# II 章 総括研究報告

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### 地球規模保健課題解決推進のための行政施策に関する研究事業 (H27-地球規模 - 指定-004) 総括研究報告書

### 高齢化とUHC に関する総括マクロビジョンに関する研究

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# Protecting human security: Proposals for the G7 Ise-Shima Summit in Japan

# Japan Global Health Working Group\*

### Summary

In today's highly globalised world, protecting human security is a core challenge for political leaders who are simultaneously dealing with terrorism, refugee and migration crises, disease epidemics, and climate change. Promoting universal health coverage (UHC) will help prevent another disease outbreak similar to the recent Ebola outbreak in west Africa, and create robust

health systems, capable of withstanding future shocks. Robust health systems, in turn, are the prerequisites for achieving UHC. We propose three areas for global health action by the G7 countries at their meeting in Japan in May, 2016, to protect human security around the world: restructuring of the global health architecture so that it enables preparedness and responses to health emergencies; development of platforms to share best practices and harness shared learning about the resilience and sustainability of health systems; and strengthening of coordination and nancing for research and development and system innovations for global health security. Rather than creating new funding or organisations, global leaders should reorganise current nancing structures and institutions so that they work more e ectively and e ciently. By making smart investments, countries will improve their capacity to monitor, track, review, and assess health system performance and accountability, and thereby be better prepared for future global health shocks.

### Introduction

In 2015, human security emerged as a core global challenge. Disease epidemics, terrorism, refugee and migration crises, and climate change had consequences that were felt around the world. These events showed the fundamental weaknesses in key global health functions that require collective action, such as the management of cross-border externalities (e.g. Ebola outbreaks), the provision of global public goods (e.g. Ebola vaccines), <sup>1</sup> and effective leadership and stewardship of global systems.<sup>2, 3</sup> The challenges of 2015 showed that national and global health systems and governance are in urgent need of reform and reinforcement.<sup>4, 5</sup>

Last year was also a major turning point in global health policy. The United Nations General Assembly adopted the 2030 Agenda for Sustainable Development and Sustainable Development Goals (SDGs), emphasising universality, sustainability, and cross-sector global partnerships. The scope of health challenges has expanded from infectious diseases and child and maternal health, outlined in the 2000 Millennium Development Goals (MDGs), to include non-communicable diseases (NCDs) as the result of demographic and epidemiological transitions.<sup>6</sup> The focus of global health policy has expanded beyond disease-specific programs to embrace health systems strengthening (HSS), universal health coverage (UHC) and its sustainability.<sup>7</sup>

In May 2016, Japan will host the G7 Summit for the first time since 2008. Taking place in the era of SDGs and in the aftermath of the Ebola crisis, this summit offers a key opportunity to advance the global health agenda. The G7 can identify shared actions that will strengthen health systems at global, regional and national levels, and use the summit to enhance global health cooperation. At past summits it has hosted, Japan has emphasized the value of global health and rallied countries to new initiatives. At the 2000 Kyushu-Okinawa Summit Japan championed the establishment of the Global Fund to Fight AIDS, Tuberculosis and Malaria. Japan's leadership at the Hokkaido-Toyako Summit in 2008 brought greater global attention to the key roles of health financing, health workforce, and health information in health systems.<sup>7</sup>

Japan will renew its commitment to global health at the 2016 G7 Summit, aiming for G7 countries and partners to address the collective challenges the world faces with effective and equitable responses.<sup>8</sup> Since October 2014, the inter-disciplinary, multi-stakeholder Japan Global Health Working Group (JGHWG) convened to guide summit talks on global health and human security. In this paper we review challenges and propose actions in global health for the upcoming G7 Summit in Japan. We first discuss human security, a core concept of Japanese foreign policy, and show how UHC contributes to human security and facilitates progress towards the SDGs. We then identify key contemporary global health challenges, using Japan's experiences as examples. We conclude with recommendations for the 2016 Ise-Shima G7 Summit.

