadequate. More broadly, the zero-nominal growth policy for assessed contributions that has now been in place for many years has eroded the work of the Secretariat.

35. Beyond WHO's core funding, proposals for a Contingency Fund are currently being developed. Such an arrangement should highlight prevention, rather than simply response, and therefore should be available at an early stage. Clear arrangements on decision triggers for the release of funds must be made. The Panel appreciates and supports the four characteristics – flexibility, transparency, alignment and predictability – for the Fund. While the proposed Contingency Fund is largely directed to WHO, the Panel would find it helpful if the Director-General had some discretion for payments to countries for staffing issues, including hazard pay and insurance for, and evacuation of, health care workers.

Workforce

36. The Panel welcomed the plan for an expanded and stronger global health emergency workforce. It strongly supports strengthening the national components of the workforce, especially by building national capacity through training and simulation exercises. The Panel also supports proposals for increasing standby capacity across WHO and/or partners and having pre-agreed arrangements for foreign medical teams. This will require the strengthening of partnerships with a variety of actors. WHO also has a role to play in developing and implementing workforce protocols and training materials, as well as managing workforce information.

FUTURE WORK

37. By the time the Health Assembly takes place, the Panel plans to have made initial visits to severely affected countries and the Regional Office for Africa. In addition, over the next weeks, Panel members will have met with other United Nations organizations, partners and other agencies involved in the response. In countries, Panel members will meet with government officials, international and local health care workers and communities. The aim is to gain as much understanding as possible about what did and did not work in the field, so that the Panel's recommendations are grounded in evidence and experience. During the latter part of June 2015, the Panel will hold its third and final meeting. The final report will be released shortly thereafter. The Panel will work closely with and inform the work of the United Nations Secretary-General's High-level Panel on the Global Response to Health Crises, and will provide guidance to the work of the forthcoming IHR Review Committee.

Appendix

COMPOSITION OF THE PANEL

1. Dame Barbara Stocking was appointed to chair the Panel. She was formerly Chief Executive of Oxfam GB, where she led major humanitarian responses. Currently she is President of Murray Edwards College, University of Cambridge, United Kingdom. The other Panel members are: Professor

Jean-Jacques Muyembe-Tamfun, Director-General of the National Institute for Biomedical Research, Democratic Republic of the Congo; Dr Faisal Shuaib, Head of the National Ebola Emergency Operations Center, Nigeria; Dr Carmencita Alberto-Banatin, independent consultant and advisor on health emergencies and disasters, Philippines; Professor Julio Frenk, Dean of the Faculty, Harvard T. H. Chan School of Public Health, Boston, Massachusetts, United States of America; and Professor Ilona Kickbusch, Director of the Global Health Programme at the Graduate Institute of International and Development Studies, Geneva, Switzerland.

OBJECTIVES AND TERMS OF REFERENCE

2. Resolution EBSS3.R1 requested “the Director-General to commission an interim assessment, by a panel of outside independent experts, on all aspects of WHO’s response, from the onset of the current outbreak of Ebola virus disease, including within the United Nations Mission for Ebola Emergency Response, in implementing the WHO’s Emergency Response Framework, and in coordination, including resource mobilization, and functioning at the three levels of the Organization, to be presented to the Sixty-eighth World Health Assembly”. The Panel’s terms of reference are to:

- assess the roles and responsibilities of WHO at the three levels of the Organization in responding to the outbreak and how these evolved over time;
- assess the implementation of the tools at WHO’s disposal (in particular the Emergency Response Framework, and the International Health Regulations [2005]) to carry out its mandate before, at the onset of, and during the outbreak;
- assess WHO’s actions at the onset of the outbreak and during the outbreak (timeliness, appropriateness, scale, effectiveness), including (i) coordination within the Organization and with Member States, in particular the directly affected countries, and other partners, (ii) resource mobilization and (iii) communications;
- assess WHO’s role within and its contribution to United Nations-wide efforts (within UNMEER);
- assess the strengths and weaknesses of those actions, determine lessons learnt that could be applied to the existing ongoing situation and for the future (including capacity, tools, mechanisms including coordination and communications, structures, ways of working, resources);
- provide recommendations to guide the current response and to inform future work, including with regard to the strengthening of organizational capacity to respond to outbreaks and the establishment of a contingency fund.

TIMELINE AND PROCESS

3. The Panel met on 30 March–1 April 2015 in WHO headquarters in Geneva. The agenda included: a review of the scope of the interim assessment and interactions with other assessments; and determination of the method of work and the work plan for the duration of the process. Briefings were given on: WHO’s mandate and financing, implementation of the 2011 IHR Review Committee recommendations, WHO’s role within UNMEER, and the current performance audit being conducted by the Office of Internal Oversight Services. The Panel heard presentations on activities that took place throughout the outbreak, and plans for a Global Emergency Health Workforce and a Contingency Fund. The Panel interviewed, by videoconference, Mr Tony Banbury, Former Special Representative of the Secretary-General, First Head of UNMEER; Dr David Nabarro, United Nations Special Envoy for Ebola; and, in person, Mr John Ging, Director, Coordination and Response Division, United Nations Office for the Coordination of Humanitarian Affairs. The Panel also held a session with interested Member States, during which the Chair briefed Member States on the ongoing work and plans, and heard views on, and their expectations of the Panel’s work.

4. The second meeting of the Panel was held from 19 to 21 April 2015 in Geneva. This meeting heard further briefings on the Global Emergency Health Workforce and the Contingency Fund, and also received an update on the performance audit being conducted by the Office of Internal Oversight Services. There were also briefings on Communications in support of WHO's Ebola efforts and an update on ongoing research and development activities. The Panel met with a number of other organizations which were involved in Ebola work in the affected countries, including Médecins Sans Frontières (MSF), the International Federation of Red Cross and Red Crescent Societies (IFRC), the International Organization for Migration (IOM), the Steering Committee for Humanitarian Response (SCHR), the International Council of Voluntary Agencies and Save the Children. At a session with the Member States, the Panel heard perspectives on WHO's role during the outbreak, in particular the strengths and weaknesses in its response, key lessons learnt during this period and areas for improvement in WHO.

5. Panel members plan to travel to the three most severely affected countries, and to the Regional Office for Africa, within the coming weeks. They will also meet with officials of United Nations agencies, governments, and partners involved in the response. The Chair will provide a briefing on the Panel's work to the United Nations Secretary-General's High-level Panel on the Global Response to Health Crises at its first meeting.

UPDATE ON WORK COMPLETED

6. The Panel determined that while a careful analysis was required of what happened, why it happened, and what could be improved in future, it should not focus solely on Ebola outbreaks. This was to ensure that the Panel's recommendations would help WHO to be ready for the unexpected in the future, rather than just able to deal with the last major emergency.

7. The Panel also stressed that its assessment is to be a learning exercise. The Panel's overriding concern is to understand what happened and to advise on the resources, systems, people, and changes in the organizational culture needed to improve future performance.

8. The Panel was asked to assess WHO's role and contribution to efforts across the United Nations system, and its interface with other parts of the global health and global humanitarian systems. The Panel will not, however, review these directly, as the United Nations Secretary-General has established a high-level panel, chaired by Tanzania President Jakaya Kikwete, to examine the response of the wider international community. Given that WHO is called upon to direct and coordinate these wider systems in matters of health, the Panel is reviewing how well WHO carried out this broader role. The Panel will complete its work as soon as possible after the Health Assembly, so that its findings can feed into the Secretary-General's high-level panel.

Document A68/26 (Report by the Director-General)

2014 Ebola virus disease outbreak and follow-up to the special session of the Executive Board on Ebola: options for a contingency fund to support WHO's emergency response capacity

1. Pursuant to the request in resolution EBSS3.R1, this report provides options on the size, scope, sustainability, operations, sources of financing and accountability mechanisms for a contingency fund. The options consider possible internal sources of funding from within WHO's existing Programme budget and take into account other relevant financing mechanisms and emergency funds already in operation or being considered, at regional and global levels. These options have

been developed on the basis of consultations with Member States, and take into account the first report of the Ebola Interim Assessment Panel.¹⁶⁹

BACKGROUND

2. When Ebola virus disease was first confirmed in West Africa, WHO's only sources of financing for an early, rapid response were regular budget lines and the modest bridge financing already in place for emergency responses. WHO issued its first appeal to underwrite its Ebola response on 27 March 2014, and a second on 10 April 2014. In response, donors contributed US\$ 7 006 230, although processing requirements meant that funds were available on 5 June 2014. Additionally concerning is that most of the funds were highly specified, which inhibited the ability to match funding to need as the crisis evolved. It may be that early access to adequate flexible funds would have mitigated the adverse health consequences in this and other emergencies, and in turn reduced long-term costs to the countries, the Organization and their partners.

3. Article 58 of WHO's Constitution stipulates that a special fund to be used at the discretion of the Executive Board shall be established to meet emergencies and unforeseen contingencies. There have been several attempts to establish such a fund, including the Executive Board Special Fund, established in 1954 and last used in 1977, and the Public Health Emergency Fund, established in 2009 in response to the 2009 H1N1 influenza pandemic. The Public Health Emergency Fund has been used to support early response on several occasions, including the current Ebola virus disease outbreak. However, the Fund is not self-sustaining and, as at 31 December 2014, the balance was US\$ 86 000.

4. In 2011, the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009 recommended the creation of a public-health emergency fund of at least US\$ 100 million, to be held in trust in a location and form that would be readily accessible to WHO. It recommended that the fund support surge capacity, rather than the purchase of materials, and be released in part or whole during a declared Public Health Emergency of International Concern. Although the Health Assembly urged Member States to support the implementation of the recommendations of the Review Committee, it was decided to look to Programme budget to support WHO's emergency response work rather than creating a separate fund.

5. The Ebola virus disease outbreak in West Africa concretized the need for a contingency fund to support WHO's ability to carry out its core functions in the context of an emergency. The Executive Board agreed in principle in resolution EBSS3.R1 to establish such a fund. As WHO undertakes reform of its emergency capacities to fulfil its constitutional mandate, one of the keys to ensuring that it is able to respond effectively and rapidly to emergencies with health consequences will be appropriate financing. A contingency fund should be operated under agreed principles and be fit for purpose, with appropriate size, scope, sustainability, operations, sources of financing and accountability mechanisms.

GUIDING PRINCIPLES OF A CONTINGENCY FUND

6. A set of principles, which harmonize with the principles that have emerged from WHO's financing dialogue, should guide WHO's contingency fund. The first of these is *flexibility*. To eliminate the possibility of the priorities of an emergency response being driven by restrictions on funds rather than articulated and measured need, the resources in a contingency fund would ideally be fully flexible. Where flexibility is impossible, it may be considered that earmarking should be discussed

¹⁶⁹ Document A68/25.

and agreed with the Organization, to ensure **alignment** with its operational plan for a given response.

7. A contingency fund should be **sustainable**, to provide predictable funds, in line with the financing dialogue. Ideally, a broad contribution base would exist, to ensure reliable replenishment of the fund's capital and/or draw down funds. At the moment, 20 donors provide more than 80% of WHO's funding. The vulnerability inherent in this situation makes broadening the donor base across the Organization, and in particular to support its emergency response capacities, essential.

8. To ensure that a contingency fund responds to unmet need it must be **complementary** to existing and planned financial mechanisms to which WHO does or will have access. A contingency fund should add to or merge with, rather than duplicate, existing funds. These include:

- (a) WHO's Rapid Response Account, established in 2009 to finance WHO's rapid response to humanitarian emergencies in accord with WHO's emergency response framework performance standards and emergency standard operating procedures. The Rapid Response Account is a revolving fund, initially funded with US\$ 1.2 million from the United Kingdom of Great Britain and Northern Ireland, and has since been supported by other donors;
- (b) WHO-Nuclear Threat Initiative Emergency Outbreak Response Fund, established in 2002 by the Nuclear Threat Initiative, a charity in the United States of America, and WHO to ensure rapid deployment of WHO and Global Outbreak Alert and Response Network experts to respond to infectious disease outbreaks, naturally occurring events or biological weapons;
- (c) regional funds, including the emergency funds that have been established in the African Region, Region of the Americas and the South-East Asia Region, the development funds in the European and Western Pacific regions (comprising set aside amounts from the respective regional programme budgets), and the fund due to be created in the Eastern Mediterranean Region; and
- (d) external funds including, but not limited to, the United Nations Central Emergency Response Fund, the United States Centers for Disease Control and Prevention's CDC Foundation's Global Disaster Response Fund, the IMF's Catastrophe Containment and Relief Trust, and the pandemic emergency facility being considered by the World Bank to provide surge financing in the event of an emergency.

9. To create and maintain confidence in the Organization and donor willingness to contribute to a contingency fund, there must be standards for **accountability** and **transparency** in how it is operated. In order to enhance transparency, the design of a contingency fund should err on the side of **simplicity**.

10. To be effective, a contingency fund designed to support emergency response must be **adequate, available** and rapidly (i.e., within hours) **accessible** when needed, with a minimum number of steps for authorization and disbursement. Funds should not be geographically limited, but instead be **globally** available to optimize the speed of worldwide and/or interregional response. This universality also ensures that the potential donor base will be as inclusive as possible. The clear goal of a WHO contingency fund should be its early use to **prevent**, whenever possible, a given event escalating into a Public Health Emergency of International Concern or Grade 3 emergency.

OPTIONS

11. WHO has explored options regarding the size, scope, sustainability, operations, sources of financing and accountability mechanisms of a contingency fund.¹⁷⁰

Size

12. Given the history of WHO's emergency response work,¹⁷¹ the minimum balance of the WHO contingency fund should correspond to the projected cost of the Organization mounting a vigorous and enhanced response to up to five Grade 2 or higher emergencies concurrently, each for the first six months. This value can be derived from both historical spending, and projected increased costs of enhanced WHO emergency capacity, deployment of the Director-General's proposed plan for a global health emergency workforce¹⁷² and a more aggressive approach to early phase disease outbreak containment and control.

13. WHO spent US\$ 15 million during the first three weeks of the response to the H1N1 (2009) pandemic. In the first six months of its response to the Ebola outbreak in West Africa, WHO's appeals for funding raised US\$ 26 918 620.

14. Although not limited to the first months of response, the budgeted (but largely unfunded) costs of WHO's response to Grade 3 emergencies other than the Ebola virus disease outbreak are also informative. In April 2015, WHO's appeals for these emergencies totalled US\$ 283.9 million.¹⁷³

15. Taken as a whole, these experiences reflect well on the recommendation of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009, which called for a US\$ 100 million fund.¹⁷⁴ With funding at this level and adequate non-financial capacities in place, WHO could more reliably and effectively mount responses to emergencies with health consequences when they take place, even when there is more than one at a time, thereby mitigating escalation whenever possible.

Scope

16. The scope of the proposed fund must be broad enough to allow WHO to be an effective responder, while ensuring that it remains a contingency fund, which by definition is not intended to cover all emergency response activities. In light of organizational experience, the intent of resolution EBSS3.R1 and the proposed guiding principles for the contingency fund, a reasonable scope would include all emergencies with health consequences graded at 2 and above.

17. The fund should be available during the first phase of WHO's response to an emergency, regardless of where it takes place. To be useful, the fund should support all aspects of WHO's response work, including mobilization of the proposed global health emergency workforce and response-related preparedness and surveillance in areas at high risk.

18. However, to ensure that appropriate allocation of core funds are provided to WHO's emergency programme across all levels of the Organization, the breadth of a fund's scope must be balanced.

¹⁷⁰ In accord with the request of the Executive Board, each of these parameters has been discussed by Member States; to facilitate this, the Secretariat has shared the materials developed during this report's writing publicly at http://www.who.int/about/who_reform/emergency-capacities/en/ (accessed 30 April 2015).

¹⁷¹ See document A68/23.

¹⁷² See document A68/27.

¹⁷³ Central African Republic: US\$ 15 million; Iraq US\$ 120.3 million; South Sudan: US\$ 16.8 million; and Syrian Arab Republic: US\$ 131.6 million.

¹⁷⁴ Resolution WHA64.1.

The contingency fund should ensure that WHO is not hindered in its response capacity by lack of immediately available funds, but once appeal or other funding is available and adequate, the contingency fund should no longer support the response effort. Moreover, the contingency fund should not be drawn on to the exclusion of complementary regional facilities, where those exist.

19. Similarly, although a contingency fund should support any spending category (e.g., personnel, related logistics and supplies, and travel) when it is being used, it is not intended to finance bulk procurement or stockpiling of supplies. Nor is a contingency fund of this type intended to fund substantive research and development, which requires greater financial investment than contemplated and active and long-term partnership.

Sustainability

20. Sustainability is one of the most important features of a contingency fund, as demonstrated by the quick exhaustion and lack of replenishment of funds in earlier mechanisms. The most successful of WHO's current emergency funding mechanisms are WHO-Nuclear Threat Initiative Emergency Outbreak Response Fund and the WHO Rapid Response Account. Both are revolving funds for which the expectation is that funds drawn down will be reimbursed, as and when possible, through appeals funding or, with donor concurrence, with any grant funds remaining following a response effort.

21. With a view to ensuring that a contingency fund is sustainable and will provide adequate support to WHO's emergency response over time, a WHO contingency fund should similarly be revolving, providing funds to WHO offices in the form of reimbursable loans. These loans can be potentially forgivable at the end of each biennium in the case of lack of appeal or other funding, including the Programme budget, adequate to repay the amount received. Funds from appeals and external emergency finance mechanisms can also serve as sources of replenishment as these contributions become available.

22. As an extra precaution, long-term donor agreements (e.g., 10–20 years) could also be sought to ensure a minimum balance for the fund. Such agreements would both ensure a minimum balance and provide a guaranteed income stream to borrow against, in the event of a major catastrophic emergency necessitating surge financing above and beyond the balance available.

Operations

23. Operationalizing and accessing a contingency must be easy enough to allow for rapid response, but require enough checks and balances to comply with the guiding principles of accountability and transparency. As noted earlier, the Rapid Response Account for humanitarian emergencies and the Nuclear Threat Initiative Fund for disease outbreak response are both considered successful funding mechanisms, although they currently operate with modest balances (about US\$ 1 million and less than US\$ 500 000, respectively). Disbursements are made for graded emergencies on the decision of the relevant WHO departmental directors in consultation with the regional and country offices. Justification is required, but there is minimal bureaucracy as the aim is to provide rapid funding for immediate response.

24. To promote simplicity, the contingency fund should replace existent but disused funds within WHO headquarters. To ensure that the lessons from the Nuclear Threat Initiative Fund and the Rapid Response Account are captured, the contingency fund should absorb them, while keeping their straightforward operational model.

25. Using the Emergency Response Framework grading system as the trigger for drawing down the contingency fund provides a transparent, common and rapid mechanism for allowing immediate action against known performance standards. This approach accommodates the declaration of a

Public Health Emergency of International Concern under the International Health Regulations (2005), which are automatically graded as 3, without requiring the emergency to escalate to that level or tying a release of funds to an Emergency Committee process. The Emergency Response Framework has been developed to be coherent within the international emergency response system, including the Inter-Agency Standing Committee, and to operate in coordination with the Office for the Coordination of Humanitarian Affairs, when appropriate.

Sources of financing

26. Although assessed contributions meet the guiding principles for the contingency fund, consultations with Member States have indicated that there would be significant difficulties in reaching agreement on additional and substantial assessed contributions to finance the contingency fund. Given these concerns, the WHO contingency fund will be financed through voluntary contributions. To ensure sustainability, contributions will come from a broad range of sources, including traditional bilateral donors, humanitarian and health emergency donors, foundations, charities and philanthropies. Contributions may be in the form of funds that remain with the donor, but can be withdrawn when the Organization needs them, provided that agreement can be reached on appropriate indications for disbursement, consistent with the principles and purpose of the contingency fund.

27. Consistent with the ongoing discussions on WHO's approach to non-State actor engagement, private sector contributions may be sought within the policies of WHO. Sectors that would be particularly negatively impacted by an emergency with health consequences or which have operations in high-risk areas may have an interest in contributing.

Accountability

28. A key to WHO's ability to respond to emergencies is its integrity. Countries invite the Organization and its experts in to support local responders, look to WHO for technical and normative guidance, and work in partnership in developing strategic and operational plans. Part of this integrity is full accountability for expenditures. As noted earlier, robust accountability structures also increase confidence in donors, which may commensurately increase opportunities for funding.

29. To ensure accountability and transparency, the fund would be subject to WHO's Financial Regulations and Financial Rules and would be under the delegated authority of the Director-General, while including built-in flexibility to allow for rapid access. WHO's governing bodies will provide oversight and will have full access to the contingency fund's financial, implementation and performance data.

30. Once the contingency fund is operational, any and all spending will be closely matched to verifiable outcomes or to the results of sound modelling exercises (for example, estimations of deaths averted) to provide stakeholders with the best possible data on impact. These data will be disseminated through reports to the WHO governing bodies, articles in appropriate publications and corporate communications with the general public. Resource mobilization professionals will use this information to make the case for further investment in a contingency fund. The Global Fund to Fight AIDS, Tuberculosis and Malaria provides a good model for this approach.

31. In response to Member State calls for increased transparency and accountability around WHO's financing, the Secretariat is developing a web portal to track and report on how contingency funds are sourced, programmed and spent.

CONCLUSION

32. In order to meet the need for available, flexible funding in the early days of WHO's response to an emergency with health consequences, and particularly in anticipation of WHO having greater

capacity to mount enhanced, more vigorous responses, it is proposed that a WHO contingency fund be established. The fund will bridge the gap between the start of an emergency and the point at which WHO has adequate funds as a result of appeals.

33. Given the difficulties of assessing the risk of escalation at the time of the first appeal, it is proposed that the bridge funding extend for a period of three to six months from the start of an emergency of Grade 2 or higher. A minimum balance of US\$ 100 million is proposed for the contingency fund, based on the recommendations of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009 whose implementation was urged by the Health Assembly in resolution WHA64.1 in 2011. It is proposed that disbursement be at the discretion of the Director-General or his/her delegate and that the fund follow WHO's established rules and regulations with adjustments necessary for rapid access. The fund's performance will be reported to the governing bodies and disseminated externally, to enhance transparency and meet the standards of other similar funding structures.

34. The purpose of the proposed WHO contingency fund is to finance reliably and quickly WHO's initial response to emergencies with health consequences, which will save lives, alleviate suffering, provide medical care to those in need, enable preparedness and surveillance in surrounding areas at high risk and, whenever possible, quickly address factors that could lead to escalation of a given emergency.

ACTION BY THE HEALTH ASSEMBLY

35. The Health Assembly is invited to adopt the draft decision in document A68/51 establishing a contingency fund with the described parameters.

Document A68/27 (Report by the Director-General):

Global health emergency workforce

1. The Ebola virus disease outbreak in West Africa has been unprecedented in many ways. In particular, the need for and deployment of many thousands of national and international responders over a sustained period of time has distinguished this outbreak response from others.

2. Although there have been clear and notable examples of excellence and deep commitment on the part of national and international responders, managing the massive deployment was highly complex. The process of mobilizing the people necessary to tackle the Ebola outbreak exposed gaps in the national and international health workforce infrastructures. At the national level, the numbers of health workers were limited, ill-trained and not properly equipped. Although networks and partnerships exist to deploy international responders, and in many cases performed very well, they faced challenges in terms of scale, quality assurance, training, coordination, financing and opportunities to share lessons learnt between and among deploying partners.

3. Mindful of these difficulties and of WHO's constitutional mandate as the directing and coordinating authority on international health work with responsibility for furnishing appropriate technical assistance and, in emergencies, necessary aid, the Executive Board in resolution EBSS3.R1 requested the Director-General to develop a plan for a more extensive global health emergency workforce that can be promptly and efficiently deployed, for service in countries that request or accept such assistance, for adequate periods of time, and with adequate resources.

4. This report contains a conceptual plan for a workforce established in order to respond to acute or protracted risks and emergencies with health consequences and identifies the actions that the Secretariat will be required to take in the coming months.

SCOPE

5. In order to respond to emergencies with health consequences, caused by the full spectrum of hazards, the required health worker competencies include the following.

- (a) **Public health:** ensuring that the public health aspects of emergency response are taken into consideration requires epidemiologists, laboratory scientists, case finders, contact tracers, infection prevention and control specialists, safe burial experts, event-specific specialists (for example, respiratory specialists in the case of volcanoes) and risk and event assessment specialists.
- (b) **Clinical care:** providing adequate patient care, for affected populations and international responders, requires doctors, nurses, pharmacists, midwives, physiotherapists, community care providers, dentists, psychologists, counsellors, social workers and psychosocial specialists.
- (c) **Coordination:** managing complex responses across multiple active sites requires professionals with strategic leadership skills and critical analytic, thinking, planning and management capacity such as programme managers, strategic planners and political analysts.
- (d) **Social mobilization:** engaging and motivating a wide range of partners (including community leaders and networks, civic and religious groups, local decision-makers and influencers) at national and local levels to raise awareness of and demand for a particular service requires advocates, communications experts and social and cultural anthropologists.
- (e) **Communications:** ensuring that the status of an emergency, WHO's work in response and requests for the assets needed are all communicated effectively, requires strategic communications experts, public relations specialists, graphic designers, web engineers and campaign designers.
- (f) **Logistics:** instituting the appropriate structures and systems to guide, organize and support the response requires logisticians, supply chain managers, engineers (for example, water and sanitation), security specialists and fleet management and drivers.
- (g) **Information management:** ensuring that information is recorded, organized, available and analysable through the course of the response to an emergency requires computer scientists, data entry and management specialists, and geographic information system specialists, all with the ability to set up, manage and analyse health- and emergency-specific data.
- (h) **Core services:** systemic support is essential throughout the response to an emergency with health consequences and requires specialists in human resources, resource mobilization, project management, and budget and finance and grant management, as well as administrative support.

6. In addition, depending on the emergency, competencies may be needed in research and development, in order to develop and deploy new vaccines, therapies, and diagnostics, and to guide the research and development agenda, and in health system strengthening in order to ensure infection prevention and control and safe reactivation of essential services.

7. Leveraging a scaled-up global health emergency workforce effectively requires robust, improved systems for pre-deployment, deployment and decommissioning. This paper considers how a global

health emergency workforce can be set up and operated, looking at issues of scale, pre-deployment (establishment of rosters, quality assurance and training), deployment (planning, initiating and deploying and medical evacuation) and decommissioning (repatriation, post-mission support and capturing lessons learnt). It also considers the matter of appropriate governance and financing.

8. Under this plan, WHO – in collaboration with relevant partners and stakeholders – will strengthen the pre-deployment and readiness of existing pools of talent by establishing rosters, by implementing quality assurance measures and by developing and conducting training and simulation exercises. In order to improve the deployment process, WHO will do the following: redesign and, where necessary, create new mechanisms to plan deployment; establish the criteria for initiating deployments; design and implement systems for smooth deployment itself; and institute an effective and accessible medical evacuation process. Regarding decommissioning, the plan aims to ensure that all deployees are appropriately and efficiently repatriated, while incorporating mechanisms to capture lessons learnt and provide post-mission health and psychosocial support.

SCALE

National responders

9. National health workers, national nongovernmental organizations, faith-based organizations, community and youth groups and other similar entities are the core of the global health emergency workforce and are necessarily the first responders to an emergency with health consequences.

10. Governments have the primary role and responsibility in developing robust domestic health systems, including a health workforce. WHO's priority is to support countries to develop robust core capacities. The Secretariat will work closely with Member States, and in particular those vulnerable to risks and emergencies with health consequences, to build essential skills by developing and providing training and by developing technical guidelines for establishing: (a) a national health emergency workforce; (b) national alert and response; (c) procedures for country reception of global workforce members; and (d) procedures that uphold national regulations on licensing, customs, accreditation and registration.

International responders from networks and partnerships

11. There are existing networks and partnerships that are established to provide international responders. These networks need to be expanded and strengthened to provide the scale, diversity of skills and numbers required for a large-scale response.

12. The Global Outbreak Alert and Response Network supports the coordination of international response, and pools human and technical resources from existing institutions and networks to support international outbreak identification, confirmation and response. WHO will work with partners in the Network in order to strengthen international alert and response capacities, expanding the number of member institutions, strengthening networks of expertise and increasing the number of languages represented in the Network.

