

Japan

This document is a compilation of all questions, justifications, and sources used to determine the 2021 Global Health Security Index scores for Japan. For a category and indicator-level summary, please see the Country Profile for Japan.

CATEGORY 1: PREVENTING THE EMERGENCE OR RELEASE OF PATHOGENS WITH POTENTIAL FOR INTERNATIONAL CONCERN	4
1.1 Antimicrobial resistance (AMR)	4
1.2 Zoonotic disease	6
1.3 Biosecurity	12
1.4 Biosafety	21
1.5 Dual-use research and culture of responsible science	23
1.6 Immunization	28
CATEGORY 2: EARLY DETECTION AND REPORTING FOR EPIDEMICS OF POTENTIAL INTERNATIONAL CONCERN	28
2.1 Laboratory systems strength and quality	28
2.2 Laboratory supply chains	31
2.3 Real-time surveillance and reporting	32
2.4 Surveillance data accessibility and transparency	34
2.5 Case-based investigation	40
2.6 Epidemiology workforce	42
CATEGORY 3: RAPID RESPONSE TO AND MITIGATION OF THE SPREAD OF AN EPIDEMIC	44
3.1 Emergency preparedness and response planning	44
3.2 Exercising response plans	48
3.3 Emergency response operation	50
3.4 Linking public health and security authorities	52
3.5 Risk communications	53
3.6 Access to communications infrastructure	55

3.7 Trade and travel restrictions	56
-----------------------------------	----

CATEGORY 4: SUFFICIENT AND ROBUST HEALTH SECTOR TO TREAT THE SICK AND PROTECT HEALTH WORKERS 58

4.1 Health capacity in clinics, hospitals, and community care centers	58
4.2 Supply chain for health system and healthcare workers	61
4.3 Medical countermeasures and personnel deployment	65
4.4 Healthcare access	66
4.5 Communications with healthcare workers during a public health emergency	68
4.6 Infection control practices and availability of equipment	70
4.7 Capacity to test and approve new medical countermeasures	70

CATEGORY 5: COMMITMENTS TO IMPROVING NATIONAL CAPACITY, FINANCING PLANS TO ADDRESS GAPS, AND ADHERING TO GLOBAL NORMS 73

5.1 International Health Regulations (IHR) reporting compliance and disaster risk reduction	73
5.2 Cross-border agreements on public health and animal health emergency response	74
5.3 International commitments	75
5.4 Joint External Evaluation (JEE) and Performance of Veterinary Services Pathway (PVS)	77
5.5 Financing	78
5.6 Commitment to sharing of genetic and biological data and specimens	81

CATEGORY 6: OVERALL RISK ENVIRONMENT AND VULNERABILITY TO BIOLOGICAL THREATS 82

6.1 Political and security risk	82
6.2 Socio-economic resilience	86
6.3 Infrastructure adequacy	88
6.4 Environmental risks	89
6.5 Public health vulnerabilities	90

Category 1: Preventing the emergence or release of pathogens with potential for international concern

1.1 ANTIMICROBIAL RESISTANCE (AMR)

1.1.1 AMR surveillance, detection, and reporting

1.1.1a

Is there a national AMR plan for the surveillance, detection, and reporting of priority AMR pathogens?

Yes, there is evidence of an AMR plan, and it covers surveillance, detection, and reporting = 2, Yes, there is evidence of an AMR plan, but there is insufficient evidence that it covers surveillance, detection, and reporting = 1, No evidence of an AMR plan = 0

Current Year Score: 2

Japan has a national AMR plan for the surveillance, detection and reporting of priority AMR pathogens. The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that Japan developed the National Action Plan on AMR 2016-2020 in 2016 under the WHO Global Action Plan on AMR. [1]

The National Action Plan on Antimicrobial Resistance (AMR) 2016-2020, released on 5 April 2016, addresses the stated goal of continuously monitoring AMR and use of antimicrobials with strategies for surveillance, testing and reporting. Surveillance addresses healthcare, nursing care, veterinary medicine, livestock production and aquaculture. Detection is enforced through monitoring of antimicrobial use at medical institutions and implementation of one health surveillance inclusive of humans, animals, food and the environment. Mandatory protocol and procedures are provided for reporting. [2]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 13 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). 5 April 2016. "National Action Plan on Antimicrobial Resistance (AMR) 2016-2020". [<https://www.mhlw.go.jp/file/06-Seisakujouhou-10900000-Kenkoukyoku/0000138942.pdf>]. Accessed 13 December 2020.