### Human security and UHC in the SDG era

The core of Japan's foreign policy is a deep commitment to a "proactive contribution to peace" standing on the concept of "human security".<sup>8</sup> Human security protects the vital core of all human lives in a way that enhances human freedoms, fulfillment, and capabilities.<sup>9,10</sup> It complements national security by focusing on individual and community security, and is achieved by protecting people from crucial and pervasive threats and developing capacity to cope with difficult situations. Women and children are especially affected by human security threats such as armed conflicts. Japan's Prime Minister Shinzo Abe specifically reminded the world to commit to improve the health of the most vulnerable populations, particularly women.<sup>11</sup> Human security represents both a top-down and a demand-driven bottom-up process, and promotes a comprehensive view of how to improve overall wellbeing.<sup>7</sup> The Ebola crisis highlights the importance of focusing more attention on human security—at both individual and population levels—in global health debates.<sup>12</sup>

UHC—defined as a system in which all people have access to quality health services without financial hardship—serves as an instrument to link individual and population security. UHC ensures universal access to health-care services, essential vaccines, and medicines.<sup>13</sup> Human security demands protection of health of all individuals, and thus UHC is integral to human security.<sup>14</sup> UHC includes not only medical services, but also a well functioning health system that mobilises community health workers, supports community volunteers, and empowers mothers to manage the health and health care of their children with an emphasis on equity—as reflected in Japan's historical experiences.<sup>15</sup>

The SDGs draw together the concepts of human development and human security in new ways. Efforts to ensure people's health and safety, including UHC, are embedded in each of the 17 SDGs and reflect the human security approach. The SDGs create an opportunity to connect different sectors and link individuals, families, and communities in action to achieve UHC around the world. One of the SDGs is to revitalise the global partnership for sustainable development (Goal 17). It emphasises the importance of promoting effective public, private, and civil society partnerships,<sup>16</sup> since comprehensive health initiatives require action by civil society alongside government efforts, as illustrated by experience with HIV/AIDS and tobacco control.<sup>5,17</sup>

# Global health challenges: using a health system approach to promote human security

Amartya Sen<sup>18</sup> has argued that mortality can be viewed as an indicator of economic success or failure. Japan is regarded as one of the most successful countries in the world for many health indicators. Japan's life expectancy has increased by more than 30 years since the end of World War 2, and health outcomes have been top-ranked worldwide since the early 1980s. Through UHC, Japan has rapidly improved population health outcomes, achieved economic growth, and enhanced social stability, equity, and solidarity.<sup>19</sup> Progressive realisation of UHC is an attainable goal even where resources are low,<sup>20</sup> and Japan's experience shows UHC's crucial role in improving human security. The implementation of UHC forces individual countries and the global health community to identify the challenges that prevent entire populations from having access to low-cost and effective health services.

Addressing these obstacles is within reach, but will require a restructuring of the global health architecture at both national and global levels. The Japan Global Health Working Group analysed the global health architecture by examining the recommendations for strengthening the core functions of global health from recent studies.<sup>4,5,21-23</sup> On the basis of this analysis, we propose the following major goals and actions to improve the global health architecture. The goals (ie, what should be done) to accelerate progress towards human security are to

enhance preparedness and response towards threats to human security; to achieve sustainable and high-quality health-care systems, particularly in the context of NCDs and population ageing; and to promote research and development, and system innovations. The actions (ie, how to implement the goals) to help mount effective global responses to shared health security challenges require effective leadership and coordination, to enable different actors to work together effectively and to set common priorities and guidelines for activities to achieve common goals; accountability, to define responsibilities of different actors, monitor performance, and ensure achievement of predefined objectives; and sustainable investment, to secure financial and technical assistance for countries and vulnerable populations.

Based on this 3•3 matrix, we identified global challenges to the achievement of UHC for human security (figure) In this section we elaborate these challenges to the three goals, highlighting relevant experience in Japan and related issues in other countries.

<i>Figure</i> : Global challenges surrounding major goals and actions to achieve human security and
UHC