13. The 2005 Inter-Agency Standing Committee's humanitarian reform process resulted in the creation of the cluster approach and the designation of global cluster heads in 11 areas of humanitarian activity. WHO has been designated Cluster Lead Agency for Health.¹⁷⁵ The Global Health Cluster is made up of more than 40 international humanitarian health organizations that work together to build partnerships and mutual understanding and to develop common approaches to humanitarian health action. Under the present plan, the Global Health Cluster will expand its network of affiliated organizations, ensuring predictable deployment of individuals and teams in order to provide emergency health services, health sector coordination, planning, information

¹⁷⁵ See resolution WHA65.20, which supported WHO in fulfilling its role as the Global Health Cluster lead agency.

management and communications during the response to acute or protracted risks and emergencies with health consequences.

14. Foreign medical teams are trained, self-sufficient groups of health professionals that treat patients affected by an emergency, under the terms of WHO's *Classification and minimum standards for foreign medical teams in sudden onset disasters*.¹⁷⁶ In response to Member State interest, in 2014 WHO established a dedicated unit to coordinate, manage and assure the quality of foreign medical teams. In order to expand the capacity and effectiveness of foreign medical teams, WHO is now developing a global registration system to verify and classify all teams that meet the WHO minimum standards for deployment. When fully implemented the registry will serve as a deployment and coordination mechanism, allowing a country affected by an emergency with health consequences to call on teams that have been pre-registered and quality-assured and inform those teams of the specific standard operating procedures and requirements for access to their country (including rules on importation of pain relief and registration as a doctor).

15. With the objective of increasing and complementing the Organization's skilled surge capacity, WHO has signed standby agreements with Canadem, iMMAP, the Norwegian Refugee Council and RedR Australia. Under these agreements, these organizations will provide a variety of trained and experienced staff who can be rapidly deployed for between three and six months in the event of a grade 3 emergency. WHO will increase the number of partners with whom it has signed stand-by agreements, which will help to provide an expanded range of options to support a predictable response for filling human resource gaps in a given response.

16. The WHO Emerging and Dangerous Pathogens Laboratory Network comprises relevant global and regional networks of high security human and veterinary diagnostic laboratories that collaborate to increase capacity for earlier diagnosis and management of outbreaks and infections in respect of emerging and acute endemic disease threats. Network laboratories are also partners in mounting the response of the Global Outbreak Alert and Response Network. The importance of laboratory capacity was highlighted in the Ebola outbreak in West Africa and WHO is committed to expanding and deepening the Network and building capacities in this area.

17. WHO's Emergency Communication Network, drawn from people who successfully completed in-depth training sessions, has a pool of 50 communications experts who have completed the pre-deployment training. WHO will expand the network and improve communications across all emergency response operations.

18. WHO also collaborates with regional and subregional networks, agencies and organizations in responding to emergencies with health consequences. These include intergovernmental organizations like the Association of Southeast Asian Nations, the Secretariat of the Pacific Community, the Caribbean Community Secretariat, the African Union, and the West African Health Organization. In the case of the Ebola outbreak, the African Union and the Economic Community of West African States' West African Health Organization were key parts of the response, training and deploying hundreds of health care workers and public health specialists to the West African countries. WHO worked with these organizations, the World Bank and the United Nations Office for Project Services to create an operational platform for these deployments and the support of the deployees. Governmental agencies including the European Centre for Disease Prevention and Control and the United States of America's Centers for Disease Control and Prevention, many of whom are also partners in the Global Outbreak Alert and Response Network, also work with WHO in

¹⁷⁶ Classification and minimum standards for foreign medical teams in sudden onset disasters. Geneva: World Health Organization; 2013. Available at http://www.who.int/hac/global_health_cluster/fmt_guidelines_september2013.pdf (accessed 11 May 2015).

emergency response, deploying public health and laboratory experts and conducting research into the pathogens that cause outbreaks, as they did for the Ebola response. WHO will continue and expand these relationships.

WHO standing and surge staff capacity

19. Standing capacity refers to those human resources dedicated to emergency preparedness and response. WHO has four critical functions in responding to emergencies with health consequences – namely, leadership, information, technical expertise, and core services – and will have a critical mass of standing staff capacity with appropriate skills, across all levels of the Organization to fulfil these at all times.

20. WHO will increase its dedicated emergency response staff from the current 530 full-time equivalents. Most emergency response staff members will be based at country level, with a significant number at the regional level in order to provide direct support to the country teams. A core team will work at headquarters.

21. WHO is also committed to increasing its operational capacity, to complement its technical and normative strengths and will engage logisticians at all levels of the Organization, and in particular in high-risk countries. They will be charged with logistic preparedness and readiness, as well as assessment and field support operations, and will be rapidly deployable as part of the first-line responders, responsible for implementing WHO's operational platform in coordination with governments and partners.

22. WHO's surge capacity is the ability of the Organization to draw on existing, non-emergency specific human resources when unforeseen emergencies or a deteriorating situation require a rapid and effective increase in response. In order to ensure that the response is proportionate to the scale of a given emergency, WHO will also identify a reserve corps of surge-ready staff members, with skill sets, including languages, that complement those of the standing emergency capacity. This capacity should also include the ability to rapidly scale down, when the need has been met. WHO will establish a roster, based on a staff profiling exercise across the Organization, to identify sufficient staff to allow it to rapidly and predictably respond to an event requiring a global response.

United Nations agencies, funds and programmes

23. As part of the United Nations system, WHO has the advantage of having sister agencies, funds and programmes replete with expertise across all governmental sectors.¹⁷⁷ During the Ebola outbreak, it became clear that the capacities that WHO and the WFP brought to the subnational response would benefit from closer collaboration. A new, formal legal relationship established between the organizations is supporting a joint operations platform across the three countries, leveraging WFP's expertise in large-scale humanitarian logistics and WHO's expertise in outbreak response and health logistics. WHO and WFP will refine their collaboration and explore the full range of emergency response opportunities that this partnership presents. Similar arrangements are being explored with the United Nations Office for the Coordination of Humanitarian Affairs, UNFPA and UNICEF.

24. WHO is also considering durable agreements with other United Nations entities that would expand the global health emergency workforce. One possibility would be to streamline staff transfer, loan and secondment mechanisms. Another would be to partner with the United Nations Volunteers Programme, to allow for the deployment of, among others, retired WHO staff members,

¹⁷⁷ In the case of response to the Ebola outbreak in West Africa, the United Nations Mission for Emergency Ebola Response, the United Nations' first public health mission, harnessed the capacity of the system.

thereby capturing a potentially rich source of experience and knowledge that is otherwise difficult to access.

OPERATIONALIZING THE WORKFORCE

Pre-deployment and readiness

Rosters

25. The first step in managing the global health workforce is identifying, as much as possible, its members. Deployment rosters have proven tremendously effective in partner organizations and modalities for establishing similar databases for the global health emergency workforce will be developed.

26. The internal WHO rosters will reflect the dedicated standing capacity in emergency response departments across all three levels of the Organization, and those staff members in other departments, and in regional and country offices, who have been identified as being part of the surge capacity. Selecting surge-ready staff members will entail first the staff profiling exercise, as a first filter for finding staff with expertise and experience relevant to emergency response. WHO will then hold follow-up discussions with staff members identified as candidates and their supervisors in order to verify skill sets and map other variables (including type and length of contract and type of post funding). Once identified, surge staff will be assembled into teams with complementary skill sets. The teams will be trained on a regular basis (including through simulations) to ensure their readiness.

27. The Global Outbreak Alert and Response Network, including the WHO Emerging and Dangerous Pathogens Laboratory Network, works with technical institutions worldwide to maintain inventories of technical response capacity, and ensure the rapid availability of experts and international response teams. The Organization's Emergency Communication Network maintains rosters, and the foreign medical teams unit's registry will serve the same purpose. The Global Health Cluster and standby partners also have databases of available experts, as do those United Nations entities that are involved in emergency response. One valuable contribution of the global health emergency workforce will be to harmonize these systems, making the information more accessible and coherent across platforms.

Quality assurance

28. It is vitally important that people deployed to work on an emergency response have training and skills at the appropriate level and of the necessary quality in order to enable them to perform their assigned duties and maintain appropriate vigilance for risks and hazards. It is dangerous to individuals and to the collective response work to deploy people with inadequate experience or a lack of expertise with the hazard involved, without training and mentorship. As it is difficult to determine competency based solely on self-reported educational and professional experience, WHO will develop a process to verify training, experience and language proficiencies. In light of the essential need to expand the scope of the workforce, WHO will develop systems for mentorship and training to give people who lack elements of a complete response-ready profile the opportunity to fill in gaps, for instance by pairing epidemiologists with broad response experience with those who are newer and, between emergencies, providing development opportunities for young professionals. One existing example of the development of workforce members through mentorship and training is found in WHO's polio programme, where experts come to WHO for periods of 3–6 months for training and selected job placements at all levels of the Organization. They then return to their home institution and form a cadre of responders known to WHO and familiar with organizational procedures, who are available for emergency deployments. This complements and supports the strategy of increasing the number of core WHO positions, especially in ensuring adequate numbers of experts for large and protracted events.

29. In addition to verifying and building individual experts' readiness, WHO is mindful of the need for standardized protocols and information management for the global health emergency workforce as a whole. WHO will work with partners to promote and adapt existing quality assurance standards, understanding that while possibly optimal, global standards can be difficult to adopt. At the same time, WHO will work with partners to maximize the interoperability of elements of the workforce by, for example, agreeing on common terminology and developing generic functional job descriptions.

Training

30. Three multi hazard pre-deployment training systems are currently in place within WHO. The Global Outbreak Alert and Response Network regional and global training activities are supported by a global faculty that draws on technical expertise, and existing training institutions and networks, and that uses practical application field training and simulation exercises to create rosters of multidisciplinary outbreak response teams pulled from the Network's institutions. WHO's surge capacity training, which replaced the public health pre-deployment training programme, is a classroom-based programme that finishes with a multiday field simulation exercise for WHO staff and Health Cluster and standby partner personnel. WHO's Emergency Communications Network pre-deployment training is an intensive nine-day, operation course with a three-day field simulation for WHO experts, consultants and partner organizations. The focus is on pre-training and selecting a roster of emergency communications, risk communications, social mobilization and/or community engagement personnel for emergency response. The programme includes field support and post-mission debriefing to capture experience and lessons learnt.

31. In order to support the development of the global health emergency workforce, it is envisaged that a single emergency response training system will be set up for WHO-driven deployments.¹⁷⁸ Training packages that include simulations, that are adaptable to all hazards and suitable for rapid staff turnover and that can be easily replicated and adapted, will be standardized across partners. In order to expand the reach of these training programmes, WHO will explore options for online training modules and other non-traditional training methodologies, where safe and appropriate.

Deployment

Planning for deployment

32. In line with recently initiated reforms of WHO's emergency capacities, dedicated systems – both administrative and technological – are being developed to support the deployment of dedicated emergency response staff members, surge teams and experts from partners that effect deployment through WHO mechanisms. These systems include databases that facilitate: the matching of needs to rosters; anticipatory strategic and operational planning; and template human resource plans that can be quickly tailored to a given response context.

33. If deployment is to be successful, it is essential to have adequate financing in place. Ensuring the deployment capacity of WHO surge teams requires available, adequate funding for the deployment of responders and to compensate departments, regional and country offices that lend their staff members to the response. There is a need for pre-arranged agreements with supervisors or standing policies that prioritize emergency deployment, taking into consideration staff members who are working on projects with earmarked funding and strict deadlines.

Initiating deployment

34. Following the declaration of an emergency, rapid needs and risk assessments are conducted using standard methodologies and protocols. Based on those outcomes, robust early planning can be undertaken to ensure that the response is commensurate with need, both in size and capacities.

¹⁷⁸ Foreign medical teams are pre-trained and pre-qualified for clinical care. Hazard-specific training is all that they would require.

In any case when national capacity has been overwhelmed and a Member State requests support, the Director-General will deploy WHO's standing emergency response capacity and, where necessary, its surge capacity. When it is necessary to call on the Organization's network and partnership mechanisms, the Director-General or his or her delegate will consult with the steering committee with a view to rapid, appropriate and scalable deployment.

35. The assessment processes are constantly reapplied in any specific emergency, including evaluations of national capacity, in view of the fact that the status of emergencies and the circumstances surrounding them can change rapidly. The results of these assessments will be used to make decisions about changes to the required workforce (for example, increasing or decreasing numbers, changing expertise profile or relocating).

Deploying

36. Deployments include administrative procedures for emergency responders such as those for medical clearance, travel, visas, vaccination, insurance, field-level safety and security, accommodation, in-country transportation, health care needs, evacuation and administrative support. WHO is designing a deployment system that will holistically manage medical clearance, travel arrangements, visas, vaccination and insurance for people that the Organization deploys.

37. WHO's partnership with the WFP is designed in part to provide standard, safe accommodation and workspaces in those subnational locations where this is not available, as well as transportation to and from accommodation and field sites. WHO's security services are responsible for ensuring safety and security, both at country-level and from regional offices and headquarters, as well as through the overarching United Nations field security systems and programmes.

38. WHO works with partners and Member State governments to ensure that the health and well-being of responders, including medical care and mental health support, are adequately catered for during deployment.

Medical evacuation

39. WHO is committed to providing medical evacuation to its international responders, as necessary and appropriate, regardless of hazard, and has traditionally provided evacuation to anyone it has deployed internationally who is in need of medical treatment that goes beyond what is available in the country of deployment. In most circumstances, this requires close communication among WHO offices and with partners which deploy personnel, rapid logistic management, appropriately designed and triggered financial and insurance mechanisms and strong relationships with governments evacuating and receiving patients.

40. Some hazards, such as particularly dangerous pathogens, create exceptionally difficult circumstances for medical evacuation. In these cases, the Organization is not able to make all arrangements autonomously and must look to its partners for assistance.¹⁷⁹ During the response to the Ebola outbreak in West Africa, medical evacuation presented particular challenges in that there are only a limited number of aircraft designed to transport infected patients, and a limited number of hospitals equipped to treat them. In order to ensure that international responders could benefit from evacuation in the case of infection or suspected infection, WHO worked closely with Member States to coordinate evacuation.¹⁸⁰ WHO and the European Union's Directorate-General for

¹⁷⁹ The trilateral WHO-ECHO-SANCO partnership for medical evacuation during the West Africa Ebola outbreak provides a good model in this regard.

¹⁸⁰ The policy statement developed for the Ebola response read as follows: "The World Health Organization (WHO) has developed and operationalized comprehensive standard operating procedures for medical care of WHO staff members, consultants and other persons deployed to WHO to perform WHO work ("WHO deployees") who are suspected or confirmed to have been infected with the Ebola virus. If a WHO deployee is

Humanitarian Aid and Civil Protection (ECHO) and Directorate-General for Health and Food Safety (SANCO) developed a trilateral evacuation system, coordinated by WHO, to provide the following: patient evaluation and treatment in-country, flight coordination, systematic identification of appropriate hospitals in Europe and dedicated communication lines for requesting governmental agreement to receive patients. In addition, financing mechanisms were put in place to guarantee full payment of transport and treatment costs exceeding the amount covered by a given responder's insurance.

41. WHO will use the experience gained across its emergency responses during the Ebola outbreak in West Africa to refine and streamline its medical evacuation systems and will expand and build partnerships to best ensure the safety, health and well-being of its international responders.

Decommissioning

42. The end of a deployment and the period immediately following it are as important as the deployment itself. Current mechanisms for repatriating each deployee will be strengthened, taking into consideration any circumstances unique to their home country (for example, entry screening or isolation requirements). Additionally, participating in emergency response activities often puts people in circumstances that have a physical and mental impact on them. The system must therefore provide adequate follow-up and support in order to facilitate a smooth health transition upon a deployee's return.

43. Capturing the lessons learnt by experts while on mission is an essential component of monitoring and evaluating response performance. Although WHO has ready access to its own staff and their reports, it is more difficult to ensure that people deployed through one of the partnership mechanisms are fully debriefed and provided with opportunities to provide feedback to WHO on their experiences. WHO will use post-mission reports and deployee evaluations for assessing deployee performance and for improving overall systems.

GOVERNANCE

44. Effective emergency response requires the appropriate structure, culture and leadership across all levels of the Organization that deliver emergency response; it also requires protocols, processes and systems in place to ensure responsible management of deployments. As part of the reform of WHO's emergency capacities, the Organization is establishing an emergency response programme, which will include a unit dedicated to the direction and coordination of the global health emergency workforce. The unit will be responsible for deploying internal WHO standing and surge capacities. This role will include ensuring physical and mental health and safety and, when necessary, evacuation. The unit will also coordinate with and support networks and partnerships, and engage with the United Nations system and the private sector, as appropriate.

45. WHO will have similar units dedicated to the global health emergency workforce at all levels of the Organization, supported by appropriately tailored information management systems.

46. A steering group will be established representing relevant networks, partnerships, United Nations entities and other organizations involved in relevant emergency response deployments. The steering group's role will be to ensure harmonization across the various stages of workforce

suspected or confirmed to have been infected with the Ebola virus, WHO will arrange for his/her transportation to and admission at an appropriate facility designated by WHO within the relevant country of operation. Subject to the outcome of a risk assessment, consultation with the responsible physician and confirmation of available capacity, WHO will arrange for medical evacuation to and hospitalization at an appropriate treatment facility outside the affected country and will pay for the costs that are not covered by the insurance of the concerned WHO deployee."

operationalization, namely: pre-deployment and readiness, deployment and decommissioning. It will conduct an annual review of its emergency response activities.

47. The Director-General will report, on a regular basis, to the WHO governing bodies on progress made in implementing this plan.

FINANCING

48. Adequate funding is essential for enabling the global health emergency workforce to be deployed with full effect. Given the diverse sources of the human resources that compose the workforce, funding also will come from a combination of sources.

49. National responders are part of a national health system and are financed through national mechanisms, drawn on national and, where appropriate, international resources.

50. As part of WHO's emergency response programme, the global health emergency workforce units will be funded through the existing programme budget, as will standing and surge staff members in times of non-deployment. When a rapid response is required, the WHO contingency fund will provide the necessary resources for the internal WHO staff surge, until appeal funding (or other funding) is received, in accordance with the mechanism proposed.¹⁸¹

51. The salaries of experts who deploy through the Global Outbreak Alert and Response Network mechanisms are supported by their parent organizations, while WHO provides payments for travel and per diem and, where appropriate, hazard pay. The standby partners are funded by their donor organizations. In some cases, Global Health Cluster partners are self-funding and in others they are not. As with the internal surge, at the opening of a response the portion of costs for which WHO is responsible will be drawn from the contingency fund, until contributions tied to the response become available.

52. Partners who deploy as foreign medical teams and who collaborate with WHO through the Global Health Cluster are fully autonomous, and do not require funding from WHO.

TIMELINE

53. The key milestones for this plan are: (a) establishment of the WHO global emergency health workforce unit; (b) development of a detailed plan for operationalizing the global health emergency workforce, in light of ongoing reforms to the Organization's emergency capacities; (c) discussions with relevant partners regarding the structure and function of a steering committee to coordinate and rationalize the networks and partnerships; (d) establishment of the steering committee; (e) expansion of internal standing capacity and creation of constant, trained, skilled surge capacity across WHO; (f) development of comprehensive, coherent rosters of responders for WHO and, following discussions, for networks and partners; and (g) development of standardized training packages to help regulate and ensure the quality of responders.

54. A review of WHO's standing and surge capacity will begin in June, and WHO's global health emergency workforce unit will be established by September 2015. Its first task will be to develop the detailed plan for operationalizing the global health emergency workforce. The first discussions with relevant stakeholders will start in June 2015,¹⁸² with a view to establishing the steering committee by the end of the year. Rosters for networks and partnerships will be updated by the end of September

¹⁸¹ See document A68/26.

¹⁸² WHO will take advantage of forthcoming meetings of partnerships and networks, including the Global Health Cluster Partner Meeting, 17–19 June 2015, and the meeting of the GOARN Steering Committee, 24 and 25 June 2015.

2015, with adjustments and reviews taking place in the last quarter of 2015, as necessary. By the end of 2015, WHO will have developed post descriptions and begin the process of advertising for standing emergency capacity positions and, with partners, will have developed training packages and have a system in place.

55. It is anticipated that the Director-General will report on progress in implementing the plan for a global health emergency workforce to the Executive Board at its 138th session in January 2016.

ACTION BY THE HEALTH ASSEMBLY

56. The Health Assembly is invited to adopt the draft decision in document A68/51, endorsing the Director-General's plan for a global health emergency workforce.

16.2 Malaria: draft global technical strategy: post 2015

Document A68/28 (Report by the Secretariat):

Malaria: draft global technical strategy: post 2015

1. At its 136th session, the Executive Board considered an earlier version of this report¹⁸³ and adopted resolution EB136.R1.¹⁸⁴
2. The report has been expanded to include the full text of the draft technical strategy for malaria 2016–2030 (see Annex). A few minor changes have been made to reflect the latest available information on the malaria burden (paragraphs 6 and 7 below, and paragraphs 2 and 3 in the Annex). In addition, at the request of Member States, new text has been added to the draft strategy (paragraph 7 on climate change and paragraph 44 on integrated vector management). Finally, a few minor edits have been incorporated into the draft strategy in order to clarify the meaning (Annex, paragraphs 16, 50, 59, 63 and 90).
3. In resolution WHA58.2 on malaria control, the Health Assembly urged Member States to take concrete steps for a global expansion of malaria efforts. It also set targets including that of reducing the disease burden by at least 50% by 2010 and by 75% by 2015. Global malaria efforts and associated challenges were also the focus of resolutions WHA60.18 and WHA64.17. At the Sixty-sixth World Health Assembly, Member States expressed support for the proposal for the Secretariat to draft a global technical strategy for malaria for the post-2015 period.¹⁸⁵
4. In June 2013, the Secretariat began a global consultative process involving Member States and stakeholders, including organizations in the United Nations system, scientific and research groups, nongovernmental organizations and implementing partners. Between March and June 2014, seven regional consultations were held on a draft version of the strategy, at which more than 70 Member States were represented and more than 400 technical experts provided input. To supplement these consultations, the Secretariat hosted an online public consultation between 11 July and 15 August 2014, during which further comments were received.
5. The strategy development process was led by the Secretariat and supported by both the Malaria Policy Advisory Committee and a dedicated Steering Committee, consisting of leading malaria experts, scientists and representatives of Member States. At its meeting in September 2014, the Malaria Policy Advisory Committee reviewed and formally endorsed the revised draft document. The main strategic directions were then submitted to the Regional Committee for Europe at its sixty-fourth session (Copenhagen, 15–18 September 2014) and considered by the Programme Subcommittee of the Regional Committee for Africa (Brazzaville, 1 and 2 September 2014).

CURRENT SITUATION

6. Despite being preventable and treatable, malaria continues to have a devastating impact on people's health and livelihoods around the world. Some 3200 million people are at risk of malaria infection in 97 countries, territories and areas, and the disease killed an estimated 584 000 people in

¹⁸³ See document EB136/23 and the summary records of the Executive Board at its 136th session, second meeting.

¹⁸⁴ See document EB136/2015/REC/1 for the resolution, and for the financial and administrative implications for the Secretariat of the adoption of the resolution.

¹⁸⁵ See summary records of the Sixty-sixth World Health Assembly, eleventh meeting of Committee A, section 1 (document WHA66/2013/REC/3) (http://apps.who.int/gb/ebwha/pdf_files/WHA66-REC3/EN/A66_REC3-en-full.pdf).

2013 (uncertainty range: 367 000–755 000), most of whom were children under 5 years of age in Africa. Around the world, millions of people remain without access to malaria prevention and treatment, and most cases and deaths go unregistered and unreported. Given environmental and demographic trends, including the projected growth in the size of the world population by 2030, even more people will be living in areas where malaria is a risk, putting a further strain on health systems.

7. A critical juncture has been reached in the fight against malaria. There is both an opportunity and an urgent need to accelerate progress towards elimination. Between 2000 and 2013, a major expansion of WHO-recommended interventions has contributed to a 47% reduction in the global malaria mortality rate, and an estimated 4.3 million deaths have been averted. At present, 55 countries are on track to achieve the Health Assembly's target of reducing their malaria burden by 75% by 2015. The current package of core interventions – namely, vector control, chemoprevention, diagnostic testing and treatment – has proved to be highly cost-effective and needs to be further expanded in order to save more lives.

8. Many challenges threaten continued progress. Emerging parasite resistance to antimalarial medicines and mosquito resistance to insecticides could, if left unaddressed, render some of the current tools ineffective and trigger a rise in global malaria mortality. The global health community needs to pay close attention also to systemic and technical obstacles, such as the inherent weakness of health systems, including poor disease surveillance and limited pharmaceutical regulation; a lack of adequate technical and human resource capacities; the high prevalence of asymptomatic infections, which contribute to disease transmission; the complex biology of the malaria parasites; and the diversity of vectors and their behaviour.

DRAFT GLOBAL TECHNICAL STRATEGY FOR MALARIA 2016–2030 IN BRIEF¹⁸⁶

9. The draft malaria strategy 2016–2030 provides a comprehensive framework for countries to develop tailored programmes for accelerating towards malaria elimination. It emphasizes that progression towards malaria-free status does not consist of a set of independent stages but is a continuous process requiring a structuring of programmes in line with subnational stratification by malaria risk. It underlines the need to ensure universal coverage of core malaria interventions, and proposes milestones and goals for 2020, 2025 and 2030. It also identifies areas where innovative solutions will be essential to achieve the goals, and outlines the global financial implications of implementing the strategy. The proposed strategy is built on three pillars with two supporting elements, which are summarized below.

10. **Pillar 1. Ensure universal access to malaria prevention, diagnosis and treatment.** All core malaria interventions – namely vector control, chemoprevention, diagnostic testing and treatment – should be scaled up to cover all populations at risk. Universal coverage is a key principle of the draft strategy, applying to all core interventions. The draft strategy recommends stratification according to malaria risk, which would enable the tailoring of interventions to local contexts and ensure efficient use of resources. In order to ensure long-term effectiveness of the core interventions, countries are urged: to intensify efforts to prevent and manage biological challenges, such as drug and insecticide resistance and diverse vector behaviour; to remove all ineffective antimalarial medicines and substandard vector-control products from markets; to expand community-based diagnostic testing and treatment; and to enforce pre- and post-shipment quality testing of vector

¹⁸⁶ See Annex.

control products. The draft strategy also calls for elimination of falciparum malaria from the Greater Mekong subregion, where multidrug resistance, including artemisinin resistance, has emerged.¹⁸⁷

11. Pillar 2. Accelerate efforts towards elimination and attainment of malaria-free status. In addition to expanding interventions to all populations at risk, all countries should intensify efforts to eliminate the disease, especially in areas with low transmission. The draft strategy lists priorities for elimination, highlighting among others the importance of renewing political commitment and strengthening cross-border collaboration. At the same time, countries should seek to lower malaria transmission by reducing the pool of infections through implementation of strategies such as transmission-blocking chemotherapy for falciparum malaria and radical cure for vivax malaria. Over the next decade, new tools and approaches are expected to become available that will help to target the infectious parasite reservoir in humans.

12. Pillar 3. Transform malaria surveillance into a core intervention. Strengthening malaria surveillance is fundamental to programme planning and implementation and is a crucial factor for accelerating progress. All countries where malaria is endemic, and those receptive to malaria, should have an effective malaria surveillance system in order to direct resources to the most affected populations, identify gaps in programme coverage, detect outbreaks, and assess the impact of interventions to guide changes in programme planning and implementation. Countries should substantially strengthen malaria surveillance so that it functions as a core intervention.

13. Supporting element 1. Harnessing innovation and expanding research. In support of the three pillars, affected countries and the global malaria community should harness innovation and expand basic, clinical and implementation research. Successful innovation in product development and service delivery will make a major contribution to accelerating progress. Basic research is essential for a better understanding of the parasite and the vectors, and for the development of more effective diagnostics and antimalarial medicines, improved and innovative vector control methods, and other tools such as vaccines. Implementation research will be fundamental to optimizing impact and cost-effectiveness, and to facilitating rapid uptake of new tools. The draft strategy describes research and innovation needs for all three pillars.