1.1.1b

Is there a national laboratory/laboratory system which tests for priority AMR pathogens?

All 7 + 1 priority pathogens = 2, Yes, but not all 7+1 pathogens = 1, No = 0

Current Year Score: 1

Japan has a national laboratory/laboratory system that tests for priority AMR pathogens. The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that Japan has public and animal health laboratory networks to conduct core tests and molecular diagnostic tests, supported by a network of sentinel surveillance sites. [1]

The National Institute of Infectious Diseases (NIID) has "Laboratory manuals for pathogen detection," which covers *Acinetobacter* spp. *Pseudomonas aeruginosa*, *Enterococcus* spp. *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae*, *Klebsiella aerogenes*, *Citrobacter freundii*, *Citrobacter koseri*,

and *Serratia marcescens*. However, it is not clear whether the NIID has the capacity to test all 7+1 priority AMR pathogens. [2]

The National Epidemiological Surveillance of Infectious Disease (NESID) program targets seven antimicrobial-resistant bacteria infections for surveillance: vancomycin-resistant enterococcal (VRE), vancomycin-resistant *Staphylococcus aureus* (VRSA), carbapenem-resistant Enterobacteriaceae (CRE), multidrug-resistant *Acinetobacter* (MDRA), penicillin-resistant *Streptococcus pneumoniae* (PRSP), methicillin-resistant *Staphylococcus aureus* (MRSA) and multidrug-resistant *Pseudomonas aeruginosa* (MDRP). [3]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 13 December 2020.

[2] National Institute of Infectious Diseases (NIID). 4 June 2020. "Laboratory manuals for pathogen detection". [<https://www.niid.go.jp/niid/images/lab-manual/ResistantBacteria20200604.pdf>]. Accessed 13 December 2020.

[3] AMR Clinical Reference Center. July 2018. "National Epidemiological Surveillance of Infectious Disease". [<https://amr-onehealth.ncgm.go.jp/en/surveillance/45/>]. Accessed 13 December 2020.

1.1.1c

Does the government conduct environmental detection or surveillance activities (e.g., in soil, waterways) for antimicrobial residues or AMR organisms?

Yes = 1 , No = 0

Current Year Score: 1

The government conducts environmental detection and surveillance activities (e.g. in soil, waterways, etc.) for antimicrobial residues/AMR organisms. Japan conducts environmental AMR surveillance as part of its national One Health platform, which covers humans, animals, and the environment. [1]

The Ministry of Agriculture, Forestry and Fisheries operates the Japanese Veterinary Antimicrobial Resistance Monitoring System (JVARM) for nationwide monitoring of AMR bacteria in the environment. Three types of monitoring are conducted, targeting (1) usage volumes of antimicrobials (estimated from the volumes of sales); (2) AMR residues in indicator bacteria derived from healthy animals and in pathogenic bacteria mediated by food; and (3) AMR residues in pathogenic bacteria (clinical isolates) derived from diseased animals. Usage volume surveillance covers agrochemicals and environmental residues such as concentrations of AMRs in urban rivers. Activities conducted recently include an AMR bacteria analysis of sewage samples collected from prefectures between 2018 and 2020. [2]

[1] AMR Clinical Reference Center. 27 August 2020. "One Health Platform System". [<https://amr-onehealth-platform.ncgm.go.jp/home>]. Accessed 13 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). November 2020. "Nippon AMR One Health Report (NAOR) 2020". [<https://www.mhlw.go.jp/content/10906000/000691720.pdf>]. Accessed 13 December 2020.