		Actions		
		Leadership and coordination	Accountability	Sustainable investment
Goals	To enhance preparedness and response to threats to human security	Improvement of the WHO's leadership in global coordination • Coordination of plans and priorities among di erent agencies, across country, region, and global levels • Ensuring that countries include emergency preparedness in their national UHC plans	Strengthening of global monitoring and assessment functions (eg, independent assessment of IHR and GHSA capacity)     Identification of an international framework for outbreak response     Encouraging countries to set priorities and sequence progress to UHC     Ensuring adequate monitoring and accountability frameworks for UHC for emergency response	Securing of funding for emergencies     Advocating that countries increase funding for health into aid for global functions
	To achieve sustainable and high-quality health-care systems, particularly in the context of NCDs and ageing populations	<ul> <li>Engagement of local communities, ensuring the use of local social resources including a health workforce with adequate skills</li> <li>Addressing changes in disease structure from communicable diseases to NCDs</li> <li>Coordination of di□ erent aid organisations and partnerships on national health strategies</li> </ul>	Inclusion of long-term care needs into national and regional level HSS assessment Ensuring accountability of non-governmental organisations Enhancement of capacity for health technology assessment	Utilisation of domestic resources and funding in developing countries Advocating community-based rather than institutional-based long-term care Securing of funding for long-term care Investment in health systems to address ageing populations
	To promote research and development, and system innovations for global health security	<ul> <li>Prioritisation of development needs</li> <li>Coordination of di erent funding and implementing agencies</li> <li>Sharing of knowledge</li> <li>Harmonisation and streamlining of regulatory pathways</li> </ul>	<ul> <li>Ensuring donor and private industry accountability</li> <li>Evaluation of the performance of different product development projects</li> </ul>	Securing of su□ cient investment in health R&D, including R&D of new drugs and diagnostics, to ensure the a□ ordability and availability of new medical products Exploration of innovative mechanisms to incentivise global health R&D

Goals are what should be done to accelerate progress toward human security and actions are mechanisms to implement the goals. UHC=universal health coverage. IHR=International Health Regulations. GHSA=Global Health Security Agenda. NCD=non-communicable disease. HSS=health systems strengthening. R&D= research and development.

### Goal 1: To enhance preparedness and response towards threats to human security

Threats to human security can be natural, man made, or both. The recent Ebola crisis and previous swine and avian influenza pandemics demonstrated that disease outbreaks still pose

significant global threats, while disasters, war, and economic shocks also threaten human security. Vulnerability to such threats varies according to socioeconomic status, location, and unique individual and family circumstances.<sup>14</sup>

Natural disasters are a major threat to population health both in acute response and long-term recovery phases. The 2011 Great East Japan Earthquake and tsunami disaster caused massive destruction of local health-care facilities, but standardised health-care administrative information under UHC along with temporary copayment exemptions allowed for continuity in health-care access for people in many affected regions.<sup>24</sup> These experiences in Japan demonstrate that a strong UHC system supports robustness and resilience in public health emergencies.<sup>12</sup>

As countries work towards implementing UHC, emergency preparedness should be included in their national health strategies, and national or regional response and coordination capacity should be enhanced. Yet many countries do not have sufficient information about interventions and risk management, or adequate monitoring and accountability frameworks for UHC. Countries should focus not only on data collection and analysis (often the goal of global monitoring efforts), but also on using that information in ways that hold countries accountable to their citizens as well as donors.

Global action is also needed to improve preparedness and responses. Coordination of priorities and plans between agencies, non-governmental organisations (NGOs), and partnerships is poor, resulting in duplication, overlap, and contradiction of aid activities in some areas and gaps in others. WHO is expected to take the lead in coordinating programmes for emergency preparedness and responses, but it currently does not intervene as a regulatory agency or serve as an independent monitoring body.<sup>21</sup>

### Goal 2: To achieve sustainable and high-quality health-care systems, particularly in the context of NCDs and ageing populations

The unprecedented ageing of the world's population presents sustainability challenges to health-care systems around the world, given the ever-increasing volume and types of health-care service needs. Countries moving towards UHC must build systems capable of adapting to demographic and epidemiological transitions. Developing health-care systems should address the prevention of and support for NCDs and mental health by shifting from hospital-centered care to patient-centered chronic care within a The economic returns from investing in global health are impressive. For example, every US dollar invested in reducing infectious, maternal, and child deaths from 2015 to 2035 would return between US\$9 and \$20.<sup>2</sup> Even though health investment is the largest contributor to sustainable development, health has been slipping down the development agenda.<sup>31</sup> Official development assistance (ODA) for health declined by 2% from 2013 to 2014, threatening the impressive gains of the past decade.<sup>32</sup>