14. Supporting element 2. Strengthening the enabling environment. Strong political commitment, sustainable financing and increased multisectoral collaboration hold the key to further progress. An overall strengthening of health systems and improvement in the enabling environment will help to optimize national malaria responses, and enable the adoption and introduction of new tools and strategies in a timely manner. In turn, the expansion of malaria interventions can be used as an entry point for strengthening health systems, including maternal and child health and laboratory services, and to build stronger health information and surveillance systems. Furthermore, the empowerment of communities, a skilled health workforce and strong regulatory frameworks are also cornerstones of success.

ROLE OF THE SECRETARIAT

15. In line with its core roles, the Secretariat will continue to set, communicate and disseminate normative guidance, policy advice and implementation guidance to support country action. It will provide support to Member States in the implementation of the global technical strategy 2016–2030 and provide guidance in reviewing and updating national malaria strategies. It will work with Member States to develop regional implementation plans, where appropriate.

¹⁸⁷ The draft strategy makes specific reference to this subregion as multidrug resistance (defined here as resistance to both artemisinin and several partner drug components of artemisinin-based combination therapies) has emerged along the Cambodia–Thailand border.

16. The Secretariat will ensure that its policy-setting process responds to the rapidly changing malaria context and that its global technical guidance is regularly updated by incorporating innovative tools and strategies that are proven to be effective. In addition, it will strengthen its own capacities at the global, regional and country levels so that it is better positioned to lead a coordinated global effort to reduce the disease burden by at least 90% by 2030, and to support the implementation of all recommendations in the global technical strategy.

17. In order to enable timely procurement of commodities, the Secretariat will continue to assess and issue recommendations for products and compounds for malaria vector control, and assess and prequalify diagnostics and antimalarial medicines. The Secretariat will also continue to support efforts to monitor the efficacy of medicines and vector control interventions, and maintain global databases for efficacy of medicines and insecticide resistance.

18. The Secretariat will promote the generation of research and knowledge that is required to accelerate progress towards a world free of malaria. It will monitor implementation of the strategy and regularly evaluate progress towards the milestones set for 2020 and 2025 and the goals for 2030. It is proposed that the Secretariat report to the Health Assembly every two years for a time-limited period on progress in implementing this strategy after its adoption. The strategy will be updated at regular intervals to ensure linkage with the latest global policy recommendations.

ACTION BY THE HEALTH ASSEMBLY

19. The Health Assembly is invited to adopt the draft resolution recommended by the Executive Board in resolution EB136.R1.

ANNEX

DRAFT GLOBAL TECHNICAL STRATEGY FOR MALARIA 2016–2030

DRAFT GLOBAL TECHNICAL STRATEGY AT A GLANCE

| Vision – A world free of malaria | | | |
|---|----------------------------|----------------------------|----------------------------|
| Goals | Milestones | | Targets |
| | 2020 | 2025 | 2030 |
| 1. Reduce malaria mortality rates globally compared with 2015 | ≥40% | ≥75% | ≥90% |
| 2. Reduce malaria case incidence globally compared with 2015 | ≥40% | ≥75% | ≥90% |
| 3. Eliminate malaria from countries in which malaria was transmitted in 2015 | At least 10 countries | At least 20 countries | At least 35 countries |
| 4. Prevent re-establishment of malaria in all countries that are malaria-free | Re-establishment prevented | Re-establishment prevented | Re-establishment prevented |
| PRINCIPLES <ul style="list-style-type: none"> • All countries can accelerate efforts towards elimination through combinations of interventions tailored to local contexts. • Country ownership and leadership, with involvement and participation of communities, are essential to accelerating progress through a multisectoral approach. | | | |

| |
|---|
| <ul style="list-style-type: none"> Improved surveillance, monitoring and evaluation, as well as stratification by malaria disease burden, are required to optimize the implementation of malaria interventions. Equity in access to services especially for the most vulnerable and hard-to-reach populations is essential. Innovation in tools and implementation approaches will enable countries to maximize their progression along the path to elimination. |
| <p>STRATEGIC FRAMEWORK – comprising three major pillars, with two supporting elements: (1) innovation and research and (2) a strong enabling environment</p> <p>Maximize impact of today's life-saving tools</p> <ul style="list-style-type: none"> Pillar 1. Ensure universal access to malaria prevention, diagnosis and treatment Pillar 2. Accelerate efforts towards elimination and attainment of malaria-free status Pillar 3. Transform malaria surveillance into a core intervention |
| <p>Supporting element 1. Harnessing innovation and expanding research</p> <ul style="list-style-type: none"> Basic research to foster innovation and the development of new and improved tools Implementation research to optimize impact and cost-effectiveness of existing tools and strategies Action to facilitate rapid uptake of new tools, interventions and strategies |
| <p>Supporting element 2. Strengthening the enabling environment</p> <ul style="list-style-type: none"> Strong political and financial commitments Multisectoral approaches, and cross-border and regional collaborations Stewardship of entire health system including the private sector, with strong regulatory support Capacity development for both effective programme management and research |

BACKGROUND

1. Malaria is caused by parasites of the *Plasmodium* family and transmitted by female *Anopheles* mosquitoes. There are four different human malaria species (*P. falciparum*, *P. vivax*, *P. malariae* and *P. ovale*), of which *P. falciparum* and *P. vivax* are the most prevalent and *P. falciparum* the most dangerous. *P. knowlesi* is a zoonotic plasmodium that is also known to infect humans.

2. Despite being preventable and treatable, malaria continues to have a devastating impact on people's health and livelihoods around the world. According to the latest available data, about 3200 million people were at risk of the disease in 97 countries, territories and areas in 2013, and an estimated 198 million cases occurred (range: 124 million–283 million). In the same year, the disease killed about 584 000 people (range: 367 000–755 000), mostly children aged under 5 years in sub-Saharan Africa.¹⁸⁸ In most countries where malaria is endemic, the disease disproportionately affects poor and disadvantaged people, who have limited access to health facilities and can barely afford the recommended treatment.

3. Between 2000 and 2013, a substantial expansion of malaria interventions contributed to a 47% decline in malaria mortality rates globally, saving an estimated 4.3 million lives. In the WHO African Region, the malaria mortality rate in children under 5 years of age was reduced by 58%. During the same period, the global incidence of malaria was reduced by 30%.¹⁸⁹ Target 6.C of Millennium Development Goal 6, namely "Have halted by 2015 and begun to reverse the incidence of malaria and other major diseases", has already been reached, and 55 of the 106 countries that had malaria

¹⁸⁸ *World malaria report 2014*. Geneva: World Health Organization; 2014 (http://www.who.int/malaria/publications/world_malaria_report_2014/en/, accessed 10 March 2015).

¹⁸⁹ *World malaria report 2014*. Geneva: World Health Organization; 2014 (http://www.who.int/malaria/publications/world_malaria_report_2014/en/, accessed 10 March 2015).

transmission in 2000 are on track to achieve the goal of reducing malaria incidence by 75% by 2015, as set by the Health Assembly in 2005 in resolution WHA58.2 on malaria control.¹⁹⁰

4. Despite this progress, the disease remains endemic in all six WHO regions and the burden is heaviest in the African Region, where an estimated 90% of all malaria deaths occur. Two countries – the Democratic Republic of the Congo and Nigeria – account for about 40% of estimated mortality due to malaria worldwide. Around the world, millions of people remain without access to malaria prevention and treatment, and most cases and deaths go unregistered and unreported. Given the projected growth in the size of the world's population by 2030, more people will be living in countries where malaria is a risk, putting further strains on health systems and national malaria programme budgets.

NEED FOR A POST-2015 TECHNICAL STRATEGY

5. In the early part of the 21st century, malaria received worldwide recognition as a priority global health issue. This renewed attention ended an era of neglect between the 1960s and the late 1990s, and reversed dramatic rises in malaria morbidity and mortality rates. In order to ensure that malaria trends remain on a downward trajectory, unremitting political commitment, substantial and predictable financing, and increased regional collaboration are necessary. A powerful and coordinated global response together with continued investment in research and development will rid entire continents of the disease and eventually eradicate malaria from the world.

6. Although the implementation of core interventions expanded greatly between 2000 and 2014, the gains achieved are fragile and unevenly distributed. The human toll of malaria, and the global risk it still poses, remains unacceptably high. In many affected countries, social unrest, conflict and humanitarian disasters are major obstacles to progress. The recent outbreak of Ebola virus disease in West Africa, which affected countries that are highly endemic for malaria, has had a devastating impact on basic health service delivery, including the ability to control malaria. Recent outbreaks of malaria in countries that had been malaria-free, and resurgences in countries that have made important progress in reducing malaria morbidity and mortality rates in the past decade, highlight the continual threat of re-establishment and resurgence and the need for vigilance to ensure that these areas of transmission are promptly identified and rapidly contained.

7. Given the association between malaria transmission and climate, long-term malaria efforts will be highly sensitive to global climatic changes in the world's climate. It is expected that – without mitigation – climate change will result in an increase in the malaria burden in several regions of the world that are endemic for the disease, particularly in densely-populated tropical highlands. Increasing economic development, urbanization and deforestation are also expected to contribute to changes in transmission dynamics, while projected population growth in areas where malaria poses a high risk will increase the need to optimize coverage of interventions.

8. Malaria interventions are highly cost-effective and demonstrate one of the highest returns on investment in public health. In countries where the disease is endemic, efforts to reduce and eliminate malaria are increasingly viewed as high-impact strategic investments that generate significant returns for public health, help to alleviate poverty, improve equity and contribute to overall development.

9. The world has reached a critical juncture in the fight against malaria. There is both an opportunity and an urgent need to accelerate progress by reducing morbidity and mortality in all countries, by

¹⁹⁰ Resolution WHA58.2 on malaria control. Fifty-eighth World Health Assembly, Geneva: World Health Organization; 2005 (see document WHA58/2005/REC/1, http://apps.who.int/gb/ebwha/pdf_files/WHA58-REC1/english/A58_2005_REC1-en.pdf, accessed 10 March 2015).

increasing the number of malaria-free countries, territories and areas, and by identifying approaches that aim to reduce transmission. Progress can be hastened through a major expansion of existing interventions, by making the response to malaria a higher technical, financial and political priority, and by ensuring that the development and use of new tools and solutions are maximized.

10. Efforts to prevent and control malaria contribute to and benefit from sustainable development. The objectives of reducing the disease burden and eliminating malaria are closely linked to several of the sustainable development goals being considered for the post-2015 period. Well-established linkages and factors include the contribution of malaria to the poverty cycle, the concentration of disease in vulnerable populations and those with poor access to health services, and its detrimental impact on education through missed school days and the cognitive effects of chronic anaemia.

11. The Malaria Policy Advisory Committee, established in 2011 to provide independent strategic advice to WHO on developing policy recommendations on malaria, recommended to the Director-General the development of a draft post-2015 global technical strategy on malaria. Member States at the Sixty-sixth World Health Assembly in 2013 expressed support for its preparation.¹⁹¹ The strategy, provided that it is adopted by the Health Assembly, will succeed the previous WHO global malaria strategy, which was endorsed by the Ministerial Conference on Malaria (Amsterdam, The Netherlands, 1992) in the World Declaration on Malaria. Adoption of the draft strategy by the Health Assembly will ensure that WHO is well equipped to support the completion of the unfinished health-related Millennium Development Goals agenda, which is one of the Organization's six leadership priorities for the period 2014–2019.¹⁹²

12. **Opportunities.** Since 2000, eight countries have eliminated malaria and many others have reduced transmission to low levels. The knowledge gained from these efforts will be informative in designing programmes in the future. The next 15 years are likely to be strongly shaped by: technological advances; innovations in medicines, vaccines and vector control; and improved strategies for delivering commodities. Some of the new tools are expected to have significant additional impact, and, once validated, will need to be swiftly incorporated into national malaria responses.

13. **Challenges.** The fight against malaria is being prolonged, and in some places slowed down, by several interconnected challenges. The greatest of these is the lack of robust, predictable and sustained international and domestic financing. This is compounded by the difficulty in maintaining political commitment and ensuring regional collaboration at the highest levels. The second important challenge is biological: the emergence of parasite resistance to antimalarial medicines and of mosquito resistance to insecticides. This double threat has the potential to weaken seriously the effectiveness of malaria responses and to erode the gains recently achieved.

14. Other challenges that need to be met in order to accelerate progress are systemic and technical. They include: the inadequate performance of health systems, for instance weak management of supply chains and the unregulated private health sector in many countries, which allows the use of ineffective antimalarial medicines or vector control products; weak systems for surveillance, monitoring and evaluation, which compromise the ability to track gaps in programme coverage and changes in disease burden; the lack of adequate technical and human resource capacities to sustain and scale up efforts; the disproportionate risk of malaria among hard-to-reach populations,

¹⁹¹ Summary records of the Sixty-sixth World Health Assembly, eleventh meeting of Committee A, section 1. Geneva: World Health Organization; 2013 (document WHA66/2013/REC/3) (http://apps.who.int/gb/ebwha/pdf_files/WHA66-REC3/EN/A66_REC3-en-A11.pdf, accessed 10 March 2015).

¹⁹² WHO, Twelfth General Programme of Work 2014–2019, approved by the Sixty-sixth World Health Assembly in resolution WHA66.1. Geneva: World Health Organization; 2013 (http://apps.who.int/iris/bitstream/10665/112792/1/GPW_2014-2019_eng.pdf, accessed 10 March 2015).

including high-risk occupational groups, migrants, people in humanitarian crises, and rural communities with poor access to health services; and the lack of adequate tools to diagnose and treat effectively infections due to *P. vivax* and other non-falciparum malaria parasites.

15. Another important challenge is that many people who are infected with malaria parasites remain asymptomatic or undiagnosed and are therefore invisible to the health system. Further, in some settings the density of parasitaemia is so low in a substantial proportion of individuals that it cannot be detected with current routine diagnostic tools. These people unwittingly contribute to the cycle of malaria transmission. If future disease control and elimination strategies are to succeed, they will need to take into account this large “infectious parasite reservoir”. The expected development and availability over the next decade of new tools and approaches should help the detection and targeting of this reservoir and the clearing of plasmodia from asymptomatic carriers.

16. The emergence of drug and insecticide resistance is compounded by additional biological challenges, which need to be tackled by national malaria programmes. In some parts of the world, existing vector control tools cannot effectively protect against the disease given the diversity of malaria vectors and differences in their behaviours. In countries where both *P. falciparum* and *P. vivax* are present, the burden of disease due to *P. vivax* is more difficult to reduce because the parasite forms in the liver a dormant hypnozoite stage which is currently undetectable and leads to relapses, thereby contributing to disease transmission. In addition, human infection with zoonotic plasmodia such as *P. knowlesi* presents new challenges to malaria control and elimination.

17. This draft technical strategy provides a framework for the development of tailored programmes to accelerate progress towards malaria elimination. This framework should be the foundation of strategies for national and subnational malaria programmes. It defines a clear and ambitious path for countries in which malaria is endemic and their global partners in malaria control and elimination for the next 15 years. It emphasizes the need for universal coverage of core malaria interventions for all populations at risk, and highlights the importance of using high-quality surveillance data for decision-making in order to drive tailored responses consistent with national or subnational goals. The draft strategy identifies areas where innovative solutions will be essential for attaining its goals. It summarizes the estimated costs of implementing the strategy and provides an estimate of the research and development costs for innovative new tools.

STRATEGY DEVELOPMENT PROCESS

18. Following the support expressed by Member States at the Sixty-sixth World Health Assembly for the development of a draft global malaria strategy for the post-2015 period, the Secretariat held seven regional consultations.¹⁹³ Input was gathered from more than 400 experts representing national malaria programmes, health ministries, research organizations and implementing partners. The process, led by the Secretariat, was supported by both the Malaria Policy Advisory Committee and a dedicated Steering Committee for the Global Technical Strategy, consisting of leading malaria experts, scientists and representatives of countries in which malaria is endemic, who provided additional extensive inputs to the initial draft document. Following these consultations, a revised draft was prepared by the Secretariat for an online consultation which was open for comment between 11 July and 15 August 2014.

VISION, GOALS AND PRINCIPLES

19. The vision of WHO and the global malaria community is a world free of malaria. As part of this vision, the draft strategy sets ambitious yet feasible global targets for 2030 with milestones for

¹⁹³ WHO Global Malaria Programme, Global Technical Strategy meeting reports. Geneva: World Health Organization; 2014 (http://www.who.int/malaria/areas/global_technical_strategy/meetings/en/, accessed 10 March 2015).

measuring progress for 2020 and 2025. Countries will set their own national or subnational targets, which may differ from the global targets. The proposed goals, milestones and targets are set out in Table 1.

Table 1. Proposed goals, milestones and targets for the draft global technical strategy for malaria 2016–2030

| Vision – A world free of malaria | | | |
|---|----------------------------|----------------------------|----------------------------|
| Goals | Milestones | | Targets |
| | 2020 | 2025 | 2030 |
| 1. Reduce malaria mortality rates globally compared with 2015 | ≥40% | ≥75% | ≥90% |
| 2. Reduce malaria case incidence globally compared with 2015 | ≥40% | ≥75% | ≥90% |
| 3. Eliminate malaria from countries in which malaria was transmitted in 2015 | At least 10 countries | At least 20 countries | At least 35 countries |
| 4. Prevent re-establishment of malaria in all countries that are malaria-free | Re-establishment prevented | Re-establishment prevented | Re-establishment prevented |

20. These goals apply to all types of human malaria and have been developed after reviewing (1) the targets of national malaria programmes as stated in their national strategic plans, (2) the magnitude of decreases in the numbers of cases and deaths due to malaria between 2000 and 2012, as reported to WHO, and (3) the results of mathematical modelling of transmission of falciparum malaria in order to estimate the potential impact of applying different combinations of recommended interventions between 2016 and 2030.

21. Modelling suggests that, if coverage of malaria interventions remains at current levels, incidence could increase moderately as a result of a partial loss of malaria immunity among populations that have experienced marked reductions in transmission intensity. However, this rise and its consequences could be averted through a concerted effort to optimize the use of currently available tools, particularly vector control, at levels above 80% coverage of at-risk populations, which could significantly reduce incidence of and deaths due to malaria. Given that reaching this level of coverage will be operationally difficult, further innovations in tools and approaches are needed for elimination of transmission in areas where transmission rates are high; they are also needed in areas and for population groups that are presently hard to reach with current interventions.

22. Five principles underlie the draft technical strategy for malaria. All countries can accelerate efforts towards elimination through combinations of interventions tailored to local contexts. Country ownership and leadership, with involvement and participation of communities, are essential to accelerating progress through a multisectoral approach. Improved surveillance, monitoring and evaluation, as well as stratification by malaria burden, are required to optimize the implementation of malaria interventions. Equity in access to services, especially for the most vulnerable and hard-to-reach populations, is essential. Finally, innovation in tools and implementation approaches will enable countries to maximize their progression along the path to elimination.

PATH TO MALARIA ELIMINATION

23. Progression towards malaria-free status is a continuous process, and not a set of independent stages. Countries, subnational areas and communities are situated at different points on the path towards malaria elimination, and their rate of progress will differ and depend on the level of investment, biological determinants (related to the affected populations, the parasites and the

vectors), environmental factors, the strength of health systems as well as social, demographic, political, and economic realities.

24. At all levels of endemicity, the risk of malaria varies significantly within a country or area, and the same strategy is not necessarily appropriate for all settings within a country. As intervention coverage is increased and malaria incidence is reduced, the heterogeneity in incidence and transmission rates is likely to further increase. A key approach to optimizing malaria responses within a country will be structuring programmes in response to stratification by malaria burden and based on an analysis of past malaria incidence data, risk determinants related to the human host, parasites, vectors and the environment that together with an analysis of access to services.

25. The performance of national health systems and their adaptability to new opportunities are two of the key determinants of the rate of progress along the path. As malaria programmes reduce transmission to low or very low rates, they should shift the focus from preventing, detecting and treating clinical cases to preventing, detecting and treating every malaria infection. This change requires strengthened and sustained epidemiological and entomological surveillance systems, a requirement that can be satisfied only through substantial long-term financial and political commitment as well as significant structural and organizational changes in malaria programmes.

26. The first priority for all countries where transmission rates of malaria are high or moderate is to ensure maximal reduction of morbidity and mortality through sustained provision of universal access to quality-assured and appropriate vector control measures, diagnostics and antimalarial medicines, together with the implementation of all WHO-recommended preventive therapies that are appropriate for that epidemiological setting. These activities must be backed up by efficient disease surveillance systems, robust entomological and drug efficacy surveillance, as well as strong public health communication and behavioural change programmes.

27. In countries where the potential for malaria transmission is high, optimal application of all appropriate interventions will result in marked falls in morbidity and mortality rates, but these may not be sufficient to eliminate malaria. In these settings, additional tools will be needed to accelerate progress. Many new tools are already in development and could be available within the next five to 10 years (see section on Harnessing innovation and expanding research, paragraphs 79 et seq).

28. Once programmes have reduced transmission to very low levels, they should assess the technical, operational and financial feasibility of elimination and the programmatic capacity, including the ability of surveillance systems to track and manage every case of malaria infection, needed in order to eliminate every malaria infection. In addition to domestic considerations, available resources and preparedness, the situation in neighbouring countries and the risk of imported infections should be taken into account.

29. As programmes approach elimination or work to prevent re-establishment of transmission, all cases of malaria infection need to be detected and managed by general health services, both public and private, and reported as a notifiable disease to a national malaria registry. Patients diagnosed with malaria must be treated promptly with effective antimalarials in order to avoid preventable deaths and to decrease the probability of onward transmission in the community. In addition, entomological surveillance systems should be maintained so that appropriate vector control interventions can be introduced or modified as necessary.

PROPOSED STRATEGIC FRAMEWORK

30. In order to accelerate progress towards elimination, WHO urges affected countries and the global malaria community to maximize the impact of existing life-saving tools and strategies. Until new and improved tools and approaches become available, there is an urgent need to adopt and

expand implementation of all WHO-recommended strategies so as to increase the effectiveness of responses and end preventable malaria deaths. The draft strategy is built on three pillars with two supporting elements that guide global efforts to move closer to malaria elimination. These are summarized below.

31. Pillar 1. Ensure universal access to malaria prevention, diagnosis and treatment. The WHO-recommended package of core interventions – namely quality-assured vector control, chemoprevention, diagnostic testing and treatment – can dramatically reduce morbidity and mortality. In areas of moderate-to-high transmission, ensuring universal access of populations at risk to interventions should be a principal objective of national malaria programmes. The metrics of success are the reductions in malaria case incidence and malaria mortality rates. WHO recommends implementing two sets of interventions in a complementary way: (1) prevention strategies based on vector control, and, in certain settings and in some population groups, administration of chemoprevention, and (2) universal diagnosis and prompt effective treatment of malaria in public and private health facilities and at community level. Structuring programmes in response to stratification of malaria by disease burden and including an analysis of past malaria incidence data, risk determinants related to the human host, parasites, vectors and the environment that together with an analysis of access to services will enable the tailoring of interventions to the local context and ensure efficient use of resources.

32. Pillar 2. Accelerate efforts towards elimination and attainment of malaria-free status. Countries need to intensify efforts to reduce onward transmission of new infections in defined geographical areas, particularly in settings where transmission is low. In addition to core interventions, attaining this objective will entail targeting both parasites and vectors in well-defined transmission foci, guided by active case detection and case investigations as part of a malaria surveillance and response programme. In some settings, the achievement of elimination may require the use of medicines for prophylaxis, or other possible new approaches to remove the infectious reservoir once those are recommended by WHO. The development and adoption of innovative solutions will be essential to respond to the spread of insecticide resistance and residual transmission, and to target the hypnozoite reservoirs of *P. vivax*.

33. Pillar 3. Transform malaria surveillance into a core intervention. Strengthening malaria surveillance is fundamental to programme planning and implementation and is a crucial factor for accelerating progress. All countries where malaria is endemic and those susceptible to the re-establishment of malaria should have an effective health management and information system in place for helping national malaria programmes to direct resources to the most affected populations, identify gaps in programme coverage, detect outbreaks, and assess the impact of interventions in order to guide changes in programme orientation. At very low levels of transmission, surveillance should trigger a locally-tailored response to every detected infection, the detection of gaps in programme coverage, declines in the effectiveness of tools, or the occurrence of outbreaks.

34. Supporting element 1. Harnessing innovation and expanding research. In support of these three pillars, countries where malaria is endemic and the global malaria community should harness innovation and increasingly engage in basic, clinical and implementation research. Successful innovation in product development and service delivery will make a major contribution to accelerating progress. Basic research is essential for a better understanding of the parasites and the vectors, and to develop more effective diagnostics and medicines, improved and innovative vector control methods, and other tools such as vaccines. Implementation research will be fundamental to optimizing impact and cost-effectiveness, and facilitating rapid uptake in populations at risk.

35. Supporting element 2. Strengthening the enabling environment. Strong political commitment, robust financing and increased multisectoral collaboration are key factors for further progress. To

optimize national malaria responses, an overall strengthening of health systems and improvement in the enabling environment are also crucial. Strong health systems, both public and private, are important for reducing both the disease burden and the potential for onward transmission of parasites, and enable the adoption and introduction of new tools and strategies within the shortest possible time frame. In turn, the expansion of malaria interventions can be used as an entry point for strengthening health systems, including maternal and child health programmes and laboratory services, and to build stronger systems for health information and for disease and entomological surveillance. Finally, the empowerment of communities, capacity building and supportive supervision for a strong health workforce and regulatory frameworks are important in ensuring achievement of the vision, goals and milestones in this draft strategy.

THREE PILLARS OF THE DRAFT STRATEGY

Pillar 1. Ensure universal access to malaria prevention, diagnosis and treatment

36. The WHO-recommended package of core interventions to prevent infection and reduce morbidity and mortality comprises vector control, chemoprevention, diagnostic testing and treatment. These elements are detailed in the following paragraphs.

Vector control

37. *Maximize the impact of vector control.* Vector control is an essential component of malaria control and elimination. The capacity of vectors to transmit parasites and their vulnerability to vector control measures vary by mosquito species and are influenced by local environmental factors. Vector control must be implemented on the basis of local epidemiological and entomological data. At present, the two core, broadly-applicable vector control interventions are long-lasting insecticidal nets and indoor residual spraying.¹⁹⁴

38. National malaria programmes need to ensure that all people living in areas where the risk of malaria is high are protected through the provision, use and timely replacement of long-lasting insecticidal nets or, where appropriate, the application of indoor residual spraying. A second core intervention should not be introduced as a means of compensating for deficiencies in the implementation of the first.¹⁹⁵ However, spraying may be added in certain situations in order to either prevent or mitigate resistance in areas where nets are routinely used – the decision being informed by local data. When those two interventions are deployed together, an insecticide with a different mode of action to that used on nets should be used for spraying. Supplementary methods may be appropriate in specific settings, for instance larval source management where mosquitoes' aquatic habitats are few, fixed and findable.¹⁹⁶ Effective planning, application and monitoring of larval source management require specialized capacity that is currently lacking in most malaria programmes. This capacity needs to be built.

¹⁹⁴ WHO recommendations for achieving universal coverage with long-lasting insecticidal nets in malaria control, September 2013 (revised March 2014). Geneva: World Health Organization; 2013 (http://www.who.int/malaria/publications/atoz/who_recommendations_universal_coverage_llins.pdf, accessed 10 March 2015); WHO. An operational manual for indoor residual spraying (IRS) for malaria transmission, control and elimination. Geneva: World Health Organization; 2013 (http://apps.who.int/iris/bitstream/10665/80126/1/9789241505123_eng.pdf, accessed 10 March 2015).

¹⁹⁵ WHO guidance for countries on combining indoor residual spraying and long-lasting insecticidal nets. Geneva: World Health Organization; 2014 (http://www.who.int/malaria/publications/atoz/who-guidance-combining-irs_llins-mar2014.pdf, accessed 10 March 2015).

¹⁹⁶ WHO interim position statement: the role of larviciding for malaria control in sub-Saharan Africa. Geneva: World Health Organization; 2012 (http://www.who.int/malaria/publications/atoz/interim_position_statement_larviciding_sub_saharan_africa.pdf, accessed 10 March 2015); WHO. Larval source management – a supplementary measure for malaria vector control: an operational manual. Geneva: World Health Organization; 2013 (http://apps.who.int/iris/bitstream/10665/85379/1/9789241505604_eng.pdf, accessed 10 March 2015).