1.1.2 Antimicrobial control

1.1.2a

Is there national legislation or regulation in place requiring prescriptions for antibiotic use for humans?

Yes = 2 , Yes, but there is evidence of gaps in enforcement = 1 , No = 0

Current Year Score: 2

There is national legislation in place requiring prescriptions for antibiotic use for humans and no evidence of gaps in enforcement.

Article 49 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices ("Pharmaceutical and Medical Device Act") (Act No. 145 of 10 August 1960) establishes a category of drugs that require doctors' prescriptions for sale. [1] Antibiotics are included among prescription drugs designated by the Ministry of Health, Labor and Welfare. [2]

[1] Japanese Law Translation Database System. Act No. 145 of 10 August 1960. "Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices".
[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=27&y=11&co=01&ia=03&ja=04&ky=act+on+securing+quality%2C+efficacy+and+safety+of+products+including+pharmaceuticals&page=13>]. Accessed 13 December 2020.
[2] Pharmaceutical Society of Japan. "Prescription drugs".
[<https://www.pharm.or.jp/dictionary/wiki.cgi?%E5%87%A6%E6%96%B9%E3%81%9B%E3%82%93%E5%8C%BB%E8%96%AC%E5%93%81>]. Accessed 13 December 2020.

1.1.2b

Is there national legislation or regulation in place requiring prescriptions for antibiotic use for animals?

Yes = 2 , Yes, but there is evidence of gaps in enforcement = 1 , No = 0

Current Year Score: 2

There is national legislation in place requiring prescriptions for antibiotic use for animals. There is no evidence of gaps in enforcement. The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices ("Pharmaceutical and Medical Device Act") (Act No. 145 of 10 August 1960) applies the same prescription requirements for human antibiotics to antibiotics for animals. Article 49 states that "no proprietor of a pharmacy or seller of pharmaceuticals may sell or provide pharmaceuticals designated by the Minister of Health, Labor and Welfare to those without receiving the issuance of prescriptions from physicians, dentists or veterinarians without legitimate grounds". [1] Antibiotics are included among the drugs that require veterinarian prescriptions. [2]

[1] Japanese Law Translation Database System. Act No. 145 of 10 August 1960. "Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices".
[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=27&y=11&co=01&ia=03&ja=04&ky=act+on+securing+quality%2C+efficacy+and+safety+of+products+including+pharmaceuticals&page=13>]. Accessed 13 December 2020.
[2] Japan Veterinary Products Association. "Animal drugs that require veterinarians' prescriptions".
[<http://jvpa.jp/jvpa/?p=54>]. Accessed 13 December 2020.

1.2 ZOO NOTIC DISEASE

1.2.1 National planning for zoonotic diseases/pathogens

1.2.1a

Is there national legislation, plans, or equivalent strategy documents on zoonotic disease?

Yes = 1 , No = 0

Current Year Score: 1

There is a national law on zoonotic disease. According to the Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018), the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases ("Infectious Diseases Control Law") (Act No. 114 of 2 October 1998) mandates surveillance and notification regarding zoonotic disease incidents. [1] The law regulates infectious diseases "transmissible to human beings through animals or animal corpses" with other infectious diseases segmented into five classes, and requires veterinarians, owners and importers to comply with zoonotic disease prevention. Article 15 states that the owner of an animal suspected of carrying a disease should submit specimens to authorities, when requested. [2]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 13 December 2020.

[2] Japanese Law Translation Database System. Act No. 114 of 2 October 1998. "Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases".

[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=28&y=7&co=01&ia=03&ja=04&ky=act+on+the+prevention+of+infectious+diseases+and+medical+care+for+patients+with&page=10>]. Accessed 13 December 2020.

1.2.1b

Is there national legislation, plans or equivalent strategy document(s) which includes measures for risk identification and reduction for zoonotic disease spillover events from animals to humans?