Today's global health challenges-exemplified by the Ebola virus disease and Zika virus outbreaks. antimicrobial resistance, and the ever-present threat of a high-fatality influenza pandemic-will require increased investment in the global functions of health ODA. These fall into three groups: provision of global public goods (eg, research and development for diseases of poverty); management of externalities (eg, pandemic preparedness); and fostering of leadership and stewardship (eg, global priority setting). These are distinct from country-specific functions, such as direct financial assistance for infectious disease control or health systems strengthening. The costs of neglecting global functions are very high. For example, Ebola will cost \$6 billion in direct costs and \$15 billion in economic losses,<sup>5</sup> and the World Bank estimates that a severe influenza pandemic could result in \$3 trillion in global economic losses (equivalent to 4.8% of global gross domestic product).<sup>34</sup> Increased investments in global functions, particularly research and development, will be needed to achieve a grand convergence in health<sup>2</sup>—a reduction in infectious, maternal, and child deaths to universally low levels-and to meet the 2030 targets of the health Sustainable Development Goal (SDG 3). Support for global functions such as knowledge sharing or market shaping to lower drug prices is also an important way for donors to improve the health of poor populations in middle-income countries where economic growth might disgualify them from country-specific aid.

Out of the total amount of health ODA plus additional donor spending on research and development for diseases of poverty provided by the G7 in 2013, only 21% (\$3.6 billion of \$17.6 billion) was spent on global functions. This falls far short of the \$6 billion annually that the WHO estimates is needed to support research and development for neglected diseases.<sup>35</sup> WHO's core budget for outbreak and crisis response shrunk by half between 2012 and 2013 and between 2014 and 2015, which contributed to its delayed response to the Ebola crisis.<sup>9,36</sup> WHO's budget for influenza in 2013 was just \$7.7 million, less than a third of what New York City devotes to public health emergency preparedness.<sup>37</sup>

The global health proposals for the G7 Ise-Shima Summit will focus attention on global functions by developing a global preparedness system, building platforms for knowledge sharing, and strengthening global health research and development. These proposals will need to be met with commensurate promises of financing. community-based, integrated health-care service model to enhance quality in health and long-term care provision.<sup>25</sup>

The challenge of sustainable and high-quality health systems applies to any country, including Japan. With increasing longevity—a major success of UHC in Japan—as well as declining fertility, rising social security costs now threaten the sustainability of the health-care system.<sup>26</sup> Ageing populations shift disease structure from acute to chronic and from communicable diseases to NCDs that require ongoing care in daily life and put growing pressure on public spending.

To address its health transition, Japan is implementing various reforms<sup>27</sup> to establish an integrated community health-care system (ICCS) by 2025<sup>28</sup> that will provide comprehensive health and long-term care services within the community.<sup>25</sup> Although Japan still faces issues with human resource development, public health nurses play an important role in the ICCS through teamwork with social workers, care managers, and community volunteers.

This new system will require a paradigm shift, as proposed in *Japan Vision: Health Care* 2035, a report for the health minister drafted by young Japanese health leaders in June, 2015.<sup>29,30</sup> This report proposes that Japan's health system move from inputs to outcomes, from quantity to quality and efficiency, from cure to care, and from specialisation to integrated approaches across sectors. The new health system would emphasise fairness and solidarity, build on individual autonomy, and engage in global-health policy making. This independent panel envisions a new Japanese health system that is responsive to diverse demands, financially sustainable, and globally engaged.

This issue of resilience and sustainability of health systems is becoming central in the context of UHC across the world. Official development assistance (ODA) for health and other forms of health aid, such as funding for research and development for neglected diseases—defined as ODA+<sup>3</sup>—will be crucial to the achievement of UHC. Of the US\$22.0 billion in donor spending for ODA+ in 2013, 79% (\$17.3 billion) was for bilateral country-specific support and 21% (\$4.7 billion) for global health functions (panel).<sup>3</sup> However, ODA+ has begun to plateau, at \$36 billion according to the latest estimates.<sup>38</sup> As a result, country health systems will need to mobilise more domestic resources, learning from the experience of countries that have faced the ageing challenge first to ensure local financing is sustainable.<sup>39</sup>

# Goal 3: To promote research and development, and system innovations for global health security

Worldwide, only 1% of investments in health research and development were allocated to neglected tropical diseases in 2010,<sup>40</sup> although they affect one in seven people, mostly the poorest of those with low income. Research and development investments, clinical trials, and health research publications are heavily skewed towards high-income countries,<sup>40</sup> contributing to a shortage of essential treatment and diagnostic tools in developing countries. The global spread of infectious disease means that insufficient research and development for these diseases is an issue for the entire world.