39. Numerous situations exist where transmission of malaria parasites continues even when universal coverage with insecticidal nets or spraying has been achieved.¹⁹⁷ For optimal impact of these interventions, programmes should ensure that vectors are exposed and susceptible to the insecticides used. Long-lasting insecticidal nets counter late-night and indoor-biting mosquitoes, and indoor residual spraying targets indoor-resting mosquitoes. This means that mosquitoes that bite in the early evening, or which are outdoor biting or resting, can evade the most frequently used interventions, leading to residual malaria transmission. Transmission can continue when people are away from houses or otherwise not under nets at the times when and places where malaria vectors prefer to bite. To maximize the impact of current vector control tools where they are appropriate, countries should implement such tools effectively and should not compromise on quality through poor implementation or use of substandard products.

40. *Maintain adequate entomological surveillance and monitoring.* To enable an effective vector control response, entomological surveillance and monitoring of coverage and impact of vector control interventions must be included in national surveillance systems. Vector control should be guided by local epidemiological and entomological data including insecticide resistance and vector behaviour. Countries should collect data across all settings, including those areas that are malaria-free but at risk of re-establishment of malaria.

41. Entomological surveillance must include periodic assessment of vector species present, their abundance and seasonality, time and place of biting, resting and host preference (vector behaviour), insecticide susceptibility status and underlying resistance mechanisms in order to predict vulnerability to interventions. Also essential is routine monitoring of coverage and impact of interventions, the physical condition of long-lasting insecticidal nets, the actual use of nets and their perceived usefulness by end users, and the residual effect of insecticides. The data generated should be used to inform decisions on the timing of spraying activities, contribute to net-replacement strategies, and guide the development and deployment of tools including behavioural change communication activities.

42. *Manage insecticide resistance and residual transmission.* Even though core vector control interventions continue to be effective in most areas, growing physiological resistance of mosquitoes to insecticides and the combination of vector and human behaviour that sustains continued transmission are major challenges that require an urgent and coordinated response. If left unchecked, insecticide resistance could lead to substantial increases in malaria incidence and mortality, with devastating public health consequences. All countries where malaria is endemic, including those where resistance has yet to be detected, are urged to develop and implement plans for monitoring and managing insecticide resistance.¹⁹⁸ Strategic use of current tools preserves their efficacy. Methods of managing resistance include use of insecticides with different modes of action through either periodic changes (rotations) between rounds of indoor residual spraying or multiple combined interventions. Vector behaviour that compromises the effectiveness of core interventions must be tackled through the use of new tools. The cost of vector control products is a major barrier to the implementation of strategies to prevent and mitigate insecticide resistance and reduce residual transmission. Countries should better forecast vector control product requirements and

¹⁹⁷ WHO. Control of residual malaria parasite transmission: guidance note. Geneva: World Health Organization; 2014 (<http://www.who.int/malaria/publications/atoz/technical-note-control-of-residual-malaria-parasite-transmission-sep14.pdf>, accessed 10 March 2015).

¹⁹⁸ WHO Global Malaria Programme. Global plan for insecticide resistance management in malaria vectors. Geneva: World Health Organization; 2012 (http://apps.who.int/iris/bitstream/10665/44846/1/9789241564472_eng.pdf, accessed 10 March 2015); WHO. Test procedures for insecticide resistance monitoring in malaria vector mosquitoes. Geneva: World Health Organization; 2013 (http://apps.who.int/iris/bitstream/10665/80139/1/9789241505154_eng.pdf, accessed 10 March 2015).

support pooled procurement. Such steps should enhance manufacturers' confidence, help to stabilize the market, lead to price reductions and encourage innovation.

43. *Strengthen capacity for evidence-driven vector control.* For effective delivery and monitoring of vector control interventions, national malaria programmes need to invest in human resources and organizational and infrastructural development that will boost capacity to generate and analyse essential data.¹⁹⁹ A long-term strategic plan should be developed for building sustainable human resource capacity and establishing career structures and systems to ensure optimal delivery of vector control interventions. Such capacity underpins all activities for malaria control and elimination, and prevention of the re-establishment of the disease.

44. *Implement malaria vector control in the context of integrated vector management.* To maximize the impact of malaria vector control – including maintaining adequate entomological surveillance and monitoring, managing insecticide resistance and strengthening capacity for evidence-based vector control – national malaria programmes should apply the principles of integrated vector management. Integrated vector management is a rational decision-making process for the optimal use of resources for vector control. It seeks to improve the efficiency, cost-effectiveness, ecological soundness and sustainability of disease-vector control with the ultimate goal of preventing the transmission of vector-borne diseases. Countries should develop and implement national plans on integrated vector management as part of their broader strategy to control malaria. Because implementation of vector control involves different sectors, countries should also strengthen intersectoral coordination for maximum impact.

Chemoprevention

45. *Expand preventive treatment to prevent disease in the most vulnerable groups.* Preventive treatment strategies are key elements of the multipronged strategy to reduce disease burden and transmission, and they need to be substantially expanded to help countries to reduce their malaria burden. This intervention suppresses existing infections and prevents the consequences of parasitaemia, including disease and death. The strategies for preventive treatment vary, depending on the intensity of transmission and the level of parasite resistance to antimalarial medicines in a given region.

46. WHO-recommended preventive treatment against malaria presently includes intermittent preventive treatment of pregnant women, intermittent preventive treatment of infants, and seasonal chemoprevention for children aged under 5 years.²⁰⁰ These interventions are recommended in areas of moderate-to-high malaria transmission in sub-Saharan Africa, with seasonal malaria chemoprevention being recommended only in areas of highly seasonal transmission across the Sahel subregion. Preventive treatment strategies currently target falciparum malaria and need to be developed for other types of human malaria.

¹⁹⁹ WHO guidance note on capacity building in malaria entomology and vector control. Geneva: World Health Organization; 2013 (http://www.who.int/malaria/publications/atoz/who_guidance_capacity_building_entomology.pdf, accessed 10 March 2015).

²⁰⁰ WHO. Updated WHO policy recommendation: intermittent preventive treatment of malaria in pregnancy using sulfadoxine-pyrimethamine (IPTp-SP), Geneva: World Health Organization; 2012 (http://www.who.int/malaria/iptp_sp_updated_policy_recommendation_en_102012.pdf, accessed 10 March 2015); WHO policy recommendation on intermittent preventive treatment during infancy with sulphadoxine-pyrimethamine (SP-IPTi) for *Plasmodium falciparum* malaria control in Africa. Geneva: World Health Organization; 2010 (http://www.who.int/malaria/news/WHO_policy_recommendation_IPTi_032010.pdf, accessed 10 March 2015); WHO policy recommendation: seasonal malaria chemoprevention (SMC) for *Plasmodium falciparum* malaria control in highly seasonal transmission areas of the Sahel sub-region in Africa. Geneva: World Health Organization; 2013 (http://www.who.int/malaria/publications/atoz/smc_policy_recommendation_en_032012.pdf, accessed 10 March 2015).

47. *Protect all non-immune travellers and migrants.* Chemoprophylaxis is the administration of subtherapeutic doses of antimalarial medicines at regular intervals sufficient to prevent malaria disease. Chemoprophylaxis should be given to individuals exposed to high malaria risk in combination with advice about measures to reduce vector bites, particularly non-immune travellers, who are more susceptible to malaria illness and death. It is also recommended for travellers within countries from malaria-free areas to areas with high malaria risk.

Diagnostic testing and treatment

48. *Ensure universal diagnostic testing of all suspected malaria cases.* All patients who are suspected to have malaria should have the diagnosis confirmed by parasite detection methods such as quality-assured microscopy or a rapid diagnostic test. Both public and private sector health services should confirm diagnosis before administering antimalarial treatment. Every confirmed case should be tracked and reported in the surveillance system in order to inform programme planning. Ensuring universal diagnostic testing will reduce the over-use of artemisinin-based combination therapies – the first-line treatment for uncomplicated malaria – and reduce the drug pressure on parasites.²⁰¹

49. Expansion of diagnostic testing will provide timely and accurate surveillance data based on confirmed rather than suspected cases. Additionally, it will lead to improved identification and management of the many non-malarial febrile illnesses presumed to be malaria solely on the basis of the presence of fever. Expanding access to prompt diagnostic testing has lagged behind vector control prevention efforts, but strengthening diagnosis and treatment in all settings will help to reduce malaria morbidity and mortality. WHO recognizes that testing and radical treatment of vivax malaria safely and effectively currently requires two diagnoses: the presence of *P. vivax* parasites and glucose-6-phosphate dehydrogenase status.

50. *Provide quality-assured treatment to all patients.* Ensuring universal access to WHO-recommended antimalarial medicines is crucial in all settings in order to prevent the progression of uncomplicated malaria to severe illness and death. After diagnostic confirmation, every patient with uncomplicated *P. falciparum* malaria should be treated with quality-assured artemisinin-based combination therapy. In areas where chloroquine-susceptible *P. vivax* is present, uncomplicated non-falciparum malaria should be treated with either chloroquine or an artemisinin-based combination therapy known to be effective in the area. In addition to the artemisinin-based combination therapy or chloroquine, all non-pregnant adults and children with *P. vivax* or *P. ovale* who are not glucose-6-phosphate dehydrogenase deficient should receive a 14-day course of primaquine to prevent future relapse. Every severe case of malaria caused by *P. falciparum*, *P. vivax* or *P. knowlesi* should be treated parenterally with artesunate or artemether, followed by a full oral course of an artemisinin-based combination therapy. Severe malaria requires urgent medical attention and WHO's detailed recommendations have been made available to countries.²⁰²

51. Malaria programmes should develop detailed national treatment guidelines that take into account local antimalarial drug resistance patterns and health service capacities. Countries should select WHO-recommended artemisinin-based combination therapies with more than 95% efficacy demonstrated through therapeutic efficacy monitoring in local sites. Fixed-dose formulations (combining two different active ingredients co-formulated in one tablet) are strongly recommended as they facilitate adherence to treatment and reduce the potential misuse of individual components

²⁰¹ WHO. Universal access to malaria diagnostic testing: an operational manual, November 2011 (rev. February 2013). Geneva: World Health Organization; 2011 (http://whqlibdoc.who.int/publications/2011/9789241502092_eng.pdf, accessed 10 March 2015).

²⁰² WHO. Guidelines for the treatment of malaria, Second edition. Geneva: World Health Organization; 2010 (http://whqlibdoc.who.int/publications/2010/9789241547925_eng.pdf, accessed 10 March 2015); WHO. Management of severe malaria: a practical handbook. Third edition. Geneva: World Health Organization; 2013 (http://apps.who.int/iris/bitstream/10665/79317/1/9789241548526_eng.pdf, accessed 10 March 2015).

of co-blistered medicines. Oral artemisinin-based monotherapy should never be used for the treatment of uncomplicated malaria as this may promote the development of resistance to artemisinin.

52. *Scale up community-based diagnostic testing and treatment.* Training and deployment of community health workers and volunteers can substantially complement and extend the reach of public health services, particularly in rural and remote areas, where health infrastructures tend to be the weakest and malaria transmission the highest. The strategic use of community health workers and volunteers in malaria prevention and care not only bridges health system gaps, but ensures a continuum of care for the most disadvantaged populations. National malaria programmes should expand integrated community case management of malaria, pneumonia and diarrhoea, with a focus on children under 5 years of age.

53. *Monitor safety and efficacy of antimalarial medicines and manage antimalarial drug resistance.* Enhanced pharmacovigilance and surveillance of the efficacy of antimalarial medicines are essential in order to detect unexpected adverse events and reduced efficacy so that the most appropriate combinations can be selected for national treatment policies. Countries should monitor every two years the efficacy of first-line malaria therapies – against both falciparum and vivax malaria – using the standard WHO protocol for therapeutic efficacy studies.²⁰³ A treatment failure rate exceeding 10% should prompt a change in the national antimalarial treatment policy. For the time being, artemisinin-based combination therapies remain highly effective, provided that the partner medicines remain efficacious. Caution is required, however, as the emergence of artemisinin resistance increases the risk of resistance to the partner medicines in the combination.

54. *Contain antimalarial drug resistance.* Protecting the efficacy of artemisinin-based combination therapies and developing new combinations should be a top priority for both countries where malaria is endemic and the global malaria community.²⁰⁴ In countries and areas where artemisinin and artemisinin-based combination therapies continue to be fully effective, there is a need to promote correct medicine use with special attention to expanding diagnostic testing and quality-assured treatment and to extend all basic malaria interventions, including vector control, in order to reduce the potential emergence of resistance. Countries where artemisinin resistance is reported are urged to intensify malaria control in order to reduce the burden of the disease and delay or prevent spread of resistance. In areas of low transmission but where resistance to artemisinin is present, countries should target rapid elimination of falciparum malaria.

55. *Eliminate falciparum malaria from the Greater Mekong subregion.* *P. falciparum* resistance to artemisinin has emerged independently in multiple geographical locations in the Greater Mekong subregion in South-East Asia. The situation is worst along the Cambodia–Thailand border, where *P. falciparum* has become resistant to almost all available antimalarial medicines. The emergence of multidrug resistance could seriously threaten progress achieved in this region to date, and could lead to a rise in the disease burden in other parts of the world.²⁰⁵ Elimination of *P. falciparum* malaria is the only strategy that can prevent the spread of resistance; this should be an urgent priority in the Greater Mekong subregion, while current tools are effective.

²⁰³ WHO. Methods for surveillance of antimalarial drug efficacy. Geneva: World Health Organization; 2009 (http://whqlibdoc.who.int/publications/2009/9789241597531_eng.pdf, accessed 10 March 2015).

²⁰⁴ WHO, Global Partnership to Roll Back Malaria. Global plan for artemisinin resistance containment. Geneva: World Health Organization; 2011 (http://www.who.int/malaria/publications/atoz/artemisinin_resistance_containment_2011.pdf, accessed 10 March 2015).

²⁰⁵ WHO. Emergency response to artemisinin resistance in the Greater Mekong subregion: regional framework for action 2013–2015. Geneva: World Health Organization; 2013 (http://apps.who.int/iris/bitstream/10665/79940/1/9789241505321_eng.pdf, accessed 10 March 2013).

56. *Remove all inappropriate antimalarial medicines from markets.* All countries in which malaria is endemic should ensure that all inappropriate antimalarial medicines are removed from private sector markets. National regulatory authorities are urged to regulate against production, marketing authorization, export, import and use of oral artemisinin-based monotherapies. Countries should also take decisive steps, including surveillance and regulatory action as well as stringent follow-up, to remove ineffective antimalarial medicines from health facilities and pharmacies, including their provision through informal providers. These efforts will be crucial for preserving the efficacy of artemisinin-based combination therapies, and will make a substantial contribution to accelerating progress on the path to elimination.

Pillar 2. Accelerate efforts towards elimination and attainment of malaria-free status

57. All countries should aim to eliminate malaria. Attaining this objective will entail targeting both the vectors and parasites. Preventing contact between people and vectors will reduce onward transmission of new infections, while clearing the parasites from the large number of people with undiagnosed infections will speed declines in transmission. Over the next decade, new tools and approaches will become available which will help to target the infectious parasite reservoir in humans. The main technical recommendations summarized under this pillar are based on existing tools and approaches but the recommendations are expected to be expanded with 2–3 years.

58. *Refocus programmes.* Once the number of malaria cases has been reduced to low levels in a given country or subnational area, the malaria programmes' priorities and activities may need to be readjusted to complete the final phase of elimination. Thus, in addition to the interventions mentioned under Pillar 1, programmes should enhance surveillance to ensure that every infection is detected, implement targeted measures for attacking both parasites and vectors in order to interrupt local transmission, eliminate all parasites from humans, and manage the risk of re-establishment through imported malaria.

59. *Enact legislation.* New legislation is needed in order to support changes in programme prioritization, namely to ensure that the over-the-counter sale of antimalarial medicines is banned and that surveillance is further strengthened to include compulsory notification of all confirmed cases of infection detected in both public and private health care facilities. In addition, health ministries – with the support of relevant authorities – need to assume direct oversight of supply management for malaria medicines; build a centralized reporting system for epidemiological surveillance of malaria, for vector control data, outbreak reporting, and preparedness and response; and intensify coordination between public, private and community-based agencies and services.

60. *Renew political commitment and deepen regional collaboration.* The final phase of elimination needs strong political commitment, predictable long-term financing, and increased collaboration between neighbouring countries. In many countries, there is an urgent need to expand efforts to support at-risk communities in low-transmission areas, especially in remote and hard-to-reach areas. Solutions should be found for protecting itinerant population groups and migrant workers within and across countries by informing them of the potential dangers of the disease, and providing access to prevention tools and treatment through accessible health clinics.

61. *Reduce the number of undetected infections.* Ensuring that malaria parasites are fully cleared from infected people through public health interventions will require new approaches that are not yet part of the WHO-recommended arsenal of tools. Strategies such as mass administration of medicines have been successfully used in the past, and are currently being explored in a range of transmission settings. Research is evaluating the potential role of administering transmission-blocking medicines in high-transmission settings in order to accelerate progress towards elimination. Other research is evaluating the impact and longer-term effect of administration of effective

antimalarials to either an entire population or targeted population groups, including treatment of infected individuals screened for malaria parasites with highly sensitive tests.

62. *Implement targeted malaria vector control.* As transmission decreases to low levels in countries or subnational areas, universal coverage of populations at risk of malaria with vector control interventions should be maintained in most settings to prevent resurgences. For a given area, the defined population at risk will likely differ as programmes proceed along the path to elimination. A shift from universal coverage to targeting of vector control to specific populations or areas may be justified in circumstances where the inherent transmission potential is low, surveillance systems are strong, there is a high level of preparedness and the ability exists to respond quickly in the event of a resurgence. Targeted indoor residual spraying plays an important role in some settings as a response to outbreaks and resurgences, or to eliminate transmission foci. As transmission declines there may be an increased need for supplementary measures such as larval source management.

63. *Prevent re-establishment of local malaria transmission.* Even after the disease has been eliminated from a country or subnational area, continued importation of malaria cases means that the quality of case detection must remain high. Vigilance for possible renewed local transmission is a responsibility of the general health services as part of their normal function in communicable disease control, in collaboration with other relevant sectors (such as agriculture, environment, industry and tourism). Individuals who plan travel to areas where malaria is endemic should be provided with health information, chemoprophylaxis and advice about measures to protect against mosquito bites, aimed at reducing the importation of parasites. Visitors and migrants from endemic areas should be informed of the risks of malaria and given easy access to free-of-charge diagnostic and treatment facilities. Vector control must continue to be used to contain local outbreaks and protect areas that are known to be receptive to the resumption of transmission as well as exposed to frequent importation of malaria parasites. The patterns of vigilance that need to be applied in order to ensure the successful maintenance of the malaria-free status depend on the vulnerability and receptivity of an area. The programme for prevention of re-establishment of transmission has an unlimited duration. Thus, surveillance should be maintained in countries that no longer have transmission.

64. *Implement transmission-blocking chemotherapy.* Transmission-blocking chemotherapy is the use of effective antimalarial medicines to reduce the transmission of gametocytes, the sexual stage of plasmodia that are infectious to mosquito vectors, thereby interrupting the malaria transmission cycle. WHO recommends transmission-blocking chemotherapy to reduce malaria transmission, particularly in areas threatened by resistance of *P. falciparum* to artemisinin and as part of strategies to eliminate *P. falciparum*.²⁰⁶ This intervention is currently recommended in areas with low transmission and where treatment coverage is high. Transmission-blocking strategies are currently available for falciparum malaria but have not been developed for other malaria parasites.

65. *Detect all infections to attain elimination and prevent re-establishment.* In settings where the rate of transmission is very low, active detection and investigation of infections in addition to free malaria care and notification at health facilities are important for clearing residual foci of transmission.²⁰⁷ Case investigations and detection of infections among people who share the living

²⁰⁶ WHO. Updated WHO policy recommendation: single dose primaquine as a gametocytocide in *Plasmodium falciparum* malaria. Geneva: World Health Organization; 2012 (http://www.who.int/malaria/pq_updated_policy_recommendation_en_102012.pdf, accessed 10 March 2015).

²⁰⁷ WHO. Disease surveillance for malaria elimination: an operational manual. Geneva: World Health Organization; 2012 (http://apps.who.int/iris/bitstream/10665/44852/1/9789241503334_eng.pdf, accessed 10 March 2015); WHO. Policy brief on malaria diagnostics in low-transmission settings. Geneva: World Health Organization; 2014. (<http://www.who.int/malaria/publications/atoz/policy-brief-diagnosis-low-transmission-settings/en/>, accessed 10 March 2015).

environment with someone diagnosed with malaria at a health facility will provide information on potential exposure to the same sources of infection in order to elucidate whether local transmission is occurring or if cases have been imported.

66. *Use of medicines to reduce the parasite pool.* Use of antimalarials is an element of the elimination strategy as they can eliminate the parasite pool in the treated population and, when used preventively, reduce both the pool of susceptible individuals and transmissibility of gametocytes. In the future, WHO will assess the potential role of medicines in killing mosquitoes before they are able to transmit malaria parasites, and their potential role in treating all infections regardless of clinical symptoms or health-seeking behaviour. In work aimed at elimination, all patients with laboratory-confirmed vivax or ovale malaria should be treated with a regimen for a radical cure to clear all remaining hypnozoites, which could later cause a relapse.

67. *Devise P. vivax-specific strategies.* For elimination to succeed, greater attention must be given to *P. vivax*, a parasite less well understood than *P. falciparum*. Vivax malaria presents multiple challenges and needs specific strategies. The challenges include the following:

- *P. vivax* tolerates a wider range of environmental conditions than *P. falciparum* and therefore has a wider geographical range;
- *P. vivax* can be transmitted from humans to mosquitoes before infected people develop symptoms;
- conventional vector control methods (long-lasting insecticide-treated nets and indoor residual spraying) may be less effective against *P. vivax* because, in many areas where *P. vivax* predominates, vectors bite early in the evening, obtain blood meals outdoors and rest outdoors;
- dormant hypnozoites are more difficult to detect because the parasitaemia is typically low and because the dormant hypnozoites residing in the liver cannot be detected with existing diagnostic tests;
- hypnozoites can give rise to multiple relapses and contribute to significant morbidity and onward transmission;
- *P. vivax* hypnozoites can only be eliminated through a 14-day course of primaquine, which can produce serious side effects (haemolytic anaemia) in patients who have glucose-6-phosphate dehydrogenase deficiency, and such treatment is contraindicated in vulnerable population groups such as infants and pregnant or breastfeeding women;
- testing for glucose-6-phosphate dehydrogenase deficiency is challenging and not available in many settings;
- chloroquine-resistant vivax malaria is spreading.

68. *Use surveillance as an intervention in elimination programmes.* As malaria programmes progress towards elimination, the aim of surveillance is to detect all malaria infections, whether symptomatic or not; to investigate each individual case of infection, differentiating imported cases from those acquired locally; and to ensure that each detected case is promptly treated in order to prevent secondary infections. Although infections occur sporadically or in distinct foci, surveillance systems must cover an entire country, with particular attention to areas with ongoing or a recent history of transmission. Countries should monitor imported infections, which represent a significant

proportion of all infections in the elimination phase and may pose a risk for re-establishment of transmission in areas in which it had previously been interrupted.²⁰⁸

Pillar 3. Transform malaria surveillance into a core intervention

69. Irrespective of where countries are on the path to elimination, surveillance of malaria should be upgraded to a core intervention in national and subnational malaria strategies. Surveillance as an intervention encompasses tracking of disease and programmatic responses and taking action in response to data received. At present, most high-burden countries are not in a position to capture essential malaria data on a continuing basis, thereby making it difficult to optimize responses, assess disease trends and respond to outbreaks. Surveillance may function most intensively as an intervention when programmes are closest to elimination, but effective surveillance is required at all points on the path to elimination. The benefits of effective surveillance and the actions needed to transform surveillance are described below.

70. Strong malaria surveillance enables programmes to optimize their operations, by empowering programmes:

- to advocate investment from domestic and international sources, commensurate with the malaria disease burden in a country or subnational area;
- to allocate resources to populations most in need and to interventions that are most effective, in order to achieve the greatest possible public health impact;
- to assess regularly whether plans are progressing as expected or whether adjustments in the scale or combination of interventions are required;
- to account for the impact of funding received and enable the public, their elected representatives and donors to determine if they are obtaining value for money;
- to evaluate whether programme objectives have been met and learn what has worked and not worked so that more efficient and effective programmes can be designed.

71. *Surveillance in areas of high transmission.* Data analysis and programme monitoring are based on aggregate numbers, and actions are undertaken at a population level to ensure that all populations have access to services and there are no adverse disease trends.²⁰⁹ Accurate and timely information on numbers of and trends in malaria-associated deaths is a key requirement for tracking the progress of malaria control. Concerted efforts should be made to ensure that all admissions for malaria to hospitals and health centres and deaths from malaria therein are confirmed by a parasitological test and reported through a national surveillance system. The representativeness of hospital data should be characterized in selected sites with well-defined catchment populations and that continuously track the cause of death.

72. *Surveillance in areas of low transmission.* In areas where rates of transmission are low or moderate, there is appreciable heterogeneity in the distribution of malaria and it becomes increasingly important to identify the population groups most susceptible to disease, and to target interventions appropriately. Malaria can be concentrated in marginalized populations, such as those living in remote or border areas, itinerant and migrant workers, and tribal populations with limited access to services. It may be necessary to take diagnostic testing and treatment services directly to populations without access to services (i.e. to undertake proactive case detection and treatment). As the immunity of populations at risk wanes as interventions take effect, it is important for

²⁰⁸ WHO. Disease surveillance for malaria elimination: an operational manual. Geneva: World Health Organization; 2012 (http://apps.who.int/iris/bitstream/10665/44852/1/9789241503334_eng.pdf, accessed 10 March 2015).

²⁰⁹ WHO. Disease surveillance for malaria control: an operational manual. Geneva: World Health Organization; 2012 (http://apps.who.int/iris/bitstream/10665/44851/1/9789241503341_eng.pdf, accessed 10 March 2015).

programmes to be vigilant against potential outbreaks, with intensified reporting (e.g. weekly) of the incidence of infections and the monitoring of major determinants of transmission, such as meteorological data.

73. Surveillance in areas targeted for elimination of malaria. Malaria-specific reporting systems are increasingly needed to satisfy the additional information demands for targeting and monitoring interventions in particular risk groups and foci. As progress is made towards elimination, it becomes necessary to investigate individual cases of infection or clusters of cases in order to understand risk factors and eliminate foci of transmission. It also becomes increasingly important to ensure that surveillance systems capture data on cases detected by private sector care providers, both formal and informal. Increasing resources and capacity are required to run and maintain malaria surveillance systems that become more complex and resource-intensive in moving to the elimination phase, and additional skills, training and activities will have to be provided for the personnel involved. Strong surveillance systems need to be maintained to sustain the status of elimination once it is achieved; countries also need to monitor the risk of importation (vulnerability) and the transmission potential in risk areas (receptivity).²¹⁰

74. Invest in routine information systems. Routine information systems are crucial for surveillance at all stages of malaria control and form the basis for monitoring of malaria programme activities. Sufficient investments must be made in the management and use of data from improved routine information systems in order to generate the information needed for programme planning, implementation and evaluation. Adequate financial and logistical support is needed for provision of office supplies and equipment, training and retraining of staff, supervision of health facilities, and communications. Data reporting requires management with quality controls in place and good follow up. Building the technical capacity of staff for data analysis and interpretation is the overriding need in order to enable programmes to use surveillance information most effectively.

75. Collect necessary data for understanding disease trends and overall programme performance. Necessary information includes data on resources available for malaria control (programme financing, staff and commodities), existing levels of service provision (access to services and intervention coverage), and trends in health services utilization. It also covers data on populations affected, including malaria parasite prevalence rates and factors that are associated with a higher risk of acquiring malaria. Multiple sources of data include routine information systems (to track finances, commodity flows, service delivery, and disease trends), health facility surveys (to track implementation of services delivered by health facilities), household surveys to track programme coverage and parasite prevalence (in populations), and findings of implementation research. Entomological monitoring systems are required to update information periodically on vectors and their behaviour and susceptibility to insecticides. Therapeutic efficacy studies are essential for detecting resistance to antimalarial medicines. The weight given to different data sources will vary according to the level of malaria transmission and the maturity and capacities of a malaria programme.