Yes = 1, No = 0

Current Year Score: 1

The Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases ("Infectious Diseases Control Law") (Act No. 114 of 2 October 1998) provides measures for risk identification and reduction for zoonotic disease spillover events from animals to humans.

Zoonotic disease spillover risk identification and reduction is enforced through animal import restrictions under the law. Article 56-2 requires that anyone seeking to import live or dead animals specified by the Ministry of Health, Labor and Welfare as "likely to transmit an infectious disease to human beings" should file prior notifications.

Article 54 prohibits the import of "(i) an animal shipped from any of the areas specified by Order of the Ministry of Health, Labor and Welfare or Order of the Ministry of Agriculture, Forestry and Fisheries for respective Designated Animals by taking into consideration the status of the outbreak of an Infectious Disease and other circumstances; or (ii) an animal transported via any of the areas specified by Order of the Ministry of Health, Labor and Welfare or Order of the Ministry of Agriculture, Forestry and Fisheries as referred to in the preceding item." [1]

Furthermore, Article 5-2 states that "operators of businesses handling animals or the like (meaning persons engaged in the business of importing, storing, leasing or selling animals or animal corpses or displaying them at amusement parks, zoos, exhibitions, or other facilities or places where a large, non-specific group of persons visit) must endeavor to acquire the knowledge and skills for the prevention of infectious diseases, appropriately handle animals or animal corpses, and implement other necessary measures so as not to transmit infectious diseases from the animals or animal corpses imported, stored, leased, sold, or displayed to people." [1]

[1] Japanese Law Translation Database System. Act No. 114 of 2 October 1998. "Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases".

[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=28&y=7&co=01&ia=03&ja=04&ky=act+on+the+prevention+of+infectious+diseases+and+medical+care+for+patients+with&page=10>]. Accessed 14 December 2020.

1.2.1c

Is there national legislation, plans, or guidelines that account for the surveillance and control of multiple zoonotic pathogens of public health concern?

Yes = 1, No = 0

Current Year Score: 1

There is a national law that mandates the surveillance and control of multiple zoonotic pathogens of public health concern.

The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Infectious Diseases Control Law) (Act No. 114 of 2 October 1998) requires veterinarians to report certain zoonotic diseases [1].

The Infectious Diseases Control Law regulates zoonotic diseases as "Class IV Infectious Diseases". Class IV Infectious Diseases are (i) hepatitis E; (ii) hepatitis A; (iii) yellow fever; (iv) Q fever; (v) rabies; (vi) anthrax; (vii) avian influenza (excluding specified avian influenza); (viii) botulism; (ix) malaria; (x) tularemia; (xi) beyond what is set forth in the preceding items, any known infectious diseases specified by Cabinet Order as a disease which is transmissible to human beings through animals or animal corpses, food or drink, clothing, bedding, or other physical items and which are likely to affect the health of citizens as seriously as the diseases set forth in the preceding items.

Article 13 of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases states: "If a veterinarian has diagnosed a monkey or other animal specified by Cabinet Order with Ebola hemorrhagic fever, Marburg virus disease, or any other Infectious Disease as specified by Cabinet Order, and concludes that they are highly likely to infect human beings, which are designated from Class I Infectious Diseases, Class II Infectious Diseases, Class III Infectious Diseases, Class IV Infectious Diseases or a Novel Influenza Infection, etc., and has determined that the monkey or animal is infected or suspected to be infected with the relevant Infectious Disease, the veterinarian must immediately file a notification with the prefectural governor via the chief of the nearest public health center, stating the name of the owner of the animal (or the person controlling the animal if it is controlled by anyone other than its owner; the same applies hereinafter in this Article) and other particulars specified by Order of the Ministry of Health, Labor and Welfare, which must be filed for each of those Infectious Diseases; provided, however, that this does not apply when the animal is intentionally infected with the relevant Infectious Disease for the purpose of experimentation".

The law mandates activation of control measures, including quarantine and import restrictions, if an outbreak is confirmed [2].

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 14 December 2020.

[2] Japanese Law Translation Database System. Act No. 114 of 2 October 1998. "Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases".