For example, Ebola vaccine effectiveness was demonstrated more than 10 years ago through preclinical trials undertaken in primates, but development did not proceed because companies did not view the market incentives and sales potential as sufficient to justify continued investment.<sup>41</sup> Despite innovative approaches, such as product development partnerships that can mobilise public and private sectors,<sup>35</sup> public funding for neglected diseases has decreased in recent years as industry funding has increased.<sup>42</sup> Additionally, coordination among donors is insufficient with regard to defining research and development priorities and streamlining support processes.

Additionally, antimicrobial resistance is becoming a global threat to human and animal health, agriculture, and the environment<sup>23,43</sup> while the development of new antibiotics has declined,<sup>44</sup> highlighting the need for an alternative economic model for the development and use

### of antibiotics.

Research and development efforts are also needed to address common barriers to service delivery, such as human resources, financing, supply systems, and communications. Scientific innovations must be accompanied by health system innovations to expand effective access and utilisation, and thereby reduce the inequities in benefits that often occur.

## Proposals for the G7 agenda

We propose a series of high-priority actions for the G7 global health agenda (identified in the figure) for consideration at the upcoming G7 Ise-Shima Summit and G7 health ministers' meeting in Japan. The recommendations are structured around the three goals to achieve human security and UHC.

# **Recommendation 1: Develop a global health architecture that enables effective preparedness and responses to health emergencies**

Building on recent reports,<sup>4,5,21</sup> we recommend that the G7 should support the development of effective global preparedness and responses to health emergencies, including WHO reform with independent oversight and a clear timeline. Our specific recommendations are outlined in the following sections.

### Strengthen the framework in which the WHO reports to the UN

Under the guiding principles of the Inter-Agency Standing Committee, the so-called switch function is crucial to preventing confusion and should be left to the discretion of the UN secretary-general, on the basis of a comprehensive situation assessment.<sup>45</sup> We believe that new permanent organisations (such as the UN Mission for Ebola Emergency Response) are not desirable.

### Improve global coordination in health emergency and preparedness

The G7 should promote existing platforms such as One Health and IHP+ (International Health Partnership+) to improve coordination at the global, regional, and country levels among different aid organisations, NGOs, partnerships, and recipient countries. Countries should have the primary coordinating and preparedness role in health emergencies, whereas global and regional systems can address gaps in funding, workers, and drugs. It should also be fully recognised that technical agencies, such as the US Centers for Disease Control and Prevention and the French Institut Pasteur, and international NGOs have important roles in responding to pandemic events, but division of roles and responsibilities should be made clearer.

### Help build core capacities to implement International Health Regulations and Global Health Security Agenda as integral components of UHC

With clearly defined goals and outcomes, the G7 should support developing countries in assessing and strengthening their International Health Regulations and Global Health Security Agenda core capacities for emergency preparedness, and ensure that emergency preparedness is fully integrated into UHC implementation. These assessments should be done independently, so that transparency is ensured. Empowering communities to improve UHC implementation strengthens primary health care and emergency preparedness, surveillance, and response.<sup>46,47</sup>

# Change the focus of health system monitoring and assessment from globally controlled to country-specific mechanisms

The road to UHC is unique for each country, and monitoring mechanisms vary by level of progress and capacity. The G7 should promote a country-specific and country-focused approach under an international guiding framework for measurement of progress towards UHC. This approach should build on emerging initiatives such as the HSS roadmap<sup>48</sup> and the Primary

### Health Care Performance Initiative.

#### Strengthen and integrate disease-specific vertical initiatives on HSS

The G7 should increase HSS investments using explicitly defined benchmarks in disease-specific vertical initiatives, such as the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, the Global Polio Eradication Initiative, and Gavi, the Vaccine Alliance, while integrating these initiatives into national health strategies based on IHP+ principles. Also, the G7 should advocate for each initiative to target the most vulnerable people, such as women and children and people with disabilities, and coordinate with other initiatives such as the Global Financing Facility in Support of Every Woman Every Child.<sup>49</sup>

### Mobilise resources and their effective use for emergency responses

The G7 should support major funding mechanisms, including the WHO's Contingency Fund for Emergencies and the World Bank's Pandemic Emergency Facility,<sup>50,51</sup> to improve coordination and possibly merge them to cut waste, duplication, and corruption.