76. Develop national strategic plans that take into account the epidemiology and heterogeneity of malaria in a country. As intervention coverage is increased and malaria incidence is reduced, the heterogeneity in incidence and transmission rates increases. A key approach to optimizing malaria responses within a country or territory will be stratification, in which a country or area is divided into smaller units where different combinations of interventions may need to be delivered. National strategic plans should take into account the readiness of health systems to expand malaria programmes and identify the resources required to achieve intended levels of coverage and impact.

²¹⁰ WHO. Disease surveillance for malaria elimination: an operational manual. Geneva: World Health Organization; 2012 (http://apps.who.int/iris/bitstream/10665/44852/1/9789241503334_eng.pdf, accessed 10 March 2015).

They should define the role of different stakeholders in the implementation of the plan and set targets for monitoring progress and ensuring accountability.

77. Monitor the implementation of national malaria strategic plans at regular intervals. In particular, annual reviews should be undertaken before budgets are prepared; mid-term reviews may be conducted to assess interim progress; and a final programme review should be undertaken before development of the next strategic plan. Feedback showing the status of selected key indicators should be communicated to districts and health facilities on a monthly or quarterly basis and include private health facilities. It is important that data are summarized in ways that staff in health facilities and districts can readily assess the facilities' performance. Programme monitoring and surveillance should not be confined to malaria programme managers and implementers. Other government departments, elected leaders, community members and donors have a stake in ensuring high quality malaria programmes and need to be able to scrutinize the operations they are supporting. If involved in the review process, they can help to ensure that malaria programmes are responsive to populations' needs and that malaria control and elimination are promoted as a development priority.

78. Ensure the surveillance system is monitored. Routine health information systems and well-functioning disease surveillance enable programmes to monitor malaria financing, intervention coverage and disease trends. It is important that performance of the surveillance system itself is also monitored through metrics such as the percentage of health facilities submitting monthly reports, the proportion of health facilities receiving quarterly feedback, and, in the advanced phase of malaria elimination, the proportion of cases and deaths investigated. Other important characteristics that should be evaluated periodically include timeliness, accuracy, representativeness and validity. Monitoring the surveillance system itself will identify weaknesses and enable actions to be taken to improve surveillance, which in turn can improve the performance of the malaria programme and accelerate progress towards malaria elimination.

SUPPORTING ELEMENT 1. HARNESSING INNOVATION AND EXPANDING RESEARCH

79. Important new tools are expected to become available within the lifetime of this draft strategy. These include new and more effective medicines, new combinations of medicines, improved diagnostics, new vaccines, new insecticides and other innovative vector control tools. Until new tools are available, programmes should undertake implementation research to refine approaches to applying existing interventions most effectively and efficiently in local contexts. Implementation research will need to focus in particular on population coverage and compliance in the short and long terms as well as human resource issues. These studies should be so designed as to provide results of sufficient quality to provide evidence for policy recommendations. As candidate tools and approaches become available, they will be reviewed and advised upon by WHO and national regulatory bodies. Countries should ensure the existence of a regulatory environment that facilitates rapid assessment and appropriate uptake of validated tools is critical. Bottlenecks to the introduction of new tools must be identified through implementation research and removed early in order to facilitate immediate use once the evidence-base is available to define the appropriate conditions for their deployment. The priorities in five different areas are outlined below.

Vector control

80. Numerous potential tools and approaches are under development for overcoming the specific challenges of vector insecticide resistance and residual transmission. These include new insecticides, formulations or methods of application, new attractants and repellents, new bioactive agents (e.g. fungi or endo-symbionts), new mosquito life-cycle targets (e.g. sugar feeding, mating or oviposition phases), and genetically-modified mosquitoes. New strategies are also being explored to improve the delivery of interventions, such as the novel use of mobile-phone technology and digital mapping.

Tools are also needed for protection of people when they are outside of homes protected by core interventions owing to occupational or other reasons.

81. The improvement of existing core vector control interventions is a priority area that requires further attention, given the expected continued large expenditures on these tools. Beside the integration of new active ingredients into these interventions, the development and validation of nets with improved or prolonged residual effect and physical integrity as well as usefulness are important. Countries should therefore continue to implement operational research to improve access, ownership and usage of nets and quality and uptake of indoor residual spraying, including components of behavioural change communication.

82. It is vital that options are urgently explored to ensure timely and affordable access to improved vector control tools, including those to mitigate insecticide resistance and residual transmission. Countries and the global community must work with industry and research institutions to identify and validate markers of insecticide resistance, assess the extent and drivers of residual transmission, and evaluate candidate tools. Clear definition of the evidence needed to validate new tools is required along with a recognized process for recommending programmatic implementation.

83. Quality assurance of existing and new vector control products and equipment is crucial for sustained efficacy and safety. As global and national capacity to conduct quality control assessments is currently limited, countries must invest in building sufficient expertise and necessary facilities.

Diagnostic testing and treatment

84. Research is required to develop tools that can more readily detect low-level parasitaemia in asymptomatic carriers and ascertain the effectiveness of different screening strategies both at higher transmission levels, in order to appropriately target interventions, and when countries enter the elimination phase. Better species-specific point-of-care rapid diagnostic tests are needed for all non-falciparum malaria parasites, and diagnostics for hypnozoites of *P. vivax* are needed.

85. Simple, point-of-care rapid diagnostic tests are needed to establish the glucose-6-phosphate dehydrogenase status of individuals in order to expand access to treatment of vivax malaria with 8-aminoquinoline antimalarials.

86. A robust pipeline of new candidate therapeutic agents is required because the long-term usefulness of any medicine or combination is threatened by the emergence and spread of resistance. The ideal combination would be a safe, effective and affordable single-dose treatment that can produce radical cure, reduce transmissibility of gametocytes, with prophylactic effect for both *P. falciparum* and *P. vivax* infections, and can be used during pregnancy and in people with glucose-6-phosphate dehydrogenase deficiency. New regimens of medicines that are safe, well-tolerated, affordable, avoid promoting resistance and demonstrate broad spectrum of activity need to be developed for treatment of confirmed clinical cases and for potential mass use against the parasite reservoir, including the sexual stages of both *P. falciparum* and *P. vivax*. New regulatory pathways will need to be created to develop novel chemoprophylactic agents as well as clear research strategies for developing antimalarial medicines for preventive treatment.

87. Reliable and easily applied and interpretable tests for molecular markers of drug resistance for all components of medicine combinations are urgently required. The identification and validation of molecular markers will improve our ability to monitor the emergence and spread of resistance to each medicine compound individually. In addition to molecular markers detecting resistance of *P. falciparum*, markers are also needed to detect resistance of *P. vivax*. The monitoring of molecular markers for drug resistance, once they become available, will be useful particularly in areas of low transmission where therapeutic efficacy studies are becoming increasingly difficult to perform.

88. Context-specific strategies are required to understand better the treatment-seeking behaviours of people in regions with continuing transmission in order to increase demand for treatment, testing and recommended therapy. Innovative methods should be devised in order to ensure that both public and private providers, and those outside the formal health system, adhere to standard guidelines for detecting, treating and recording all malaria cases.

Malaria vaccines

89. Malaria vaccines are expected to be an important addition to the arsenal of tools in the future. Several vaccine candidates, with different modes of action, are currently in various stages of development to prevent *P. falciparum* and *P. vivax* infections. At least one of these (RTS,S) is close to licensure and review for policy recommendation. The global health community has called for the development and licensing, by 2030, of malaria vaccines with protective efficacy of at least 75%. Malaria vaccines are currently envisaged as a complementary tool that should not replace the core package of interventions.

Surveillance

90. Advances in information technology and communications offer prospects of increased timeliness of reporting, better sharing of data (between information systems and different levels of a health system) and enhanced data analyses. Information technology can be applied to optimize and improve procurement and supply management, early warning systems, and the mapping of gaps in service delivery. Moreover, adoption of new technologies should offer the chance to improve management of systems and strengthening capacities and the human resources involved.

91. Efforts are needed to enable better sharing of results of interventions and drug-sensitivity testing and information about advances in surveillance and research that are often generated and held by multiple institutions. All agreements for research or service delivery should include a provision for data-sharing, possibly through open-access portals.

92. Research is needed to identify which strategies are most effective in detecting cases, and to assess the effectiveness of response packages once cases have been detected.

Elimination

93. Research is required to define the range of transmission settings in which reducing transmission by targeting the parasite reservoir is an effective intervention. This research will need also to define optimum combinations of approaches and to optimize intervals between treatments and methods for monitoring the effectiveness of this intervention. The latter includes assessment of highly sensitive submicroscopic diagnostic assays for detecting both *P. falciparum* and *P. vivax* parasitaemia.

94. Relapses of infection with *P. vivax* contribute to a significant proportion of transmission of vivax malaria from its hypnozoites in the liver. Strategies aimed at this parasite reservoir need to be developed as part of vivax elimination strategies, including those for people not eligible for primaquine therapy.

95. Basic research is needed to develop new tools to prevent transmission, including vaccines that target different stages of the parasite life cycle and may be effective in preventing all infections, or by directly targeting the sexual stages and preventing infection of and from mosquitoes.

SUPPORTING ELEMENT 2. STRENGTHENING THE ENABLING ENVIRONMENT

96. Malaria interventions need to be embedded in, and supported through, a strong enabling environment that can ensure that efforts are expanded in an effective and sustainable manner. The main activities to contribute to this enabling environment are as follows.

97. *Increase international and domestic financing.* There is an urgent need to increase and sustain high-level political commitment and the availability of predictable and long-term financing for malaria programmes. International donors are encouraged to maintain and increase commitments to malaria goals and programmes; new financing solutions should be conceived to tap into emerging development financing and private sector resources. Countries where malaria is endemic are urged to increase the domestic resources directed to strengthening health systems and combating the disease. Robust and predictable financing is also essential to sustain recent successes: if countries were to fall back on existing levels of intervention coverage, because of lack of funding, some of the recent gains in global malaria efforts could be lost. Maintenance of robust malaria programmes and capacities is paramount at every step along the path to elimination and in preventing re-establishment of transmission.

98. *Ensure robust health sector response.* In many countries in which malaria is endemic, inadequate health system capacities are a major obstacle to further progress and acceleration. Substantial investments are needed to strengthen health systems, particularly basic health infrastructures, commodity-delivery systems, pharmaceutical regulation, human resources, and vital registration systems in order to improve the environment in which national malaria programmes operate. Strong collaboration between malaria programmes and other health programmes – such as reproductive health, maternal and child programmes, laboratory services and regulatory authorities (for diagnostic devices, medicines and insecticides) – is essential for the successful implementation of malaria interventions.

99. *Strengthen health workforce and malaria expert base.* In most countries where malaria is endemic, there is a chronic shortage of skilled health professionals, clinical practices are outdated, surveillance systems are inadequate, and monitoring and evaluation programmes are weak. Malaria programmes operate in a complex environment, with a continuous need to adjust responses in line with outbreaks and resurgences, changing transmission patterns, and development of drug and insecticide resistance. Robust expansion of malaria interventions requires significantly expanded human resource capacities at national, district and community levels. The education, training and motivation of health workers, programme staff and malaria researchers – including adequate mentoring, supervision, and compensation – is the key to ensuring programme effectiveness. There are several new tools on the horizon, whose introduction will require new skills and even further investments in capacity building. A strengthening of the workforce should be recognized as an essential part of health systems strengthening.

100. *Ensure the sustainability of malaria responses.* To do this and to maximize the potential of malaria investments, national malaria strategic plans should be embedded in a broader health systems approach. A stronger focus on improved supply chains for quality-assured diagnostics, medicines and vector control tools, well-planned procurement, the harnessing of new technologies for data collection and management, and better regulation and oversight of the activities of private sector pharmaceutical vendors are all crucial to making systemic improvements. High-quality and efficient provision of malaria prevention and care – in both the public and private health sectors – will benefit from, and help to build, stronger health systems.

101. *Improve government stewardship and cross-border collaboration of malaria programmes.* Given the large number of stakeholders and the important role in malaria programmes of development partners, private industry, research and academia, private sector health facilities, nongovernmental organizations and community health workers, national public health programmes in countries in which malaria is endemic should improve their overall coordination of the work on malaria. Effective cross-border collaboration between national programmes must be initiated and strengthened in order to ensure optimal coverage of intervention in these areas. National programmes should ensure that all work on programme implementation and elimination is fully in

line with national strategic priorities and complies with WHO recommendations, and that appropriate regulatory frameworks exist to ensure safe use of quality-assured tools by appropriately trained personnel.

102. *Strengthen multisectoral collaboration.* Collaboration with non-health sectors needs to be augmented. National malaria programmes should become an integral part of poverty-reduction strategies, national development plans and regional development cooperation strategies. The response should be elevated from a single-disease approach to a health-in-all-policies approach. The engagement of ministries of finance, education, environment, industry, transport and tourism is especially important, as is the active contribution of regulatory authorities. For vector control, integrated vector management sometimes offers the appropriate platform for efficient delivery of interventions.

103. *Encourage private sector participation.* The private health sector, including industry, health facilities and other actors, has a vital role in the development and delivery of commodities and services, for instance through the development of new tools and interventions and bringing them to market. A stronger engagement will be essential to improve the quality of interventions, including formal and informal private sector provision of patient care and the appropriate reporting to the national surveillance systems of all malaria cases, treatment outcomes and deaths. New and improved partnerships are needed to improve the supply chain for commodities. These partnerships can also play an important role in protecting workers who are recruited for major development projects and treating those who become infected.

104. *Empower communities and engage with nongovernmental organizations.* Close collaboration with community leaders and nongovernmental implementing partners is an essential factor for success. Malaria interventions cannot succeed unless communities adopt governmental guidance on the use of prevention tools and recommended therapies. Integrated, people-centred, community services are needed, and these should be introduced in coordination with health care providers in the public and private sectors. Populations living in remote or hard-to-reach areas and with limited access to health facilities can only be supported through community-based approaches, often in partnership with nongovernmental implementing partners. Well-planned public health communication and behavioural change programmes are essential to educating affected communities about the benefits, and correct use, of malaria prevention tools.

COST OF IMPLEMENTING THE DRAFT GLOBAL TECHNICAL STRATEGY

105. To achieve the milestones and goals set out in this draft strategy, malaria investments, including both international and domestic contributions, need to increase substantially above the current annual spending of US\$ 2500 million. The annual investment will need to increase to an estimated total of US\$ 6500 million per year by 2020 to meet the first milestone of 40% reduction in malaria incidence and mortality rates. This should then be further increased to an annual investment of an estimated US\$ 8000 million by 2025 to meet the second milestone of a 75% reduction. To achieve the 90% reduction goal, the total annual malaria spending will need to reach an estimated US\$ 9000 million by 2030.²¹¹ The cost of implementation has been estimated from the quantities of goods required for expanding interventions, multiplied by the estimated unit cost for the provider of delivering each intervention, and an analysis of surveillance and financing data available in national strategic plans and WHO's annual world malaria reports.²¹² Additional funding of an average of US\$ 673 million (range: US\$ 524 million–822 million) will be needed annually for research and

²¹¹ The confidence interval for these estimates is 95%.

²¹² All world malaria reports can be downloaded from: http://www.who.int/malaria/publications/world_malaria_report/en/ (accessed 10 March 2015).

development. This estimate stems from a risk-adjusted portfolio model of malaria research and innovation needs until 2030.

MEASURING GLOBAL PROGRESS AND IMPACT

106. Global progress in reducing mortality and morbidity and finally eliminating malaria will be based on countries' surveillance efforts. Progress will be measured using multiple data sources, including routine information systems, household and health facility surveys and longitudinal studies. Progress should be monitored through a minimal set of 14 outcome and impact indicators (see Table 2) drawn from a larger set of indicators recommended by WHO and routinely tracked by malaria programmes. Certain indicators are applicable only to subsets of countries, which are defined by levels of malaria endemicity (e.g. intermittent preventive treatment of malaria for pregnant women in sub-Saharan Africa) or by the position on the path to elimination (e.g. investigation of cases and foci for programmes engaged in malaria elimination activities). For other indicators, such as those for vector control, the population at risk who may benefit from the intervention may be defined differently for programmes at different points along the path to elimination. Countries should ensure that a baseline for at least these 14 indicators where appropriate is available for 2015 so that it is possible to monitor progress through the course of the strategy.

Table 2. Proposed indicators for the draft post-2015 global technical strategy for malaria 2016–2030

| Outcome |
|---|
| <ul style="list-style-type: none"> • Proportion of population at risk who slept under an insecticide-treated net the previous night • Proportion of population at risk protected by indoor residual spraying within the past 12 months • Proportion of pregnant women who received at least three or more doses of intermittent preventive treatment of malaria while attending antenatal care during their previous pregnancy (sub-Saharan Africa only) • Proportion of patients with suspected malaria who receive a parasitological test • Proportion of patients with confirmed malaria who receive first-line antimalarial treatment according to national policy • Proportion of expected health facility reports received at national level • Proportion of malaria cases detected by surveillance systems • Proportion of cases investigated (programmes engaged in elimination) • Proportion of foci investigated (programmes engaged in elimination) |
| Impact |
| <ul style="list-style-type: none"> • Parasite prevalence: proportion of the population with evidence of infection with malaria parasites • Malaria case incidence: number of confirmed malaria cases per 1000 persons per year • Malaria mortality rate: number of malaria deaths per 100 000 persons per year • Number of countries that have newly eliminated malaria since 2015 • Number of countries that were malaria-free in 2015 in which malaria was re-established |

ROLE OF THE SECRETARIAT

107. The Secretariat will continue to provide support to Member States and work closely with organizations in the United Nations system, donors, intergovernmental organizations, institutions of research and academia and all other technical partners whose work is fundamental to a successful implementation of this strategy. The Secretariat will undertake the following activities to help to achieve global, regional and national targets for malaria control and elimination.

108. The Secretariat will continue to set, communicate and disseminate normative guidance, policy advice and implementation guidance to support country action. It will ensure that its policy-setting process – which includes the Malaria Policy Advisory Committee – is responsive to the rapidly changing malaria context and that its global technical guidance is regularly updated to incorporate innovative tools and strategies that are proven effective. The Secretariat will continue to assess and pre-qualify vector control products, diagnostics and antimalarial medicines.

109. The Secretariat will provide guidance and technical support to Member States in reviewing and updating their national malaria strategies in line with the priority actions outlined in this draft strategy. It will ensure that its own capacities are strengthened at the global, regional and country level to enable it to lead a coordinated global effort to reduce the disease burden by at least 90% by 2030, and to support the implementation of all recommendations in this strategy. It will work with Member States to develop regional implementation plans, where appropriate.

110. The Secretariat will support countries in strengthening their national malaria surveillance systems in order to improve the quality, availability and management of malaria data, and to optimize the use of such data for decision-making and programmatic responses. It will monitor implementation of the strategy and regularly evaluate progress towards the milestones and goals set for 2020, 2025 and 2030. It will also provide support to countries for developing nationally appropriate targets and indicators to facilitate the subregional monitoring of progress.

111. In line with its core roles, the Secretariat will continue to monitor regional and global malaria trends, and make these data available to countries and global malaria partners. It will support efforts to monitor the efficacy of medicines and vector control interventions, and – to this end – maintain global databases for efficacy of medicines and insecticide resistance. It will regularly report to the regional and global governing bodies of the Organization, the United Nations General Assembly, and other United Nations bodies.

112. WHO will promote the research and knowledge generation that is required to accelerate progress towards a world free of malaria.

113. The strategy will be updated at regular intervals in order to ensure linkage with the latest policy recommendations and complementary technical guidance.

RESOLUTION 16.2:

Executive Board Resolution EB136.R1

Global technical strategy and targets for malaria 2016–2030

The Executive Board, having considered the report on malaria: draft global technical strategy: post 2015,²¹³ RECOMMENDS to the Sixty-eighth World Health Assembly the adoption of the following resolution:

The Sixty-eighth World Health Assembly,

Recalling resolutions WHA58.2 on malaria control, WHA60.18 on malaria, including proposal for establishment of World Malaria Day and WHA64.17 on malaria, and United Nations General

²¹³ Document EB136/23.

Assembly resolutions 65/273, 66/289, 67/299 and 68/308 on consolidating gains and accelerating efforts to control and eliminate malaria in developing countries, particularly in Africa, by 2015;

Acknowledging the progress made towards the achievement of Millennium Development Goal 6 (Combat HIV/AIDS, malaria and other diseases), and towards the targets set by the Health Assembly in resolution WHA58.2;

Recognizing that these gains, when complemented by further investments in new cost-effective interventions, provide an opportunity to further reduce the high burden of malaria and accelerate progress towards elimination;

Noting that approximately 200 million cases of malaria are estimated to have occurred in 2013 and that the disease led to more than 580 000 deaths in 2013, mostly in children under five years of age in Africa, and imposes a significant burden on households, communities and health services in high-burden countries, and that this number will increase unless efforts to reduce the disease burden are intensified;

Recognizing that malaria interventions are highly cost-effective yet there is a need to urgently address and overcome the barriers that hinder universal access to vector-control measures, preventive therapies, quality-assured diagnostic testing and treatment for malaria;

Recognizing also that malaria-related morbidity and mortality throughout the world can be substantially reduced with political commitment and commensurate resources if the public is educated and sensitized about malaria and appropriate health services are made available, particularly in countries where the disease is endemic;

Deeply concerned by the regional and global health threat posed by the emergence and spread of insecticide and drug resistance, including artemisinin resistance, and the systemic challenges impeding further progress, including weak health and disease surveillance systems in many affected countries;

Cognizant of the grave economic and social burden that malaria inflicts on the most vulnerable and poorest communities in countries in which malaria is endemic, and of the disproportionate burden that is borne by countries in sub-Saharan Africa, and high-risk groups, including mobile populations;

Cognizant also that a reduction in the malaria burden can improve social conditions, lift communities out of poverty, and has a positive economic and social impact;

Acknowledging that recent successes in malaria prevention and control are fragile and that further progress depends on action within and beyond the health sector, which requires long-term political and financial commitments, strong regional collaboration, the strengthening of health systems, and investments in innovation and research;

Recognizing that in the interconnected and interdependent world, no country is risk-free in respect of malaria, including countries that have recently eliminated the disease and countries that are non-endemic for malaria,

1. ADOPTS the global technical strategy for malaria 2016–2030, with:

- (1) its bold vision of a world free of malaria, and its targets to reduce malaria incidence and mortality rates globally by at least 90% by 2030, to eliminate the disease in at least 35 new countries, and to prevent its re-establishment in countries that were free of malaria in 2015;
- (2) its associated milestones for 2020 and 2025;

- (3) its five principles addressing: acceleration of efforts towards elimination; country ownership and leadership, with the involvement and participation of communities; improved surveillance, monitoring and evaluation; equity in access to health services; and innovation in tools and implementation approaches;
- (4) its three pillars of: ensuring universal access to malaria prevention, diagnosis and treatment; acceleration efforts towards elimination and attainment of malaria-free status; and transforming malaria surveillance into a core intervention;
- (5) its two supporting elements of: harnessing innovation and expanding research; and strengthening the enabling environment;

2. URGES Member States:²¹⁴

- (1) to update national malaria strategies and operational plans consistent with the recommendations of the global technical strategy for malaria 2016–2030;
- (2) to intensify national and regional efforts to reduce malaria morbidity and mortality in high-burden countries and accelerate progress towards elimination, and, where appropriate, maintain malaria-free status;
- (3) to strengthen health systems, including both the public and private sectors, and devise plans for achieving and maintaining universal coverage of WHO-recommended core malaria interventions for at-risk populations;
- (4) to intensify national, cross-border, regional and subregional efforts to address the threat posed by rising insecticide and drug resistance, including artemisinin resistance;
- (5) to promote multisectoral collaboration, educational programmes, and community involvement in order to strengthen efforts for malaria control and elimination;
- (6) to establish and strengthen, as appropriate, national malaria surveillance and response systems in order to improve the quality of data and the effectiveness and efficiency of national malaria responses;
- (7) to promote basic and applied research into malaria and accelerate the rapid development and adoption of good-quality and cost-effective new tools, in particular vaccines, medicines, diagnostics, surveillance, insecticides and vector control tools to prevent and control malaria, and to collaborate on new approaches;
- (8) to strengthen human resource capacity and infrastructure to improve the effectiveness, efficiency and sustainability of malaria responses, while ensuring integration and synergies with the wider health system;
- (9) to consider the financial implications of this resolution in the broader context of health sector development, and increase national, regional and international funding for malaria interventions, and for cross-border and regional initiatives;

3. INVITES international, regional and national partners from within and beyond the health sector, in particular those in the Roll Back Malaria Partnership, to engage in, and support, the implementation of the global technical strategy for malaria 2016–2030;

4. CALLS UPON WHO's international partners, including intergovernmental and international organizations, financing bodies, academic and research institutions, civil society and the private sector to support Member States,²¹⁵ as appropriate:

²¹⁴ And, where applicable, regional economic integration organizations.

²¹⁵ And, where applicable, regional economic integration organizations.

- (1) to mobilize sufficient and predictable funding to enable an accelerated reduction of the malaria burden, particularly in high-burden countries, and progress towards elimination, in line with the milestones and targets proposed in the strategy;
- (2) to support knowledge generation, research and innovation to speed up the development of new vector-control tools, diagnostics, medicines, vaccines, and surveillance, data management, operational delivery and implementation solutions;
- (3) to harmonize the provision of support to countries for adopting and implementing WHO-recommended policies and strategies;

5. REQUESTS the Director-General:

- (1) to provide technical support and guidance to Member States²¹⁶ for the implementation, national adaptation and operationalization of the global technical strategy for malaria 2016–2030;
- (2) to update technical guidance on malaria prevention, care and elimination regularly, as new evidence is gathered and new innovative tools and approaches become available;
- (3) to monitor the implementation of the strategy and evaluate its impact in terms of progress towards set milestones and targets;
- (4) to strengthen the Secretariat’s capacities to enable it to increase its technical support to Member States,²¹⁷ in order to meet the global milestones and targets;
- (5) to ensure that all relevant parts of the Organization, at headquarters, regional and country level, are actively engaged and coordinated in promoting and implementing the global technical strategy for malaria 2016–2030;
- (6) to report on the progress achieved to the Seventieth and Seventy-second World Health Assemblies, and at regular intervals thereafter, through the Executive Board.

²¹⁶ And, where applicable, regional economic integration organizations.

²¹⁷ And, where applicable, regional economic integration organizations.

16.4 Global vaccine action plan

Document A68/30 (Report by the Secretariat):

Global vaccine action plan

1. The attached document EB136/25 was considered and noted by the Executive Board at its 136th session.²¹⁸

ACTION BY THE HEALTH ASSEMBLY

2. The Health Assembly is invited to note the report.

Document EB136/25 (Report by the Secretariat)

Global vaccine action plan

1. In May 2012, the Sixty-fifth World Health Assembly endorsed the global vaccine action plan²¹⁹ and requested the Director-General to monitor progress and report annually, through the Executive Board, to the Health Assembly, until the Seventy-first World Health Assembly, on progress towards achievement of global immunization targets, as a substantive agenda item, using the proposed accountability framework to guide discussions and future actions.²²⁰

2. In May 2013, the Sixty-sixth World Health Assembly noted the report by the Secretariat,²²¹ including the proposed framework for monitoring and evaluation and accountability, as well as the process for reviewing and reporting progress under the independent oversight of the Strategic Advisory Group of Experts on immunization.²²²

3. In accordance with the monitoring, evaluation and accountability process,²²³ the Strategic Advisory Group of Experts on immunization reviewed progress against each of the indicators for the goals and strategic objectives of the global vaccine action plan, based on data from 2013, and prepared the 2014 Assessment Report of the Global Vaccine Action Plan.²²⁴

4. A summary of the 2014 Assessment Report by the Strategic Advisory Group of Experts on immunization is included in the Annex.

ACTION BY THE EXECUTIVE BOARD

5. The Executive Board is invited to take note of the report and to consider the recommendations for actions to be taken by the various stakeholders of the global vaccine action plan, in particular by Member States.

²¹⁸ See summary records of the 136th session of the Executive Board, second meeting.

