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AMR Alliance Japan

AMR Alliance Japan Policy Recommendations

Restructuring Diagnostic Services and Achieving the Necessary Innovation to Promote AMR Control

Background

Antimicrobial resistance (AMR) has been continuously recognized as a public health threat of greatest concern in Japan and around the world. Efforts from related parties in Japan have steadily generated results in efforts to combat AMR. In particular, Japan has made remarkable progress in antimicrobial stewardship and surveillance and is advancing efforts to establish new incentives for AMR control in the medical service fee schedule, increase surveillance coverage, and expand efforts on the international level. Despite this progress, Japan has yet to implement fundamental reforms aimed at addressing structural challenges facing the market for antimicrobials and microbiological testing. In recent years, the G7 has recognized that achieving comprehensive innovation in all areas of prevention, diagnosis, and treatment will be crucial for pandemic prevention, preparedness, and response (PPR). That perspective is in line with that of the G7 Ise-Shima Summit held in 2016 (the last time Japan served as G7 President) as well as Japan's Basic Policies for Economic and Fiscal Management and Reform every year since 2016. AMR Alliance Japan has worked to make the most of this momentum and has already presented recommendations focusing on treatment and pull incentives. For recommendations and other information related to this topic, please refer to our website (https://hgpi.org/en/tag/amr). Strengthening diagnostics capacity was discussed during the 152nd session of the WHO Executive Board held in January and February 2023, and there is growing demand around the world to rebuild testing systems or implement more innovative ones as we approach the seventy-eighth World Health Assembly (WHA) in 2025. Given these circumstances, looking to the 2023 G7 Summit in Hiroshima and beyond, we offer the following recommendations that focus on testing that will contribute to diagnostic support as a necessary step for achieving more comprehensive and effective AMR control measures.

Recommendation 1: Reaffirm that testing plays a vital role in diagnostic support and restructure diagnostic services to advance AMR countermeasures that are also compatible with a super-aging society.

Diagnostic support in the form of AMR testing is necessary for selecting antimicrobials while taking the possibility of AMR into account during infectious disease consultations. Providing appropriate diagnostic support requires proactively conducting AMR screening alongside rapid diagnostic testing to determine the need for antimicrobials in an accurate and timely manner. In countries that are home to growing numbers of older adults with preexisting conditions such as Japan and other G7 members, to fully protect physical and mental health for all generations to ensure everyone can lead healthy lives from childhood to late adulthood, other extremely important perspectives include preventing nosocomial infections and keeping AMR bacteria out of elderly care facilities. It has been said that using testing devices with the latest technology can accelerate reporting for microbial identification and drug susceptibility testing by around two days, and that the more limited medical resources are, the greater the effects that can be obtained from automating microbiological testing. As such, it will be necessary to advance policies that aim to establish systems to enable rapid AMR screening, microbial identification, and drug susceptibility testing (including genetic tests) by introducing automated testing devices and similar measures.

Recommendation 2: Develop human resources and foster an environment to enable proactive AMR screening, microorganism identification, and drug susceptibility testing (including genetic testing).

Operating and managing equipment for and interpreting the results of AMR screenings and rapid diagnostic tests require high levels of technical skill. This requires continuously developing human resources that can contribute to appropriate diagnostic support through training and other educational programs. Because of issues like increased healthcare demand and personnel shortages, in addition to introducing simplified, automated testing devices that do not require technical expertise to operate, it will also be necessary to consider the creation of easy-to-understand guidelines for operating and managing testing

AMR Alliance Japan (Secretariat: Health and Global Policy Institute)
Otemachi Financial City Grand Cube 3F 1-9-2, Otemachi Chiyoda-ku, Tokyo 100-0004 JAPAN
Global Business Hub Tokyo TEL: +81-3-4243-7156 e-mail: info@hgpi.org

equipment and interpreting results. *The Manual of Antimicrobial Stewardship* compiled by the Ministry of Health, Labour and Welfare (MHLW) and cooperating organizations provides one good example of such guidelines. *The Manual of Antimicrobial Stewardship* has been used by many health professionals, especially general healthcare staff, at all sizes and types of hospitals, and has generated some results. The methods described in that manual and others like it could be introduced in low- and middle-income countries where health resources are limited. Furthermore, testing requires a comprehensive package of resources such as testing equipment, reagents, materials, Personal Protective Equipment (PPE), facility equipment like safety cabinets and ventilation, and human resources. While some resources like PPE and testing materials are disposable, information obtained from tests can be stored in a semi-permanent manner in surveillance systems at the national or regional levels, or at healthcare institutions. This means conducting testing will require establishing an environment that provides a constant, stable supply of products that are superior in all aspects including quality, quantity, price, and specifications. With efforts spanning industry, Government, academia, and civil society, it will also be necessary to examine classification criteria to ensure they are up-to-date and in line with current circumstances in Japan while complying to Clinical and Laboratory Standards Institute (CLSI) usage guidelines.

Recommendation 3: While taking conditions at healthcare institutions and in each region into account, consider new incentives to expand diagnostic services at healthcare institutions by promoting testing systems that can be implemented in-house or that will improve the positions of and profitability for in-house and external testing departments.