# Recommendation 2: Develop platforms to share knowledge and practice regarding health system resilience and sustainability

The G7 should recommend actions for developing countries to share knowledge and collaborate in five key areas to improve the performance of health systems: the securing of health financing and development of innovative payment mechanisms; the reconfiguration of health workforce and skills; the establishment of integrated health-care systems that combine community-based health-care and social-care services; the facilitation of healthy and active ageing; and the improvement of the quality of health and long-term care services. This knowledge sharing should include policy makers, practitioners, scientists, and citizens to ensure that information and analysis are effectively used in strengthening health systems. Such platforms should support the actions discussed in the following sections.

# *Promote collaboration and dialogue between health and financial sectors to mobilise domestic funding for health system sustainability*

The G7 should advocate that low-income and middle-income countries mobilise more domestic funding with a specific goal in their national budgets (through taxation, insurance premiums, private investment, and waste reduction), based on a fiscal space analysis. Existing knowledge-sharing platforms should expand to share countries' experiences and facilitate cross-sectoral dialogue between health and finance authorities (eg, the Organisation for Economic Cooperation and Development's Joint Network of Health and Budget Officials) with particular focus on regional networks in Asia, South America, and Africa.

#### Develop expertise and institutional capacity for health systems analysis

The G7 should support countries to develop expertise and capacity for analysing health system performance. Countries need to adequately assess the strategic directions, priority areas, and benefits packages of their own health systems to cope with ageing societies and growing financial constraints. Country capacity for health technology assessment needs to be strengthened to help countries respond to medical technology advancement in the context of limited health resources and competing priorities. The G7 and relevant organisations (eg, WHO, the UK National Institute for Health and Care Excellence, and the Primary Health Care Performance Initiative) should support this development.

# Recommendation 3: Strengthen coordination and financing in research and development, and system innovations for global health security

The G7 countries should strengthen their support for research and development of new drugs and vaccines, and diagnostics (especially with regard to neglected tropical diseases and

antimicrobial resistance) and innovations in systems to finance and deliver such services. This initiative should support both upstream research (eg, design of preclinical and clinical studies, negotiation with regulatory authorities on regulatory pathways, and coordination of clinical trials) and downstream research (eg, regulatory approval, recommendations in guidelines, and market-shaping activities). In this area, the G7 should undertake the following recommendations.

### Clarify priority diseases and projects

The G7 should establish mechanisms to clarify priority diseases for development of new drugs and vaccines—in collaboration with the WHO, the World Bank Group, private industry, civil society, and academic institutions. A platform to share information about global health research and development strategies would help to reduce duplication, encourage collaboration, and reduce gaps.

### Double investment on global health research and development

The G7 countries should aim to double investments in global health research and development through product development partnerships, domestic companies, and institutions focused on neglected tropical diseases and antimicrobial resistances over the next 5 years, as advocated for in 2012 by WHO.<sup>35</sup> Additionally, the G7 should encourage countries to explore and initiate innovative research mechanisms.<sup>52</sup> One example is Japan's commitment to the Global Health Innovative Technology Fund,<sup>53</sup> a public–private partnership that invests in innovation for global health.

## Conclusion

Our world today confronts major threats to human security, including terrorism, refugee flows, and climate change. The G7 needs to take collective action to address these global challenges, since national security alone is not sufficient to motivate effective responses. Japan's experiences with human security embedded in UHC provide important lessons for global action. The world needs effective mechanisms to link individual and population security, as Japan has done, through a combination of health promotion, social stability and equity, health emergency preparedness, support for ageing populations, and global health innovation. Advancing global action on these topics is the most important global health challenge for G7 action now.

Current financing must become more effective and sustainable. Its focus should shift to low-cost, smart investments with the potential to have an impact on the building of resilient UHC systems that protect human security. The G7 Ise-Shima Summit in Japan offers a historic opportunity to make a difference on each of these crucial mechanisms, and to reaffirm that never again can we have another Ebola outbreak like the recent epidemic. We hope that our proposals will be considered and adopted at the upcoming G7 Summit in Japan.

### Contributors

All authors contributed to the draft, and have seen and approved the final version of the report.

### **Declaration of interests**

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