²¹⁹ The global vaccine action plan can be found at: http://www.who.int/immunization/global_vaccine_action_plan/en/ (accessed on 19 November 2014).

²²⁰ Resolution WHA65.17.

²²¹ Document A66/19.

²²² See document WHA66/2013/REC/3, summary record of the tenth meeting of Committee A, section 2.

²²³ See document A66/19, paragraphs 16 and 17.

²²⁴ The 2014 Assessment Report of the Global Vaccine Action Plan is posted at: http://www.who.int/immunization/global_vaccine_action_plan/sage_assessment_reports/en/ (accessed on 24 November 2014).

ANNEX

A SUMMARY OF THE 2014 ASSESSMENT REPORT OF THE GLOBAL VACCINE ACTION PLAN BY THE STRATEGIC ADVISORY GROUP OF EXPERTS ON IMMUNIZATION

1. The Global Vaccine Action Plan (GVAP) has two great ambitions, to make 2011–2020 the Decade of Vaccines:

- To deliver vaccination to all – and through this: to end inequity in vaccination, eradicate polio globally, eliminate maternal and neonatal tetanus globally, and eliminate (guided by regional targets) measles and rubella.
- To unleash vaccines' vast future potential – because their impressive history is nothing in comparison to what they could yet achieve.

2. The Strategic Advisory Group of Experts on immunization noted that there has been success in introducing new vaccines, and positive achievements in numerous countries in several areas, including the establishment and strengthening of National Immunization Technical Advisory Groups. However, progress is far off-track. Five of the six goals set by the GVAP with deadlines at the end of 2014 or 2015 still require substantial progress to get the goals on track (poliovirus transmission interruption, maternal and neonatal tetanus, measles and rubella elimination, and DTP3 coverage targets). Indeed, most have seen very little progress. Some have been missed multiple times before.

3. To get the Action Plan back on track, the Strategic Advisory Group of Experts on immunization recommends that action focus particularly on addressing five priority problems. Each problem is major, but each can be tackled, with a reasonable expectation that doing so will improve progress considerably. Each problem is detailed in the full 2014 Assessment Report of the Global Vaccine Action Plan²²⁵ of the Strategic Advisory Group of Experts on immunization, and is summarized below.

Weak GVAP implementation

4. Three years after its start date, implementation of the GVAP is patchy and slow. All countries and organizations that have committed to this endeavour should re-examine the level and nature of their contributions, and urgently make the improvements necessary to achieve results.

5. The Strategic Advisory Group of Experts on immunization recommends that:

- The Director-General of WHO, during the Sixty-eighth World Health Assembly in 2015, convene side meetings in collaboration with the GVAP secretariat agencies for countries with routine vaccination (DTP3) coverage of less than 80%, to which each Minister of Health is asked to report on the challenges, plans and timelines to improve coverage to meet the GVAP goals.
- Partners are called upon to lead a concerted effort to fill the funding gap and scale up advocacy efforts to achieve the neonatal (and maternal) tetanus elimination target by end 2015.
- Regions and countries rapidly finalize their own vaccine action plans based on the GVAP, using this assessment report as a further guide and establishing bodies to guide and monitor implementation.
- Following adoption of the GVAP and subsequent revision and adoption of regional and national plans, countries have the responsibility to ensure that immunization goals are shared, discussed and fully adopted by health care workers.

²²⁵ http://www.who.int/immunization/global_vaccine_action_plan/en/.

- Countries give civil society organizations substantially more formal involvement in the delivery and improvement of vaccination services, establishing clear responsibilities for which they are accountable.
- After consulting with the respective Regional Technical Advisory Group, every region establishes a regional verification commission, and after consulting with the respective National Immunization Technical Advisory Group, every country explores options for establishing a national verification commission, to scrutinize and monitor progress towards the measles elimination targets.
- The heads of the GVAP secretariat agencies (the Bill & Melinda Gates Foundation, GAVI The vaccine alliance, the National Institute of Allergy and Infectious Diseases, WHO and UNICEF) meet to consider this report and to agree on specific corrective actions.
- The heads of GVAP secretariat agencies report to the 2015 World Economic Forum in Davos on the plan's establishment, its lack of progress so far and what forum participants – who supported the Decade of Vaccines concept in 2010 – can do to help its implementation.
- The SAGE's GVAP assessment reports remain as standing items at the World Health Assembly until 2020.

Poor data quality and use

6. Poor quality and use of data is substantially impeding programme management and improvement.

7. The Strategic Advisory Group of Experts on immunization recommends that:

- Countries invest in improving data quality at the local level, and use data to strengthen accountability and to improve understanding of what the programmatic issues are.
- Technical agencies further develop and deploy tools to help countries with the practical task of improving the quality and use of data, with limited personnel available to do so.

Vaccine affordability and supply

8. The affordability and supply of vaccines need to be urgently examined. Each may be causing a significant problem for a large number of countries, and the current lack of proper information hinders understanding and corrective action.

9. The Strategic Advisory Group of Experts on immunization recommends that:

- Technical agencies conduct urgent assessments of (i) the extent to which the reported national-level stock-outs are affecting local vaccine supply and delivery, and (ii) the root causes of these stock-outs.
- Countries are requested to change the rules of the game on vaccine affordability, to create transparency which is in their interest. They can do this by making pricing information publicly available, and by collaborating with WHO and all technical agencies to develop solutions.
- Technical partners support countries to improve the transparency of vaccine pricing. Technical agencies themselves should do everything possible to share pricing data.

Failures of basic integration

10. Failures of basic integration mean that health care workers are repeatedly missing easy opportunities to offer vaccinations when people attend clinics with other problems.

11. The Strategic Advisory Group of Experts on immunization recommends that:

- Countries conduct studies to understand how opportunities to vaccinate people are being missed by health care workers and their systems, and act to reduce the incidence.
- WHO discusses and develops guidelines on how to fully integrate vaccination into the operation of all aspects of the health care system and to reduce missed opportunities to vaccinate.
- Countries ensure that health care workers understand and follow WHO or national guidelines on what does, and does not, contraindicate vaccination, particularly in relation to childhood febrile illness, so that vaccination is not avoided unnecessarily.

Situations disrupting immunization

12. Vaccine delivery is impeded by disruptive situations, including war and major disease outbreaks (such as Ebola, currently). Such situations will always exist. Vaccines must be delivered despite them.

13. The Strategic Advisory Group of Experts on immunization recommends that WHO expand its existing guidance on immunization in humanitarian emergencies to detail how routine and other immunization services are best maintained despite disruptive situations, such as war and disease outbreaks.

17. Health systems

17.1 Strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage

Document A66/31 (Report by the Secretariat):

Strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage

1. The Executive Board at its 136th session considered the attached document EB136/27²²⁶ and adopted resolution EB136.R7.²²⁷

ACTION BY THE HEALTH ASSEMBLY

2. The Health Assembly is invited to adopt the draft resolution recommended by the Executive Board in resolution EB136.R7.

Document EB136/27 (Report by the Secretariat)

Strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage

1. The Executive Board at its 135th session agreed to include strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage on the provisional agenda of its 136th session and that a new version of the report that it had noted would be prepared.²²⁸

GLOBAL BURDEN OF SURGICAL CONDITIONS

2. Every year, more than 234 million surgical procedures are performed globally for a wide range of conditions involving patients of all age categories and in every Member State. The many conditions requiring surgical care – including obstructed labour, congenital anomalies, diabetes, cancer, cardiovascular disease, hernias, cataracts, road traffic injuries, and injuries due to burns and falls – are common and affect people in all socioeconomic and ethnic groups.

3. Surgically treatable diseases are among the top 15 causes of disability worldwide. Conservative estimates find that 11% of the world's burden of disease stems from conditions that could be treated successfully through surgery, with higher proportions in low- and middle-income countries. As a result of such conditions going untreated, rates of maternal mortality are high, minor surgical pathologies become lethal and treatable injuries result in death. Surgical intervention is a potential treatment at some point for virtually every disease included in the Global Burden of Disease Study 2010.

²²⁶ See summary record of the 136th session of the Executive Board, eighth meeting, section 3.

²²⁷ See document EB136/2015/REC/1 for the resolution, and for the financial and administrative implications for the Secretariat of the adoption of the resolution.

²²⁸ See document EB135/2014/REC/1, summary record of the first meeting of the Executive Board at its 135th session, section 7.

4. Based on high mortality rates, the surgical conditions most in need of better surgical and anaesthesia services are accidental trauma (bone and soft-tissue injuries), tumours, obstetrical complications (including obstetrical fistula), cataracts and glaucoma, perinatal conditions and congenital anomalies, male circumcision (for prevention of HIV transmission) and other conditions including hernia and gall bladder disease. The conditions for which surgery is one of the primary clinical solutions are expected to become increasingly common in the coming years, with a rising volume of more than 45% expected for common conditions such as heart disease, cancer, diabetes and road traffic injuries between now and 2030.

5. Services, including surgical care, for these conditions are often provided through independent disease-specific initiatives rather than through a more sustainable approach of integration into comprehensive surgical services. There is a need for safe, effective and affordable antibiotics to avoid infection resulting from surgery and an urgent need to address antimicrobial resistance. The integrated delivery of surgical care is an important and growing need for the treatment of various health conditions across the life-course.

THE IMPORTANCE AND COST-EFFECTIVENESS OF SURGERY

6. Strengthening surgical capacity, particularly at the district hospital level, has been identified as a highly cost-efficient means of reducing the global burden of disease. Notably, strengthening local surgical capacity is an approach that would both provide a high degree of financial protection to populations and lower the disability-adjusted life years lost in a cost-effective manner. The benefit/cost ratio for the expansion of the surgical capacity at district hospitals has been found to be 10, with every US\$ 1 spent on strengthening local surgical capacity generating US\$ 10 through improved health and increased productivity. Timely access to safe surgical care is curative and also prevents disability from obstetric fistula and congenital anomalies such as clubfoot. Thus surgical care and anaesthesia should be considered as a core aspect of universal health coverage.

GAPS IN SURGICAL SERVICES

7. *The world health report 2008* notes that surgical care is an integral component of the continuum of primary care,²²⁹ yet it is estimated that more than 2000 million people in the world lack access to even basic surgical care.²³⁰ In addition, the delivery of anaesthesia, which is an essential component of surgical services, is limited by deficiencies in human resources, equipment availability and system capacity.²³¹

8. In many parts of the world, access to essential and emergency surgical services is extremely limited, with less developed countries concentrating available surgical care in urban centres. A baseline assessment of the current situation of surgical and anaesthesia services is needed in order to understand better what effective measures need to be taken to fill the gaps identified. Assessments using one element of the WHO Integrated Management for Emergency and Essential Surgical Care toolkit, namely the situational analysis tool to assess emergency and essential surgical

²²⁹ The world health report 2008. Primary health care – now more than ever. Geneva: World Health Organization; 2008.

²³⁰ Weiser TG, Regenbogen SE, Thompson KD et al. An estimation of the global volume of surgery: a modelling strategy based on available data. *Lancet* 2008; 372:139–144. Funk LM, Weiser TG, Berry WR, Lipsitz SR, Merry AF, Enright AC et al. Global operating theatre distribution and pulse oximetry supply: an estimation from reported data. *Lancet* 2010;375:1055–1061.

²³¹ Country assessments for Afghanistan, Democratic Republic of the Congo, Ethiopia, Gambia, Ghana, India, Indonesia, Liberia, Malawi, Mongolia, Myanmar, Niger, Nigeria, Pakistan, Papua New Guinea, Sao Tome and Principe, Sierra Leone, Solomon Islands, Somalia, Sri Lanka, Uganda, United Republic of Tanzania and Viet Nam, see http://www.who.int/surgery/publications/topic_publications/en/index3.html (accessed 24 October 2014).

care, have identified major inadequacies in numerous countries in the relevant infrastructure and human resources, and in surgical interventions, skills and equipment.²³²

9. Recently, the largest cross-sectional survey to date on the availability of caesarean delivery, one of the most basic surgical procedures, in 26 low- and middle-income countries found that 23.2% of the facilities surveyed did not perform the procedure and 2.9% did not provide complete information (data points) on the survey tool. The lack of skilled professionals and absence of adequate equipment were significant barriers to providing this surgical procedure. Even facilities that reported performing caesarean deliveries lacked sufficient skilled providers of anaesthesia and obstetric and surgical care. A background paper for *The world health report 2010* recognizes that timely caesarean sections should be offered to women in need while advocating a more rational use of caesarean sections in countries where this procedure was used excessively and unnecessarily.²³³ Gaps in access to essential surgical care are further broadened by communities' acute needs in the wake of disasters and emergencies.

10. Numerous assessments of surgical interventions in low- and middle-income countries have identified major inadequacies in infrastructure and human resources, skills, functioning equipment, medicines and other supplies. One assessment in 22 such countries demonstrated that 35% of health care facilities surveyed had no access to oxygen supplies and only 53% had continuous access to anaesthesia machines. Another assessment in 26 such countries revealed that lack of skills (53%) and non-functioning equipment (43%) were the most common reasons for caesarean deliveries not being performed and patients being referred.

11. Ketamine is widely used as an anaesthetic in human (and veterinary) medicine, especially in low- and middle-income countries in surgical care and in crisis or emergency situations. The ease of parenteral administration gives ketamine a major advantage when anaesthetic gases are impossible to use owing to limited equipment and lack of appropriately trained specialists. In addition, it carries a wide margin of safety compared with other anaesthetic agents. However, access to ketamine was reported in only 71% of the surveyed health facilities in 22 low- and middle-income countries. In many countries there is no suitable alternative that is affordable.

12. Data on access to ketamine are reported, but less is known about the availability of other medicines required for the safe conduct of emergency and surgical care. Depending on the levels of care and procedures performed, WHO has identified the needs for inhalational anaesthetics (halothane and isoflurane), local anaesthetics (lidocaine and bupivacaine hydrochloride), agents for spinal anaesthesia, preoperative and sedative medication (atropine, diazepam), muscle relaxants (neostigmine, suxamethonium chloride and vecuronium) as well as medicines for resuscitation, cardiovascular and respiratory support (adrenaline, calcium chloride, hydralazine hydrochloride, furosemide and aminophylline), and electrolyte imbalances.²³⁴

²³² WHO Integrated Management for Emergency and Essential Surgical Care e-learning toolkit, <http://www.who.int/surgery/publications/imeesc/en> (accessed 24 October 2014), English only.

²³³ Gibbons L, Belizán JM, Lauer JA, Betran AP, Merialdi M, Althabe F. The global numbers and costs of additionally needed and unnecessary caesarean sections performed per year: overuse as a barrier to universal coverage. *The world health report 2010*, background paper No. 30, 31 pp (<http://www.who.int/healthsystems/topics/financing/healthreport/30C-sectioncosts.pdf>, accessed 24 October 2014).

²³⁴ World Health Organization 2012. Guide to infrastructure and supplies at various levels of health care facilities: emergency and essential surgical care (EESC) <http://www.who.int/surgery/publications/s15983e.pdf?ua=1> (accessed 24 October 2014).

13. The quality and safety of surgical care are also areas of concern. The Second Global Patient Safety Challenge: Safe Surgery Saves Lives focuses on the safe delivery of surgical care.²³⁵ Findings from WHO's work suggest that globally surgery still involves high rates of morbidity and mortality: at least seven million people a year experience disabling surgical complications, from which more than one million die.

ACTIONS AT COUNTRY LEVEL

14. The value of incorporating surgical care into health services as a step towards providing universal health coverage has been implicit in numerous previous resolutions adopted by the Health Assembly.²³⁶ Strengthening emergency and essential surgical care and anaesthesia services will strengthen health services overall and improve outcomes, for instance, for mothers and children.

15. Although some work has been done to start to close the gaps in the coverage and quality of essential and emergency surgical care and anaesthesia, many actions can still be taken at country level to strengthen surgical services. Priority areas are discussed below.

16. **Raising awareness and building political commitment.** Awareness needs to be raised and sustained in Member States about the existence of low-cost interventions that reduce death and disability through improved access to safe surgical care and anaesthesia. Member States need to encourage the integration of surgical services at the district and subdistrict levels of care as a move towards the achievement of universal health care. As part of this effort, multidisciplinary stakeholders, including policy-makers, health providers and the media, need to be persuaded of the value of making the necessary investment to establish a firm evidence base and of providing sustainable emergency and essential surgical care services.

17. Political commitment is essential for integrating surgical care initiatives into national health plans. Political priority should be given to supporting essential surgical care and anaesthesia within primary health care and universal health care in all countries.

18. **Expanding access to emergency and essential surgical services where needed.** Member States should expand efforts to close gaps, in both infrastructure and human resources for essential and emergency surgical care. Improving workforce distribution, with special attention being given to rural areas, should be a priority, although regular assessment and assuring the availability of functioning equipment and medicines are also essential. Necessary steps would include making ketamine accessible in all facilities where anaesthesia is needed, in order to ensure safe and affordable surgical care.

²³⁵ World Alliance for Patient Safety. The Second Global Patient Safety Challenge: Safe surgery saves lives, document WHO/IER/PSP/2008.07, reprinted 2009 (<http://www.who.int/patientsafety/campaigns/en/>) (accessed 24 October 2014).

²³⁶ See resolutions WHA50.29 Elimination of lymphatic filariasis as a public health problem, WHA57.1 Surveillance and control of *Mycobacterium ulcerans* disease (Buruli ulcer), WHA57.12 Reproductive health: strategy to accelerate progress towards the attainment of international development goals and targets, WHA57.18 Human organ and tissue transplantation, WHA58.23 Disability, including prevention, management and rehabilitation, WHA58.31 Working towards universal coverage of maternal, newborn and child health interventions, WHA59.23 Rapid scaling up of health workforce production, WHA60.22 Health systems: emergency-care systems, WHA61.16 Female genital mutilation, WHA62.1 Prevention of avoidable blindness and visual impairment, WHA62.12 Primary health care, including health system strengthening, WHA63.17 Birth defects, WHA64.27 Child injury prevention, WHA65.20 WHO's response, and role as the health cluster lead, in meeting the growing demands of health in humanitarian emergencies, and WHA66.7 Implementation of the recommendations of the United Nations Commission on Life-Saving Commodities for Women and Children.

19. **Improving the quality and safety of emergency and essential surgical services.** Action in this area should be a joint priority, along with improving access to surgical care, so as to eliminate surgery-related inequities and differences in mortality and morbidity. Even though perioperative and anaesthetic-related mortality rates have progressively declined over the past 50 years, partially as a result of efforts to improve patient safety in the perioperative setting, they still remain two to three times higher in developing countries than in developed countries.

20. **Strengthening the surgical workforce.** Member States should include consideration of the surgical workforce in designing their overall strategies on health system planning. They should also foster training in surgical care and anaesthesia through exchange of knowledge and expertise, using networks and global partnerships that encourage surgical capacity-building with a special focus on first-referral health facilities and primary health care. Efforts to train locally specialists, surgeons and anaesthesiologists as well as general practitioners, nurses and clinical medical officers through various programmes have been successful in low- and middle-income countries.²³⁷ Collaborations and partnerships with professional associations and organizations could assist in task shifting in primary health care in order to redress shortage of surgical health workforce and to help to strengthen health systems.

21. Educational institutions need to review curricula for training in surgery and anaesthesia so as to ensure that health facilities adapted to meet the growing use of surgical services and the provision of continuing education for the surgical workforce.

22. **Improving data collection, monitoring and evaluation for policy and decision-making.**

Evidence-based plans and policies need to be implemented to ensure the successful expansion of access to essential surgical services. Monitoring and evaluation are necessary to ensure and sustain both improved access to surgical services and their quality and safety. Proper surgical records and adequate follow-up are crucial to ensuring safe procedures and their monitoring.

23. **Fostering global collaboration and partnerships.** Coordination between international organizations, national governments, health ministries, professional bodies, nongovernmental organizations and academic institutions is needed in order to sustain viable capacity-building in education, training and research.

ACTION BY THE SECRETARIAT

24. In a global collaborative effort with Member States, the Secretariat elaborated the WHO Integrated Management for Emergency and Essential Surgical Care toolkit in order to guide policies and research for evidence-based planning and improvement of the quality and safety of surgical services, including the training of health care workers in essential procedures. The Secretariat will expand its work on capacity-building through the use of this toolkit.

25. Approaches and tools, such as the WHO CHOICE project for choosing interventions that are cost-effective²³⁸ and the WHO global database on emergency and essential surgical care,²³⁹ will be used to provide evidence-informed analyses for investment planning and identifying the financial resources needed to strengthen surgical services.

26. The Secretariat will work with Member States to ensure that surgical services at district and subdistrict levels of care – such as those for emergencies, trauma, obstetrics and anaesthesia – are

²³⁷ Johnson WD. Surgery as a Global Health Issue. *Surg Neurol Int.* 2013 April;4:47.

²³⁸ Cost effectiveness and strategic planning (WHO-CHOICE), <http://www.who.int/choice/cost-effectiveness/en/> (accessed 24 October 2014).

²³⁹ WHO EESC Global Database, http://who.int/surgery/eesc_database/en/ (accessed 24 October 2014).

assessed and monitored with standardized tools such as the WHO Integrated Management for Emergency and Essential Surgical Care toolkit, which includes recommendations on minimum standards for surgical and anaesthetic services.

27. The WHO Global Initiative for Emergency and Essential Surgical Care²⁴⁰ continues to be the cornerstone of the Secretariat's work in this area. The continuing work of this global forum provides a solid foundation for collaboration and partnerships to support Member States in strengthening their surgical care systems.

ACTION BY THE EXECUTIVE BOARD

28. The Board is invited to note this report.

RESOLUTION 17.1:

Executive Board Resolution EB136.R7

Strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage

The Executive Board, having considered the report on strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage,²⁴¹ RECOMMENDS to the Sixty-eighth World Health Assembly the adoption of the following resolution:

The Sixty-eighth World Health Assembly,

Recognizing that each year more than 234 million surgical procedures are performed globally for a wide range of common conditions requiring surgical care, affecting all age groups – including obstructed labour, birth defects, cataracts, cancer, diabetes, acute abdominal conditions, burns and injuries from domestic and industrial and road accidents – and that conditions for which surgery is one of the primary clinical solutions are expected to become increasingly common in the coming years;

Noting that many surgically treatable diseases are among the top 15 causes of physical disability worldwide and that 11% of the world's burden of disease stems from conditions that could be treated successfully through surgery, with low- and middle-income countries being the most affected;²⁴²

Recognizing that each year more than 100 million people sustain injuries globally, more than 5 million people die from violence and injury, and that 90% of the global burden of violence and injury mortality occurs in low- and middle-income countries;²⁴³

Noting that more than 289 000 women die every year in childbirth and that approximately a quarter of maternal deaths, as well as infant deaths and disabilities that result from obstructed labour,

²⁴⁰ <http://who.int/surgery/globalinitiative/en/> (accessed 24 October 2014).

²⁴¹ Document EB136/27.

²⁴² See the WHO global burden of disease website, at: http://www.who.int/topics/global_burden_of_disease/en/ (accessed 29 January 2015).

²⁴³ The injury chart book: a graphical overview of the global burden of injuries, Geneva: World Health Organization; 2002 (<http://whqlibdoc.who.int/publications/924156220X.pdf?ua=1>, accessed 29 January 2015).

haemorrhage and infection, could be avoided if safe surgery and anaesthesia were universally available;²⁴⁴

Noting also that the sustainable provision of emergency and essential surgical care and anaesthesia is a critical part of integrated primary health care, lowers mortality and disability, reduces deaths resulting from birth defects, and prevents other adverse health outcomes arising from the burden of injuries and noncommunicable diseases;²⁴⁵

Noting further the relevance of emergency and essential surgical care and anaesthesia in achieving the Millennium Development Goals and for attending to the unfinished business post-2015, including universal health coverage;²⁴⁶

Recognizing the importance of timely referral and the existence of standards and protocols, such as those defined in the WHO Integrated management for emergency and essential surgical care, in the continuum of care,²⁴⁷ and recalling that resolution WHA55.18 on quality of care: patient safety urges Member States to establish and strengthen science-based systems, necessary for improving patients' safety and the quality of health care, including the monitoring of drugs, medical equipment and technology;

Recognizing also that emergency and essential surgical care and anaesthesia are a neglected but efficacious and cost-effective addition to the basic package of health services and that strengthening emergency and essential surgical capacity together with anaesthesia, particularly at the first-level referral hospitals, is a highly cost-efficient solution to the global burden of disease;

Noting the importance of analgesia in surgery and anaesthesia, and that a large proportion of the global population has limited access to opioid analgesics for pain relief, and patients with moderate and severe pain often do not receive the treatment they need, that 5.5 billion people (83% of the world's population) live in countries with low to non-existent access, that 250 million (4%) have moderate access, that 460 million (7%) have adequate access, and that insufficient data are available for 430 million people (7%);²⁴⁸

Recognizing that balanced policies and regulations for improving access to controlled medicines, while preventing their misuse, have been successfully implemented in a number of countries;

Emphasizing the need for Member States,²⁴⁹ with the support of the Secretariat, the United Nations Office on Drugs and Crime, and the International Narcotics Control Board, to ensure that efforts to prevent diversion and abuse of narcotic drugs and psychotropic substances under international control, pursuant to the United Nations international drug control conventions, do not result in inappropriate regulatory barriers to medical access to such medicines;²⁵⁰

²⁴⁴ See the WHO website on maternal mortality, at <http://www.who.int/mediacentre/factsheets/fs348/en/> (accessed 29 January 2015).

²⁴⁵ See the WHO primary surgical care package website, at: <http://www.who.int/entity/surgery/publications/s16378e.pdf> (accessed 29 January 2015).

²⁴⁶ PLoS Medicine Editors. "A crucial role for surgery in reaching the UN Millennium Development Goals" PLoS medicine 5.8 (2008): e182.

²⁴⁷ WHO Integrated management for emergency and essential surgical care: see <http://www.who.int/surgery/publications/imeesc/en/> (accessed 29 January 2015).

²⁴⁸ Seya M-J., Gelders SFAM. Obianuju Uzoma Achara. Milani B. and Scholten WK. A first comparison between the consumption of and the need for opioid analgesics at country, regional, and global levels.. Journal of Pain & Palliative Care Pharmacotherapy. 2011;25:6–18.

²⁴⁹ And, where applicable, regional economic integration organizations.

²⁵⁰ See resolution WHA67.19.

Recalling that resolution WHA56.24 on implementing the recommendations of the *World report on violence and health* requested the Director-General to provide technical support for strengthening trauma and care services to survivors or victims of violence, and that resolution WHA57.10 on road safety and health recommended Member States to strengthen emergency and rehabilitation services for victims of road-traffic injuries;

Recognizing that 15% of the world's population live with a disability, and recalling that resolution WHA58.23 on disability, including prevention, management and rehabilitation urged Member States to promote early intervention and take necessary steps for the reduction of risk factors contributing to disabilities, especially during pregnancy and for children, and to put into practice the most effective actions to prevent disabilities, which include timely and effective surgery where required;

Aware of the critical importance of health system strengthening for providing access to quality, safe, effective and affordable emergency and essential surgical care and anaesthesia, and recalling resolution WHA60.22 on health systems: emergency-care systems, which recognized that improved organization and planning for the provision of trauma and emergency care, including surgery, is an essential part of integrated health-care delivery;

Recalling also resolution WHA64.6 on health workforce strengthening, which urges Member States to prioritize, in the context of global economic conditions, public sector spending on health, as appropriate, to ensure that sufficient financial resources are available for the implementation of policies and strategies to scale up and retain the health workforce, particularly in developing countries, and to recognize it as an investment in the health of the population that contributes to social and economic development, including access to emergency and essential surgical and anaesthesia services;

Recalling further resolution WHA66.10 on the follow-up to the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, which calls for action to prevent and control cardiovascular diseases, cancer, diabetes and chronic respiratory diseases, and noting the important role of surgical care for diagnosis, treatment and cure of a significant portion of these diseases;

Aware of the critical importance of access to and responsible use of effective antimicrobial agents for safe surgery, and recalling resolution WHA67.25 on antimicrobial resistance, which urges Member States to take urgent action to combat antimicrobial resistance;

Recalling resolution WHA67.19 on strengthening of palliative care as a component of comprehensive care throughout the life course, which urges Member States²⁵¹ to promote collaborative action to ensure adequate supply of essential medicines in palliative care, and requests the Director-General to explore ways to increase the availability and accessibility of medicines used in palliative care through consultation with Member States relevant networks and civil society, as well as other international stakeholders, as appropriate;

Acknowledging the work already done by WHO Global Initiative for Emergency and Essential Surgical Care in the WHO programme for emergency and essential surgical care, the World Alliance for Patient Safety and the Alliance's second global patient safety challenge: safe surgery saves lives;

Concerned that inadequate investment in the infrastructure of health systems, inadequate training of the surgical care health workforce, and the absence of a stable supply of surgical equipment and necessities in many countries impede progress in improving delivery of emergency and essential surgical care and anaesthesia;

²⁵¹ And, where applicable, regional economic integration organizations.