When AMR screenings and rapid diagnostic tests are conducted at hospitals, they are performed at clinical laboratories in microbiology departments. However, the costs of testing devices and reagents continue to soar while the points assigned to them in the medical service fee schedule have only gone down. Furthermore, payment methods like diagnosis procedure combination (DPC) payments, medical consultation fees, and other factors mean that in many cases, reimbursements cannot be obtained for testing. This means there are poor prospects for profitability for microbiology laboratories, which has resulted in a trend among small and medium-sized hospitals to downsize testing systems and outsource testing. It also must be noted that regardless of size, all clinical laboratories must outsource tests that are not conducted frequently and have high maintenance costs. On the other hand, conducting testing within healthcare institutions allows treatments to be provided more rapidly while accumulating information over the long term, which helps create an environment that benefits patients with both communicable and non-communicable diseases. Anticipation is high for efforts to expand in-house testing systems at healthcare institutions over the long term by reexamining the testing and incentive systems with a focus on tests for organisms that are highly infectious in relative terms but not highly prevalent on a national scale (such as tuberculosis) or tests for which costs are shouldered by each healthcare institution (such as those for detecting Extended Spectrum Beta-Lactamase (ESBL) and Carbapenemase-producing *Enterobacteriaceae* (CPE)). When doing so, ample consideration must be given to circumstances at healthcare institutions and in regions. In particular, to expand diagnostic services at small and medium-sized hospitals, flexible consideration must be given to how to utilize or apply the premium for reinforcing collaboration established in April 2022 to strengthen systems for collaborating with large hospitals and third-party testing companies as well as systems for rapidly conducting tests and reporting results.

Conclusion: The international collaboration needed for AMR control and its significance

As we enter the post-COVID-19 era, antimicrobials and testing have crucial roles to play if we are to enjoy continued peace, stability, and prosperity. For example, Ukraine is currently faced with the issue of AMR in the form of an epidemic of multi-drug resistant tuberculosis (MDR-TB). As discussions on international agreements regarding infectious diseases like the International Health Regulations (IHR) and the Pandemic Treaty continue to advance, it will be important to promote AMR countermeasures based on the concept of One Health, in which the health of humans, animals, and the environment are viewed as one. To this end, opportunities for discussions that cut across fields and advocate for that approach should be established at G7 Summits and other high-level meetings. It is imperative that Japan fulfill its commitments to the international community based on the fact that infectious disease control cannot be fully implemented by countries acting alone and that each country's interests are adjacent to those of the entire world.

About AMR Alliance Japan

AMR Alliance Japan was established in November 2018 as multi-stakeholder, collaborative organization dedicated to the improvement of public health through the promotion of AMR countermeasures. As of May 2023, its members include, in alphabetical order: MSD K.K., The Children and Healthcare Project, Shionogi & Co., Ltd., Shimadzu Diagnostics Corporation, Sumitomo Pharma Co., Ltd., The Japanese Society of Antimicrobials for Animals, Nippon Becton Dickinson Co., Ltd., The Japan Medical Association, The Japanese Society for Medical Mycology, The Japanese Society of Pharmaceutical Health Care and Sciences, The Japanese Society of Chemotherapy, The Japanese Society for Infection Prevention and Control, The Japanese Association for Infectious Diseases, The Japanese Society for Pediatric Infectious Diseases, The Japan Pharmaceutical Manufacturers Association, The Japanese Society of Therapeutic Drug Monitoring, The Japan Society of Hospital Pharmacists, The Pharmaceutical Society of Japan, The Japan Pharmaceutical Association, The Japanese Society for Clinical Microbiology, bioMérieux Japan Ltd., Himeji City, Pfizer Japan Inc., and Meiji Seika Pharma Co., Ltd. Health and Global Policy Institute (HGPI) serves as its secretariat.

About Health and Global Policy Institute

Health and Global Policy Institute (HGPI) is a non-profit, independent, non-partisan health policy think tank established in 2004. In its capacity as a neutral think-tank, HGPI involves stakeholders from wide-ranging fields of expertise to provide policy options to the public to successfully create citizen-focused healthcare policies. Looking to the future, HGPI produces novel ideas and values from a standpoint that offers a wide perspective. It aims to realize a healthy and fair society while holding fast to its independence to avoid being bound to the specific interests of political parties and other organizations. HGPI intends for its policy options to be effective not only in Japan, but also in the wider world, and in this vein the institute will continue to be very active in creating policies for resolving global health challenges. HGPI's activities have received global recognition. It was ranked second in the "Domestic Health Policy Think Tanks" category and third in the "Global Health Policy Think Tanks" category in the Global Go To Think Tank Index Report presented by the University of Pennsylvania (as of January 2021, the most recent report)

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Otemachi Financial City Grand Cube 3F 1-9-2, Otemachi Chiyoda-ku, Tokyo 100-0004 JAPAN
Global Business Hub Tokyo TEL: +81-3-4243-7156 e-mail: info@hgpi.org