Recognizing that relevant, meaningful and reliable measures of safe emergency and essential surgery and anaesthesia are needed for assessment and monitoring, and to foster political and public support;

Acknowledging that many countries are unable to meet the threshold of 2.28 skilled health professionals per 1000, and many surgical procedures, including basic suturing, episiotomies, and draining of abscesses, can be successfully completed by other trained health care workers through task-sharing at the district and subdistrict levels;²⁵²

Considering that additional efforts are required globally to strengthen the provision of emergency and essential surgical care and anaesthesia so as to ensure timely and effective delivery to those who need such care in the overall context of the health system, and related health and health-promotion initiatives,

1. URGES Member States:²⁵³

- (1) to identify and prioritize a core set of emergency and essential surgery and anaesthesia services at the primary health care and first referral hospital level, and to develop methods and financing systems for making quality, safe, effective and affordable emergency and essential surgical care and anaesthesia services accessible to all who need it, including promoting timely referral and more effective use of the health care workforce through task-sharing, as appropriate, as part of an integrated surgical care network in order to achieve universal health coverage;²⁵⁴
- (2) to integrate emergency and essential surgical care and anaesthesia in primary health care facilities and first-referral hospitals, and to promote emergency and essential surgery and anaesthesia capacity as components integral to achieving universal health coverage;
- (3) to promote the provision of emergency and essential surgical care and anaesthesia and ensure that ministries of health take a lead role in, and intersectoral coordination mechanisms, including among all health care providers, are in place for, reviewing and strengthening the provision of such care;
- (4) to promote access to essential medicines, including controlled medicines, antibiotics, medical devices and diagnostics used in anaesthesiology and surgery that are of quality, safe, efficacious, affordable, and are used responsibly and appropriately and in line with WHO guidelines;
- (5) to carry out regular monitoring and evaluation of the emergency and essential surgical care and anaesthesia capacity of health care facilities to identify unmet infrastructural needs, human resource needs, training and supply needs;
- (6) to collect and compile data on number, type, and indications of surgical procedures performed, referrals, and perioperative mortality in their respective countries, and to share such data as appropriate;
- (7) to strengthen infection prevention and control as a critical element of ensuring quality and safety of emergency and essential surgical care and anaesthesia;
- (8) to develop and implement surgical care and anaesthesia policies to assure minimum standards for a skilled workforce, adequate equipment, infrastructure and supplies, and

²⁵² The world health report 2006. Working Together for Health. Geneva: World Health Organization; 2006.

²⁵³ And, where applicable, regional economic integration organizations.

²⁵⁴ See the WHO emergency and essential surgical care website, at <http://www.who.int/surgery/publications/imeesc/en/> (accessed 29 January 2015).

documenting, monitoring, and evaluation of access to and quality of services, to be embedded in programmes and legislation based on current knowledge and considerations promoting the right to the enjoyment of the highest attainable standard of health;

- (9) to ensure that appropriate core competencies are part of relevant health curricula, training, and education of students from various relevant disciplines such as medical, nursing, midwifery, and other surgical care providers, as well as continuing education for professionals involved in provision of surgical care and anaesthesia;

2. REQUESTS the Director-General:

- (1) to foster multisectoral networks and partnerships, multidisciplinary policies and action plans, and support national, regional and global efforts to develop science-based approaches to prevention, screening, and implementation of emergency and essential surgical care and anaesthesia and to enhance teaching and training programmes;
- (2) to facilitate collaboration among Member States²⁵⁵ to share and exchange information, skills and technology essential to strengthening surgery and anaesthesia services;
- (3) to raise awareness of cost-effective options to reduce morbidity, mortality and prevent or treat disability and deformity through improved organization and planning of provision of anaesthesia and surgical care that is appropriate for resource-constrained settings, and continue to organize regular expert meetings to further technical exchange and build capacity in this area;
- (4) to establish mechanisms to collect emergency and essential surgical and anaesthesia case log data in order to increase understanding of unmet needs and improve the global capacity for surgery and anaesthesia in the context of universal health coverage;
- (5) to devise relevant, meaningful and reliable measures of access to and safety of emergency and essential surgery and anaesthesia, and make available a means of performing risk adjustment of indicators such as the perioperative mortality rate, and reporting and benchmarking of these measures;
- (6) to collect, assess and report related cost data on the delivery of emergency and essential surgical care and anaesthesia, as well as the economic impact of their availability;
- (7) to support Member States²⁵⁶ in the development and implementation of policies and regulations for ensuring access to quality, safe, efficacious and affordable-essential medicines, including controlled medicines for pain management, medical devices and diagnostics that are used in emergency and essential surgical care and anaesthesia;
- (8) to continue, through WHO's access to controlled medicines programme, to support Member States in reviewing and improving national legislation and policies with the objective of ensuring a balance between the prevention of misuse, diversion and trafficking of controlled substances and appropriate access to controlled medicines, in line with United Nations international drug control conventions;
- (9) to work with the International Narcotics Control Board, the United Nations Office on Drugs and Crime, health ministries and other relevant authorities at global, regional and national levels in order to promote the availability and balanced control of controlled medicines for essential and emergency surgical care and anaesthesia;
- (10) to further cooperate with the International Narcotics Control Board to support Member States²⁵⁷ in establishing accurate estimates in order to enable the availability of medicines

²⁵⁵ And, where applicable, regional economic integration organizations.

²⁵⁶ And, where applicable, regional economic integration organizations.

²⁵⁷ And, where applicable, regional economic integration organizations.

for emergency and essential and surgical care and anaesthesia, including through better implementation of the guidance on estimating requirements for substances under international control;

- (11) to support Member States²⁵⁸ to devise policies and strategies that enhance the skills of the appropriate health workforce for emergency and essential surgical care and anaesthesia, especially at primary health care and first referral hospital level;
- (12) to set aside adequate resources for the Secretariat, in line with the Proposed programme budget 2016–2017 and the Twelfth General Programme of Work, 2014–2019 for strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage;
- (13) to work with Member States and other relevant partners to design strategies that provide support to Member States for mobilizing adequate resources to achieve the objectives of strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage;
- (14) to report back to the Seventieth World Health Assembly in 2017 on progress in the implementation of this resolution.

²⁵⁸ And, where applicable, regional economic integration organizations.

17.3 Substandard/spurious/falsely-labelled/falsified/counterfeit medical products

Document A68/33 (Report by the Director-General):

Substandard/spurious/falsely-labelled/falsified/counterfeit medical products

1. The attached document EB136/29 was noted by the Executive Board at its 136th session.²⁵⁹ The Board also adopted decision EB136(1) in which it decided to request the Sixty-eighth World Health Assembly to postpone the review of the Member State mechanism by one year, to 2017, as proposed by the mechanism in its report.²⁶⁰

ACTION BY THE HEALTH ASSEMBLY

2. The Health Assembly is invited to consider the request made in decision EB136(1).²⁶¹ Should the Health Assembly agree with the Board's request, it is invited to adopt the following draft decision:

The Sixty-eighth World Health Assembly, having considered the report on substandard/spurious/falsely-labelled/falsified/counterfeit medical products²⁶² and decision EB136(1) of the Executive Board, decided to postpone the review of the Member State mechanism by one year, to 2017, as proposed by the mechanism in its report.

Document EB136/29 (Report by the Director-General)

Substandard/spurious/falsely-labelled/falsified/counterfeit medical products

The Director-General has the honour to transmit to the Executive Board at its 136th session the report of the third meeting of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products (see Annex), which met in Geneva from 29 to 31 October 2014.²⁶³

ANNEX

REPORT OF THE THIRD MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/FALSIFIED/COUNTERFEIT MEDICAL PRODUCTS

1. The third meeting of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products met from 29 to 31 October 2014 in Geneva and was chaired by Ambassador Alberto Pedro D'Alotto of Argentina with the following vice-chairpersons: Dr

²⁵⁹ See summary records of the 136th session of the Executive Board, ninth meeting.

²⁶⁰ See document EB136/2015/REC/1.

²⁶¹ "The Executive Board, having considered the report of the third meeting of the Member State Mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products [document EB136/29, Annex], decided to request that the World Health Assembly postpone the review of the Member State mechanism by one year, to 2017, as proposed by the mechanism in its report."

²⁶² Document A68/33.

²⁶³ The goal, objectives, and terms of reference for this mechanism were approved at the Sixty-fifth World Health Assembly in resolution WHA65.19, and are set out in the Annex to the resolution.

Paul Botwev Orhii of Nigeria; Ms Lou Valdez of the United States of America; Mr Alastair Jeffrey of the United Kingdom of Great Britain and Northern Ireland; Ambassador Carole Lanteri of Monaco; Mr Rolliansyah Soemirat of Indonesia; Dr V.G. Somani of India; and Ms Ruth Lee of Singapore.²⁶⁴ The session was attended by 63 Member States and one regional economic integration organization.

2. The mechanism reviewed the outcome of the informal technical meeting on recommendations for health authorities to detect and deal with actions, activities and behaviours that result in SSFFC medical products. The mechanism agreed to language proposed by the Chair of the informal meeting for the paragraphs on which agreement had not been reached, with the understanding that the reference to the medical products supply chain in its entirety in paragraph 6 of the outcome document should mean from starting materials to finished products, as indicated in paragraph 8(a). The outcome document is attached at Annex 1.

3. The mechanism reviewed the outcome of the informal technical meeting on element 5(b) of the work plan on the identification of activities and behaviours that fall outside the mandate of the mechanism. The mechanism revised a list of actions, activities and behaviours that fall outside the mandate of the mechanism, but did not reach consensus on the title, a paragraph in the introductory section and elements 3 and 7 of the document. The mechanism requested that the Steering Committee further consult on the document with a view to proposing language for the remaining issues in the paper for submission to the fourth meeting of the Member State mechanism on SSFFC. The outcome document is attached at Annex 2.

4. The mechanism welcomed the Secretariat's presentations on the activities and budget of the Member State mechanism, and expressed concern over the unfunded activities in the budget.

5. Several Member States expressed their intention to contribute to the activities of the Member State mechanism on SSFFC.

6. The mechanism expressed appreciation for the Secretariat's presentation on the WHO Global Surveillance and Monitoring Project. The Secretariat was requested to provide to Member States the schedule of future workshops, further information on the working definitions used by the Secretariat in identifying SSFFC medical products under the project and to further expand the project to cover all regions.

7. The mechanism reviewed a proposal by the Steering Committee on proposals and priorities for implementation of the work plan. The mechanism revised and agreed the list of prioritized activities for 2014–2015, which is attached at Annex 3. With respect to the costs and funding of the activities, the Secretariat was requested to provide updated information for the next meeting of the Steering Committee. Furthermore, the mechanism decided that:

- (a) Activity A will be led by Brazil.
- (b) Activity B will be supported by Switzerland and United Kingdom of Great Britain and Northern Ireland and that the Secretariat prepare a draft terms of reference for the focal point network for discussion by the Steering Committee at its next meeting and posted on a web platform in advance of the meeting.
- (c) Activity C will be led by Argentina.
- (d) Activity D will be led by the Secretariat.

²⁶⁴ The following vice-chairpersons were unable to attend the meeting: Mr Amadou Mactar Dieye of Senegal, Dr Fareha Bugti of Pakistan. WHO has been informed that new vice-chairpersons from the Eastern Mediterranean region and China will be nominated.

- (e) Activity F will be led by the Secretariat and would involve the convening of an expert group to conduct the study. Updates on this work, including on the methodology and scope of the study, would be reported to the next meeting of the Steering Committee for consideration and posted on a web platform in advance of the meeting.
- (f) Work on the prioritized list of activities should begin in advance of the next meeting of the Steering Committee and begin with electronic consultations using the Secretariat's web platform.

8. The mechanism decided that a study to increase understanding and knowledge on the links between accessibility and affordability and their impact on the emergence of SSFFC medical products and to recommend strategies to minimize their impact will be included on the next provisional list of activities for consideration by the fourth meeting of the Member State mechanism.

9. The mechanism requested the Secretariat to take into account the costing of the mechanism activities in the finalization of the Proposed programme budget 2016–2017.

10. The mechanism requested that at the next meeting the Secretariat provide an update on paragraph 2(11) of resolution WHA67.20 on Regulatory system strengthening for medical products, which request the Director-General to ensure that any activity carried out under the resolution does not duplicate or circumvent the work plan and mandate of the Member State mechanism on SSFFC.

11. The Member State mechanism discussed the review of the Member State mechanism by the Health Assembly in 2016 in accordance with resolution WHA65.19 and decided to request that the World Health Assembly postpone the review of the Member State mechanism by one year.

12. The mechanism decided to request that the Steering Committee discuss at its next meeting the alignment between the commencement and the end/expiration of the term of office of the vice-chairpersons and the term of the rotating chair.

13. The Member State mechanism decided that its next meeting would be held during October or November 2015.

ANNEX 1

RECOMMENDATIONS FOR HEALTH AUTHORITIES TO DETECT AND DEAL WITH ACTIONS, ACTIVITIES AND BEHAVIOURS THAT RESULT IN SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/FALSIFIED/COUNTERFEIT MEDICAL PRODUCTS

I. INTRODUCTION

1. The existence of SSFFC²⁶⁵ medical products in the market and their consequence to public health make national and/or regional regulatory authorities (NRRA) face the need for structuring and improving their processes, and establishing proactive strategies for the effective prevention and combat against the actions, activities and behaviours that result in these products.

²⁶⁵ For the purpose of this document, SSFFC will be used in accordance with reference to the footnote in Resolution WHA65.19: *"The Member State mechanism shall use the term 'substandard/spurious/falsely-labelled/falsified/counterfeit medical products' until a definition has been endorsed by the governing bodies of WHO"*, and the current document will not prejudice any further negotiation in relation to the definition within the MSM on SSFFC medical products.

2. In light of this challenge, it is paramount that the measures implemented by NRRAs be previously defined and that authorities be prepared to prevent, detect and take action in cases of actions, activities and behaviours that result in SSFFC medical products. The purpose of this document is not to establish rigid work procedures but to provide guidelines for coordinated action, based on the growing experiences of the countries, which are intended to serve as reference to NRRAs for action definition and execution.

3. These guidelines will not exhaust the discussion on the topic, but represent a significant step in the process of strengthening NRA capacities, with the intent to make them more effective in the interest of protecting public health.

4. The activities described in this guide may be considered and adapted by NRRAs, according to the legal, regulatory and operational structure of each country or region, from a public health perspective, excluding trade and intellectual property considerations.

II. STRATEGIES BY NRA TO DETECT ACTIONS, ACTIVITIES AND BEHAVIOURS THAT RESULT IN SSFFC MEDICAL PRODUCTS

5. Some tasks and work processes are significant for the detection of actions, activities and behaviours that result in SSFFC medical products:

- quality monitoring (inspections) and control (laboratory testing) in the supply chain;
- alerts from track and trace systems in those countries where such systems have been implemented;
- global and/or regional alerts issued from another NRA and/or WHO;
- reception, assessment and investigation of reports or notifications (generated by any person, such as manufacturers, wholesalers, distributors, consumers and whistle-blowers, as appropriate).

II.1. Quality monitoring and control

6. Field procedures/inspections are important to verify compliance with national regulations, including current good manufacturing and distribution practices. It is advisable that monitoring activities be carried out in accordance with established procedures, using a risk-based approach that assesses the weaknesses of the medical products supply chain in its entirety and other pieces of information previously obtained, such as the names of the companies involved or tracing activities resulting in the highest number of suspect SSFFC medical products.

7. Therefore, it is important to establish a specific monitoring programme on the distribution chain, including the consideration of compliance history related to good manufacturing/ distribution practices, in order to detect SSFFC medical products and evaluate the appropriate documentation held by regulated establishments related to the sale and distribution of the products and the legality of suppliers and customers. Another important point is to take into account the data obtained from quality monitoring and control tasks to determine measures and work processes that strengthen the regulated medical product supply chain and minimize or prevent the introduction of SSFFC products.

8. Based on the established strategies and objectives, the operational approaches should include the following cornerstones:

- (a) verification of current good manufacturing and distribution practices in the supply chain of medical products, from starting materials to finished medical product, as appropriate;
- (b) verification of the medical products distribution chain, by checking the origin/source and destination for each transaction or transfer of possession;

- (c) identification of SSFFC medical products in the chain (through any means, such as post-marketing surveillance, coordination with customs, other law enforcement agencies and marketing authorization holders);
- (d) identification and investigation of actions, activities and behaviours that result in SSFFC medical products;
- (e) collection of samples for verification and/or analysis;
- (f) recall and/or prohibition of the distribution and use of SSFFC medical products detected (including recall at patient's level).

II.2. Alerts from track and trace systems

9. Product track and trace systems are very useful tools that enable the detection of actions, activities and behaviours that may result in SSFFC medical products.

10. When developing such systems, it is important to observe the circumstances triggering alerts in order to conduct targeted inspections. Some aspects to take account of in alert tracking include the detection of duplicated codes, the attempt to divert serialized products that were previously invalidated for having been stolen, sent out for destruction, intended for marketing outside the national territory, dispensed to patients or any other similar situation.

11. All alerts stemming from track and trace systems must be considered and evaluated; and those posing a greater risk for public health must be prioritized.

II.3. Reception of alerts, reports and notifications

12. The health NRA should keep open and accessible communication channels with the public (e.g. health professionals, patients and consumers) and with other relevant authorities providing a method for the public to submit reports or notifications and responding to such submissions in a timely fashion.

13. It is recommended that the reports be received through different ways, such as in-person, by post mail, telephone or e-mail. Reports or notification should be recorded, documented and organized systematically, preferably using a single information system.

14. Regardless of the channels specifically created to receive this type of report, it is advisable that, where appropriate, the report reception system on suspected SSFFC medical products is communicated to pharmacovigilance or investigation systems concerned with product quality problems.

15. Always considering the particular aspects of each case, it is advisable to have the sample, if possible, attached to a report form on the suspected SSFFC medical products containing as much pertinent data as possible, including but not limited to: identification and description of the problem, contact details for the person or entity reporting the problem, product name (International Nonproprietary Name and brand name, if any), batch, manufacturing date, expiry date, manufacturer or marketing authorization holder (hereinafter MAH), location/source where the product was acquired (online, authorized or unauthorized establishment), and description of any adverse events due to the use or application of the suspected SSFFC medical product.

III. ASSESSMENT OF ALERTS, REPORTS AND NOTIFICATIONS RECEIVED

16. It is recommended that a risk assessment be performed in the evaluation of reports received, bearing in mind the seriousness of the event, the frequency of occurrence and the use of the

medical product, to determine the potential impact to public health, as per the relevant national or regional regulatory framework.

17. Some of the elements to be considered when assessing the seriousness of reports include: the therapeutic indication, route of administration, dosage, recommended patient population (e.g. those concerned by the medical fields of paediatrics or geriatrics, pregnant women or others with compromised immune systems), toxicity, potency, narrow therapeutic ratio, chronic use, psychotropic substances and volumes.

18. All notifications should be assessed by the NRRA as soon as possible. Further inspections and eventual corrective actions should be prioritized on the basis of the health risk identified. NRRA and other relevant authorities may utilize covert investigative methods when looking into reports of suspected SSFFC medical products, collaborating with their law enforcement counterparts, as necessary.

IV. INVESTIGATION OF ACTIONS, ACTIVITIES OR BEHAVIOURS RESULTING IN SSFFC MEDICAL PRODUCTS

19. In general, the identification or detection of an SSFFC medical product represents a starting point for the identification of the actions, activities or behaviours that caused its occurrence.

20. Investigation is extremely important for NRRA evidence-based decision-making and its purpose is to identify possible threats to public health and their causes. Therefore, this activity requires knowledge, technical skill and the experience of the investigator.

21. Based on the risk assessment and the definition of the cases to be investigated on a priority basis, the approach to suspected SSFFC medical products, and actions, activities and behaviours resulting in SSFFC medical products comprises a series of systematic, specific and supplementary actions and should follow a set yet flexible work procedure, in order for adequate containment measures to be adopted in a timely and effective manner.

22. Every action is to be recorded by the NRRA, preferably, in an investigation file including all gathered evidence, in which all the procedures conducted based on the measures adopted and the information obtained are included chronologically.

23. With a view to taking swift and effective action, it is critical that NRRA establish an action strategy based on the elements and data collected in each case. Some of the aspects and information to take account of include:

- if the action, activity or behaviour was performed intentionally and deliberately;
- if the action, activity or behaviour took place inside or outside of the regulated chain;
- custody of SSFFC medical product sample or the need to obtain the product sample;
- need for conducting an inspection at the product manufacturer or MAH premises among others;
- need for requesting additional information from companies, individuals, organizations or other stakeholders involved in the case;
- need for conducting field surveillance/monitoring actions;
- need for information exchange with other institutions;
- logistical and operational aspects;
- need for establishing a public-oriented dissemination strategy of the case;

- need for information exchange with other NRRA and WHO.

24. The action plan should be dynamic, reviewed and updated based on the results obtained in each case. According to the needs of each case, different activities can be adopted at different times of performance. As an example, actions can be categorized as follows:

(a) Immediate actions

- confirming the suspicious SSFFC medical products and characterizing the action, activity or behaviour;
- containing the situation to prevent and reduce the risk to public health from the action, activity or behaviour resulting in SSFFC medical products;

(b) Short-term actions

- communicating and disseminating case related information to appropriate parties;
- identifying the persons or entities to be held accountable;

(c) Long-term actions

- follow through with the investigation and appropriate health care support.

IV.1. Immediate actions

25. Actions to be implemented in an urgent manner in order to confirm the suspicion of an SSFFC medical product, and prevent and reduce the risk to public health.

IV.1.1. Confirming the suspicious SSFFC medical products and characterizing the action, activity or behaviour

26. To confirm the suspected SSFFC medical product, it is useful to have available the allegedly irregular sample in sufficient quantities for laboratory analysis or, at least, some of its components (e.g. packaging and labels), in order to conduct a careful visual comparison with a sample of the genuine authorized product.

27. It is paramount that consideration be given to the differences in elements such as packaging, labels, characteristics and physical aspects of the various components of the product (e.g. shape, colour and odour); general printing characteristics, typography, wording in labels, patient information leaflets/inserts; and batch coding form, manufacture and expiration date.

28. It is advisable that MAHs retain samples of the batches of products and/or packaging materials released to the market, where applicable legislation does not provide for such retention.

29. In the case of a report or notification wherein no sample was provided, it is of vital importance to obtain the sample directly from the patient or the establishments where, according to the notification or report, the product is being marketed or used.

30. It is important to include thorough documentation of the handling of such samples and maintain secure procedures for ensuring a transparent chain of custody for possible subsequent criminal investigation or prosecution where the sample may be used as evidence. In such circumstances, it is critical to maintain the integrity of the sample.

IV.1.2. Testing in quality-control laboratories

31. The use of basic or complete analytical assays based on methodologies encoded in official standards such as pharmacopoeias, compendia, methodologies of the MAH acknowledged, approved or authorized by the NRRRA or others legally accepted, will be useful in reinforcing any determination made on the suspected sample. This will be particularly useful in situations where the physical comparative and/or other sensory-affecting examination between the allegedly SSFFC sample and the authentic medical product has not rendered final conclusions. This testing may represent a measure to determine the composition of the product and assess the product for possible toxicity, contamination, and/or undeclared composition that might cause adverse reactions. This may generate an updated risk assessment.

32. Likewise, even when tests results are satisfactory for a particular sample, it should be taken into account that no knowledge is available about the product's manufacturing process and the quality system adopted by the manufacturer of the suspected sample. On the other hand, it is not possible to ensure dose consistency and manufacture batch homogeneity, which is why the actions, activities and behaviours resulting in SSFFC medical products must always be considered as high risk, regardless of the analytical results.

IV.1.3. Containing the situation to prevent and reduce the risk to public health from the action, activity or behaviour resulting in SSFFC medical products

(a) Prohibition regulations

33. The NRRRA should evaluate the need of implementing regulations prohibiting the distribution and use of SSFFC medical products. In this connection, consideration should be given to the possibility of extending the prohibition to the whole product, if the number of SSFFC medical product batches was significant.

(b) Recall from market

34. If the batch or batches of products that are linked to actions, activities and behaviours that result in SSFFC medical products detected in the market are related to batches legitimately distributed by the MAH, among others, the NRRRA should evaluate the need for ordering to a market recall from distribution channels, in order to minimize the risk to patients.

35. The MAH or the manufacturing authorization holder should audit and qualify the units recovered from distribution channels and inform the NRRRA about the results obtained.

36. Disposal and destruction of SSFFC medical products should follow appropriate national or regional legislation or procedures to prevent such products from being reintroduced or sold to the public.

(c) Contingency plan for supporting patients and their relatives

37. The NRRRA, in coordination with concerned stakeholders, should develop plans and procedures for implementing an emergency system when needed, taking into account the following aspects:

- telephone and in-person attention of inquiries;
- collection of samples for verification;
- medical guidance and/or referral to specialized healthcare and/or toxicology centres;
- coordination with relevant stakeholders for additional resources, as needed;
- communication strategy for disseminating the information to the public.

(d) Reporting the case at international level

38. The NRRRA should evaluate the case or cases of detection of actions, activities or behaviours resulting in SSFFC medical products and report to the possible affected Member States. Establishing and maintaining a network of national focal points is crucial for this type of communication.

IV.1.4. Field actions or inspections

39. Field actions represent an opportunity for the collection of material evidence or evidence of the actions, activities and behaviours that result in SSFFC medical products. Therefore, it is important to establish a monitoring programme for the distribution chain, in order to detect actions, activities and behaviours that resulted in SSFFC medical products and assess the acquisition or possession documentation held by such companies.

40. At national level, there are competent institutions for conducting criminal investigations, should there be criminal provisions stipulated for crimes related to SSFFC medical products. The primary role of the NRRRA should be focused on the adoption of health measures and providing support to the institutions conducting criminal investigations.

IV.2. Short-term actions

41. These actions are concerned with the objective of communicating relevant facts of the case to the public, healthcare professionals and other authorities and relevant stakeholders, as applicable; its potential risks on health; preventing the consumption and exposure by patients; and of identifying the parties involved in the actions, activities and behaviours resulting in SSFFC medical products.

IV.2.1. Communicating and disseminating relevant information about the case

42. The information about a confirmed case of detection of actions, activities and behaviours resulting in SSFFC medical products should be published on the NRRRA official website, with immediate access to its content. It is important that this information be transmitted to the WHO reporting database and to various entities and organizations, in order to complete the measures initiated by the NRRRA, with a view to reducing patients' exposure as much as possible.

43. Such information may include:

- general information on the case;
- comparative photographs of the legitimate/authorized medical product versus the SSFFC medical product;
- procedures to be followed by those in possession of medical products with the characteristics of the product identified as SSFFC;
- regions of the country where SSFFC medical products and/or actions, activities and behaviours that result in SSFFC medical products have been detected;
- medical information related to the consumption of the SSFFC medical product.

44. It is important that the actions and activities conducted by NRRAs ensure adequate information be given to the public, while not compromising investigations and judicial activities, if at all possible.

IV.2.2. Identifying the entities responsible for actions, activities and behaviours that result in SSFFC medical products

45. Where appropriate, the NRRA should share the information with other relevant authorities, the action, behaviour or activity detected that result in SSFFC medical products, and all the evidence in its possession is to be submitted.

46. In this regard, it is important, from a public health perspective, that cooperation between NRRA and other relevant authorities occur in a transparent and coordinated manner.

IV.3. Long-term actions

IV.3.1. Maintenance of the alert state

47. The maintenance of the alert state involves a series of activities aimed at detecting new activities, measures or behaviours resulting in SSFFC medical products; evaluating the effectiveness of the measures adopted and the support to patients.

(a) Continuity of the monitoring programme

48. The monitoring programme on the distribution chain of medical products should be continued with the purpose of:

- eliminating from the distribution channels those medical products governed by prohibiting regulations issued by the NRRA;
- obtaining any type of information related to the origin of the SSFFC medical products;
- verifying new lines of introduction of SSFFC medical products in the distribution channels;
- verifying the existence of new batches of the identified SSFFC medical product;
- verifying the existence of products with the same active substance and/or the same manufacturer or distributor as those of the SSFFC medical product detected, that may also be SSFFC;
- following up of the market recall after it has been ordered;
- monitoring other batches of the medical product identified as SSFFC by means of tracking and tracing systems.

(b) Continuity of the contingency plan for health care community support

49. The health care community should be kept apprised of the situation and be instructed to remain vigilant in purchasing practices.

50. Patients and their relatives should continue receiving support for the purpose of following up the cases reported and verifying the possible occurrence of new cases.

IV.3.2. Continuity of collaboration with authorities in charge of the investigation

51. The NRRA should have at their disposal qualified personnel who can work with authorities in charge of the investigation, in order to provide technical collaboration in investigational procedures that so require it.

V. ASSESSMENT OF PREVENTION STRATEGIES

52. Results obtained should be assessed, taking into account the behaviours that resulted in the SSFFC medical products and in order to establish strategies to prevent the future occurrence of actions, behaviours and activities similar to those detected.

53. To this end, following a comprehensive assessment of the case, the NRRA may implement, inter alia, new strategies for control; inspectorate strengthening; safety measures on products; legislation oriented to preventing certain actions or behaviours.

V.1. Strengthening regulatory requirements on medical products

54. Following a comprehensive assessment of the case, the NRRA may implement, inter alia, new strategies for control; inspectorate strengthening; safety measures on products; legislation oriented to preventing certain actions or behaviours.

V.2. Developing awareness campaigns for the public and healthcare providers

55. NRRAs should develop strategies to raise awareness of actions, activities and behaviours that result in SSFFC medical products. Such awareness campaigns should include the dangers posed by such products, tips on identifying such SSFFC medical products, and recommendations on how to safely purchase medical products.

ANNEX 2

Actions, activities and behaviours that fall outside the mandate of the Member State mechanism [and separated from the list of actions, activities and behaviours that result in SSFFC medical products] [as they][[and] do not result in a public health risk]

Objective 4 of the MSM's terms of reference as reflected in Element 5 of the work plan mandated the mechanism to identify a list of actions, activities and behaviours that result in SSFFC medical products being prevented and controlled due to the health risk they present to the population and also identify those that fall outside the mandate of the mechanism and separate them from the aforementioned list.

Annex I of document A/MSM/2/6 lists the actions, activities and behaviours that result in SSFFC medical products. The list set out below is a non-exhaustive list of actions, activities and behaviours that fall outside the mandate of the MSM and they should be separated from the actions, activities and behaviours that result in SSFFC medical products. This list could be subject to revisions and adjustments in the future.

[The rationale behind this exercise is to ensure that unauthorized actions, activities and behaviours and medical products will face regulatory actions; whereas authorized actions, activities and behaviours and medical products not posing health risks will not face unjustified regulatory actions, in order not to hamper access to quality, safe and efficacious medical products.]

The term "regulatory authority" used in this paper means the national or regional regulatory authority for medical products.

1. Actions, activities and behaviours in violation of laws other than medical product regulations, such as actions or behaviours in conflict with taxation, duties, customs laws.
2. Actions, activities and behaviours relating to manufacturing, storage, distribution, import and export of quality medical products authorized by the national and/or regional regulatory authority.
3. Actions, activities and behaviours of licensee/authorization holders involving minor deviations, as determined by national and/or regional regulatory authorities, which do not compromise the quality or which do not pose a health risk, [such as minor [unintentional] deviations in good manufacturing practice.]

4. Actions, activities and behaviours related to medical products, exclusively meant for own use of a traveller and carried by himself/herself.
5. Actions, activities and behaviours that are related to the protection or infringement and enforcement of intellectual property rights, including data exclusivity.
6. Actions, activities and behaviours related to medical products meant solely for the purpose of research and development and laboratory testing[,] not for human use.
7. [Actions, activities and behaviours] [in case of medical products in transit, which are in compliance with the regulatory requirements of the country of export and the country of final destination.][which may not be in compliance with the regulatory requirements of the country of transit [while preserving the integrity of the medical product in transit.][and except if there are grounds for suspecting the existence of SSFFC medical products.]]
8. Importing, exporting, distributing, including transporting, storing, supplying or selling authorized/licensed medical products from a country to another country where there is no market authorization/licence existing for that product in order to meet a national emergency, extreme urgency or humanitarian crisis with the consent of the country concerned.

ANNEX 3

| LIST OF PRIORITIZED ACTIVITIES BY THE MEMBER STATE MECHANISMS FOR 2014– 2015 Prioritized activities | Relevant item(s) of the work plan | Activities |
|--|--|---|
| A. Develop recommendations for the Health Authorities engaged in the detection of SSFFC medical products and establish a strengthening and tool-generating programme to contribute to Member States' training | 1, 2, 3, 4, 6.(e), 7.(c), 8 | <p>1. Establish and convene an MSM working group comprised of experts from Member States to:</p> <p>(i) draft recommendations to strengthen NRRAs in their prevention, detection and response to SSFFC medical products, including on criteria for risk classification and assessment prioritization of cases of SSFFC medical products;</p> <p>(ii) develop training material for NRRAs in hard and soft copy, multilingual, virtual and face-to-face formats focused on the prevention, detection and response to SSFFC medical products.</p> |
| B. Create a focal point network for the exchange of information and consultation at large among Member States and establish an ongoing virtual exchange forum | 2, 4, 6.(h), 7, 8.(a) | <p>1. Develop terms of reference for a focal point network, while utilizing and building upon the existing network of focal points established in 80 Member States and 18 procurement agencies as part of the WHO Surveillance and Monitoring system.</p> <p>2. Develop an online portal to facilitate communication and information exchange.</p> <p>3. Publish a monthly bulletin in addition to WHO Medical Product Alerts.</p> |

| | | |
|--|---|--|
| C. Establish a working group to survey the technologies, methodologies and “track and trace” models in place and to be developed to analyse their advantages and disadvantages and to survey the available authentication and detection technologies and methodologies and analyse their advantages and disadvantages | 1.(a), 1.(b), 2, 3, 4, 6.(a), 6.(b), 6.(d), 6.(e), 6.(f), 7, 8.(a), 8.(b) | <p>1. Establish and convene a working group comprised of Member States experts to assess and report on:</p> <p>(a) existing “track and trace” technologies in use by Member States; and</p> <p>(b) existing field detection devices in use or available to Member States.</p> |
| D. Identify WHO areas working on the issue of access to quality, safe, efficacious and affordable medical products and request a report on the current state of affairs | 8 | 1. Engage the WHO Secretariat to review and report on all WHO activities on access to quality, safe, efficacious and affordable medical products, from an SSFFC medical products approach. |
| E. Create a working group to develop and leverage existing recommendations for effective risk communication and recommendations for awareness campaigns on SSFFC medical products and related actions, activities and behaviours. | 3, 8.(a) | <p>1. Establish a working group, including communication experts to develop or leverage recommendations for effective risk communication and awareness campaigns specifically tailored for regions/subregions and stakeholder groups.</p> <p>2. Produce samples of hard and soft copy material, video and broadcast material.</p> <p>3. Assess the use of social media for raising awareness.</p> <p>4. Identify full range of stakeholders and audiences.</p> <p>5. Develop key and innovative advocacy material.</p> |
| F. A proposal for a study on the public health and socio-economic impact of SSFFC medical products | 3.(b), 8.(c) and 8.(d) | 1. Establish an expert group of health economists to conduct a study on public health and socio-economic impact of SSFFC medical products, convene 3 meetings in Geneva and report. |
| G. Governance, management and secretariat costs to support the above activities | | ²⁶⁶ Organizing Member State mechanism meetings, steering committees and working groups. Coordination of activities and implementation by headquarters and regional offices. |

²⁶⁶ As endorsed, see document A67/29, Annex 3 on budget and cost implications.

DECISION 17.3:

Executive Board Decision EB136(1): Substandard/spurious/falsely-labelled/falsified/counterfeit medical products

The Executive Board, having considered the report of the third meeting of the Member State Mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products,²⁶⁷ decided to request that the World Health Assembly postpone the review of the Member State mechanism by one year, to 2017, as proposed by the mechanism in its report.

²⁶⁷ Document EB136/29, Annex.

17.5 Global strategy and plan of action on public health, innovation and intellectual property

Document A68/35 (Report by the Secretariat):

Global strategy and plan of action on public health, innovation and intellectual property

BACKGROUND

1. The global strategy on public health, innovation and intellectual property and the agreed parts of the related plan of action were adopted by the Sixty-first World Health Assembly,²⁶⁸ with the final plan of action being adopted by the Sixty-second World Health Assembly.²⁶⁹
2. The World Health Assembly asked for biennial reporting on implementation, in addition to comprehensive evaluation of the strategy after four years.²⁷⁰ Furthermore, the Health Assembly requested the Director-General “to conduct an overall programme review of the global strategy and plan of action in 2014 on its achievements, remaining challenges and recommendations on the way forward to the Health Assembly in 2015 through the Executive Board”.²⁷¹
3. In its report to the Executive Board at its 133rd session,²⁷² the Secretariat proposed an approach of combining the evaluation and the overall programme review into a single instrument and provided additional information on the scope, modalities and process for the combined exercise.
4. Building on the discussions on this subject at the 133rd session of the Executive Board, the Secretariat presented to the Executive Board at its 136th session a proposal²⁷³ for a process and timeline for the comprehensive exercise (combining the evaluation and the overall programme review) that would foresee presentation of the evaluation report to the Health Assembly in May 2017.
5. Having considered the report, the Executive Board decided by decision EB136(17) to recommend to the Sixty-eighth World Health Assembly to extend the deadline of the overall programme review to 2018. It further requested the Director-General to provide a report to the Sixty-eighth World Health Assembly on options, in consultation with Member States, for the conduct of the comprehensive evaluation and the overall programme review, including whether to combine the two instruments, sequencing, terms of reference, timing and options for establishing an evaluation management group with the goal of completing this exercise by 2018.
6. In response to that request, this paper outlines options for the following:
 - (a) combining the two instruments, including terms of reference, timelines and process;
 - (b) undertaking the comprehensive evaluation and overall programme review separately in a staggered manner, including terms of reference, timelines and processes for each of these instruments;
 - (c) establishing the evaluation management group in support of the comprehensive evaluation.

²⁶⁸ Resolution WHA61.21.

²⁶⁹ Resolution WHA62.16.

²⁷⁰ See document WHA61/2008/REC/1, resolution WHA61.21, Annex, paragraph 41.

²⁷¹ Resolution WHA62.16, paragraph 6.

²⁷² Document EB133/7.

²⁷³ Document EB136/31.

7. Although the biennial reporting requirements are well defined, there is no specific guidance in the global strategy and plan of action on how to conduct the overall programme review and the comprehensive evaluation. For the purposes of this paper, the broad definitions described below are proposed for (i) the comprehensive evaluation and (ii) the overall programme review.

8. The comprehensive evaluation will comply with the WHO evaluation policy and be guided by the processes and methodology proposed in the *WHO evaluation practice handbook*.²⁷⁴ In the current context, this evaluation is envisaged as a formative evaluation i.e. an evaluation conducted during the implementation phase of the global strategy and plan of action, with the intention of documenting achievements, gaps and remaining challenges and of making recommendations on the way forward.

9. The overall programme review will be a more policy-oriented, forward-looking exercise. Using specific terms of reference, the programme review will consider the findings of the comprehensive evaluation, together with other technical and managerial aspects of the programme, with a view to identifying what needs to be improved and modified in the next stages of the global strategy and plan of action. The programme review will add a broader policy perspective to the assessment, but it will not apply the methodology of an evaluation. Furthermore, while it will also seek to undertake an assessment of implementation of the global strategy and plan of action (both success factors and challenges), it also offers possibilities for broader engagement of different stakeholders at various stages of the process.

OPTIONS FOR CONSIDERATION

Combining the two instruments

10. As noted above, a suggested approach to combine the two instruments and terms of reference for such an exercise were outlined in document EB133/7. This was further elaborated in the proposal for a process and timeline set out in the Secretariat's report to the Executive Board at its 136th session (document EB136/31).

Undertaking the comprehensive evaluation and overall programme review separately in a staggered manner

11. The approach for undertaking the comprehensive evaluation and overall programme review separately in a staggered manner, starting with the evaluation and following with the programme review, is presented below. It is further illustrated in Annex 1.

Terms of reference of the comprehensive evaluation

12. The overall purpose of the comprehensive evaluation is to assess the status of implementation of the eight elements of the global strategy:

- (a) prioritizing research and development needs
- (b) promoting research and development
- (c) building and improving innovative capacity
- (d) transfer of technology
- (e) application and management of intellectual property to contribute to innovation and promote public health
- (f) improving delivery and access
- (g) promoting sustainable financing mechanisms

²⁷⁴ WHO evaluation practice handbook. Geneva: World Health Organization; 2013.

(h) establishing monitoring and reporting systems.

13. Covering the period 2008–2015, the evaluation would document achievements, gaps and remaining challenges and make recommendations on the way forward. It would also inform the overall programme review.

14. The scope of the evaluation would cover implementation of the eight elements of the strategy itself and the 108 specific actions defined in the action plan. It would look at such implementation by all stakeholders listed in the action plan at different levels (global, regional and national), including looking at implementation by national governments, the WHO Secretariat and other relevant stakeholders.

15. The evaluation would comply with the WHO evaluation policy. It would be commissioned and managed by the WHO Evaluation Office, supported by an ad hoc evaluation management group.

16. The evaluation would be conducted by an external independent evaluator, selected through an open tender. The evaluator would be an independent external organization or team with appropriate knowledge of the subject of the evaluation and skill mix, as well as relevant experience in performing evaluations involving innovation strategies in public health and access to medical products and technologies.

17. The evaluation would be conducted using a combination of methods in order to answer the evaluation questions adequately, including: a review of available literature; use of existing data and information from various existing sources; collection of qualitative and quantitative data, including through questionnaires to stakeholders listed in the action plan; and country case studies as appropriate. The evaluation methodology will be further elaborated by the evaluation team in its inception report and discussed with the ad hoc evaluation management group. The salient points of the inception report and comments from the evaluation management group will be included in the report of the Secretariat to the Executive Board at its 138th session.²⁷⁵

18. The evaluation team would conduct the analysis and deliver a report setting out its findings, including recommendations. The Secretariat would provide the necessary support to the evaluation team during the evaluation exercise.

19. It is proposed that the process for the comprehensive evaluation is initiated shortly after the Sixty-eighth World Health Assembly in June 2015, with the final evaluation report presented to the Executive Board in January 2017 for forwarding to the Health Assembly in May 2017.

Role and composition of the ad hoc evaluation management group

20. In view of the scope and complexity of this evaluation, and in line with the WHO evaluation policy, an ad hoc evaluation management group would be convened to assist in selecting the evaluation team, reviewing the evaluation inception report and the draft evaluation report, and ensuring that the final draft meets appropriate quality standards. The evaluation management group would be kept informed of progress and should be available to respond to queries from the evaluation team. As the evaluation process progresses, the evaluation management group may refer additional ideas and provide suggestions to the evaluation team for consideration.

21. Options for consideration concerning the composition of the ad hoc evaluation management group include:

²⁷⁵ In addition, a progress report on implementation of the global strategy and plan of action will be presented to the Executive Board at its 138th session.

- (a) six independent external experts (four subject matter experts and two evaluation specialists);
- (b) the six Officers of the Executive Board (the precedent for this is the evaluation management group for the stage two evaluation of WHO reform);
- (c) 12 independent external experts (all subject matter experts; identified from a pool of experts proposed by Member States, representing all six regions) and two evaluation experts from the United Nations Evaluation Group;
- (d) a combination of options (a) and (b), i.e. six independent external experts and the six Officers of the Executive Board.

Terms of reference of the overall programme review

22. The overall programme review will be a more policy-oriented, forward-looking exercise. The programme review will consider the findings of the comprehensive evaluation, together with other technical and managerial aspects of the programme, with a view to identifying what needs to be improved and modified in the next stages of implementation of the global strategy and plan of action. The programme review will add a wider perspective to the assessment by looking at the broader political and policy environment influencing the implementation of the global strategy and will make recommendations on the way forward. A key characteristic of the programme review is that it would actively engage relevant stakeholders during various stages of the process, including all stakeholders identified in the global strategy and plan of action: Member States, the WHO Secretariat, other intergovernmental organizations such as UNCTAD, WIPO and WTO, and other relevant stakeholders.

23. Different models for conducting programme reviews exist in WHO, and these cover different levels of complexity; examples include the mechanisms for review of the International Health Regulations (2005). For the overall programme review for the global strategy and plan of action, the model described below is proposed for consideration.

24. The overall programme review would be conducted by a panel of experts with a broad mix of expertise, practical experience and backgrounds covering the eight elements of the strategy, including experts from developed and developing countries (options: (a) independently identified by the Director-General without inputs from Member States, or (b) identified by the Director-General from a pool of experts proposed by Member States). In either case, adequate regional representation would be ensured.

25. Building on the high-level objectives of the review, more detailed terms of reference would be developed. The terms of reference and composition of the programme review panel would be presented to the Executive Board at its 140th session in January 2017. The review panel would elaborate its method of work and conduct a major portion of its work through plenary meetings at WHO headquarters. It would be supported by a small secretariat working closely with the Evaluation Office.

26. The panel would review documents and hear evidence from individuals representing all stakeholders identified in the global strategy and plan of action: Member States, the WHO Secretariat, other intergovernmental organizations such as UNCTAD, WIPO and WTO, and other relevant stakeholders. The panel may also seek broader inputs to the process through a public hearing and web-based consultations. As deemed necessary, the review panel may undertake country and site visits. Furthermore, the panel's deliberations would be informed by the report of the comprehensive evaluation undertaken by the external evaluation team.

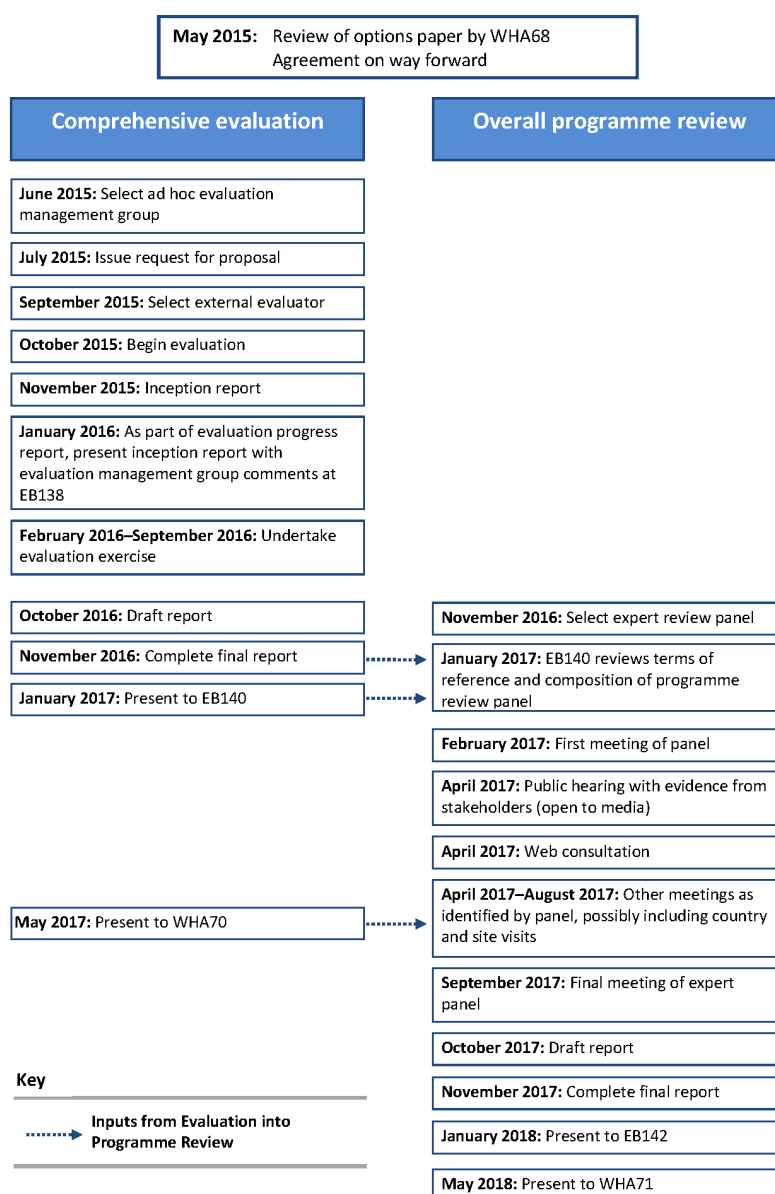
27. It is proposed that the process for the overall programme review starts in November 2016. A progress report will be presented to the Seventieth World Health Assembly in May 2017, and the final report of the comprehensive review, which will be presented to the Executive Board at its 142nd session in January 2018 and to the Seventy-first World Health Assembly in May 2018, will make specific recommendations on the way forward for implementation of the global strategy and plan of action until 2022.

ACTION BY THE HEALTH ASSEMBLY

28. The Health Assembly is invited to note the report and to take a decision on the options for the conduct of the comprehensive evaluation and the overall programme review of the global strategy and plan of action on public health innovation and intellectual property.

ANNEX

PROPOSED TIMELINES AND LINKAGES BETWEEN THE COMPREHENSIVE EVALUATION AND OVERALL PROGRAMME REVIEW



DECISION 17.5:

Executive Board Decision EB136(17): Global strategy and plan of action on public health, innovation and intellectual property

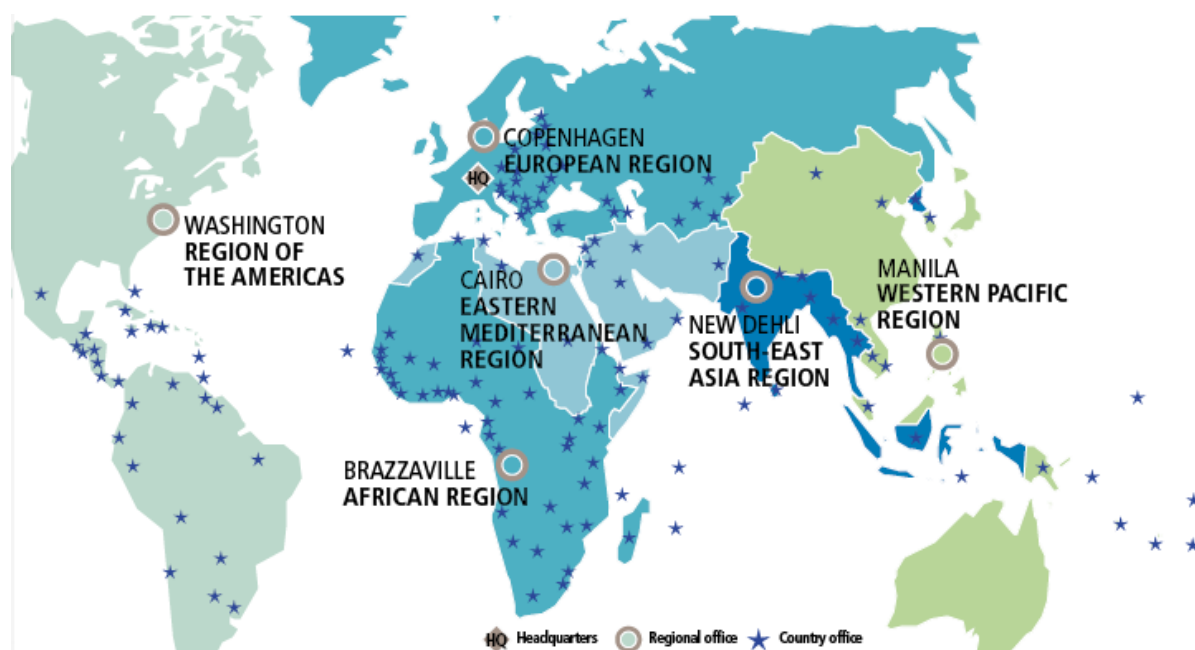
The Executive Board, having considered the report by the Secretariat on evaluation of the global strategy and plan of action on public health, innovation and intellectual property,²⁷⁶

- (1) decided to recommend to the Sixty-eighth World Health Assembly to extend the deadline of the overall programme review of the global strategy and plan of action on public health, innovation and intellectual property on its achievements, remaining challenges and recommendations on the way forward to 2018, recognizing it was not presented in 2015, as requested by resolution WHA62.16;
- (2) decided also to recommend to the Sixty-eighth World Health Assembly to extend the time frame of the plan of action on public health, innovation and intellectual property until 2022;
- (3) requested the Director-General to provide a report for the Sixty-eighth World Health Assembly on options, in consultation with Member States, for the conduct of the comprehensive evaluation and the overall programme review of the global strategy and plan of action on public health, innovation and intellectual property, on its achievements, remaining challenges and recommendations on the way forward, including whether to combine the two instruments, sequencing, terms of reference, timing and options for establishing an evaluation management group with the goal of completing this exercise by 2018.

²⁷⁶ Document EB136/31.

ANNEX 1. STRUCTURE OF WHO

Six Regional Offices



| | | | |
|---|--|---|---|
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| <p>Regional Office for Africa (AFRO): Cit  du Djou , P O Box 06 Brazzaville Republic of Congo Tel: +242 770 0202 / +47 241 39100 Fax: +47 241 39503 Email: regafro@afro.who.int</p> | <p>Algeria Angola Benin Botswana Burkina Faso Burundi Cameroon Cape Verde Central African Republic Chad Comoros Congo C te d'Ivoire Democratic Republic of the Congo Equatorial Guinea</p> | <p>Eritrea Ethiopia Gabon Gambia Ghana Guinea Guinea-Bissau Kenya Lesotho Liberia Madagascar Malawi Mali Mauritania Mauritius Mozambique Namibia Niger</p> | <p>Nigeria Rwanda Sao Tome and Principe Senegal Seychelles Sierra Leone South Africa South Sudan Swaziland Togo Uganda United Republic of Tanzania Zambia Zimbabwe</p> |

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|---|--|---|--|
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| <p>Regional Office for Europe (EURO): UN City Marmorvej 51 DK-2100 Copenhagen O Denmark Tel: +45 45 33 7000 Fax: +45 45 33 7001</p> | <p>Albania Andorra Armenia Austria Azerbaijan Belarus Belgium Bosnia and Herzegovina Bulgaria Croatia Cyprus Czech Republic Denmark Estonia Finland France Georgia Germany Greece Hungary</p> | <p>Iceland Ireland Israel Italy Kazakhstan Kyrgyzstan Latvia Lithuania Luxembourg Malta Monaco Montenegro Netherlands Norway Poland Portugal Republic of Moldova Romania Russian Federation</p> | <p>San Marino Serbia Slovakia Slovenia Spain Sweden Switzerland Tajikistan The former Yugoslav Republic of Macedonia Turkey Turkmenistan Ukraine United Kingdom of Great Britain and Ireland Uzbekistan</p> |
| <p>Regional Office for the Eastern Mediterranean (EMRO): Monazamet El Seha El Alamia Street Extension of Abdul Razzak Al Sanhoury Street P O Box 7608, Nasr City, Cairo 11371, Egypt Tel: +202 2276 50 00 Fax: +202 2670 24 92 or 24 94</p> | <p>Afghanistan Bahrain Djibouti Egypt Iran (Islamic Republic of) Iraq Jordan Kuwait</p> | <p>Lebanon Libya Morocco Occupied Palestinian Territory Oman Pakistan Qatar</p> | <p>Saudi Arabia Somalia Sudan Syrian Arab Republic Tunisia United Arab Emirates Yemen</p> |

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|--|---|--|---|

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