[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=28&y=7&co=01&ia=03&ja=04&ky=act+on+the+prevention+of+infectious+diseases+and+medical+care+for+patients+with&page=10>]. Accessed 14 December 2020.

revention+of+infectious+diseases+and+medical+care+for+patients+with&page=10]. Accessed 14 December 2020.

1.2.1d

Is there a department, agency, or similar unit dedicated to zoonotic disease that functions across ministries?

Yes = 1, No = 0

Current Year Score: 0

There is insufficient evidence that Japan has a department, agency or similar unit dedicated to zoonotic disease that functions across ministries.

The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states the absence of any regular information sharing process for zoonotic diseases other than avian influenza. [1] The "One Health" surveillance committee exists as a multiagency committee specializing in antimicrobial resistance (AMR) in the areas of human health, animals, food and the environment. The AMR Clinical Reference Centre's One Health Surveillance Committee's interministerial coordination role is not clearly defined. Nippon AMR One Health Report (NAOR) 2018 states that the committee is chaired by the Director-General of the Health Service Bureau of the Ministry of Health, Labor and Welfare and comprised of "experienced experts and other stakeholders." The report cites the Ministry of Agriculture, Forestry and Fisheries and the Ministry of the Environment as "cooperating government agencies." [2]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 14 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). 30 October 2018. "Nippon AMR One Health Report (NAOR) 2018". [<https://www.mhlw.go.jp/content/10900000/000530087.pdf>]. Accessed 14 December 2020.

1.2.2 Surveillance systems for zoonotic diseases/pathogens

1.2.2a

Does the country have a national mechanism (either voluntary or mandatory) for owners of livestock to conduct and report on disease surveillance to a central government agency?

Yes = 1, No = 0

Current Year Score: 1

Japan has a national mandatory mechanism for owners of livestock to conduct and report on disease surveillance to a central government agency.

Article 13 of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases ("Infectious Diseases Control Law") (Act No. 114 of 2 October 1998) states that the owner of an animal must file a notification with the prefectural governor via the nearest public health center upon learning that the animal is infected or suspected of being infected with any of the infectious diseases specified under the law, before a veterinarian's assessment. Local government authorities receiving a notification must immediately inform the Ministry of Health, Labor and Welfare as such.

[1]

[1] Japanese Law Translation Database System. Act No. 114 of 2 October 1998. "Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases".

[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=28&y=7&co=01&ia=03&ja=04&ky=act+on+the+prevention+of+infectious+diseases+and+medical+care+for+patients+with&page=10>]. Accessed 14 December 2020.

1.2.2b

Is there legislation and/or regulations that safeguard the confidentiality of information generated through surveillance activities for animals (for owners)?

Yes = 1, No = 0

Current Year Score: 0

There is no evidence of laws or guidelines on the confidentiality of information generated through surveillance activities for animals (for owners). The Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases ("Infectious Diseases Control Law") (Act No. 114 of 2 October 1998), which requires zoonotic disease prevention, does not have provisions safeguarding the privacy of information sources. [1] There is no evidence of such privacy protection available from the websites of the Ministry of Health, Labor and Welfare or the Ministry of Agriculture, Forestry and Fisheries. [2, 3] The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) includes no information on privacy protection with regard to animal surveillance activities. [4] The standard notification form required to be filled by veterinarians includes the name and address of the owner of an animal in question. [5] The Act on the Protection of Personal Information (Act No. 57 of 30 May 2003) does not include provisions on the confidentiality of information generated through surveillance activities for animals. [6]

[1] Japanese Law Translation Database System. Act No. 114 of 2 October 1998. "Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases".

[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=28&y=7&co=01&ia=03&ja=04&ky=act+on+the+prevention+of+infectious+diseases+and+medical+care+for+patients+with&page=10>]. Accessed 14 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). "Zoonotic Disease".

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/kenkou/kekkaku-kansenshou18/index.html]. Accessed 14 December 2020.

[3] Ministry of Agriculture, Forestry and Fisheries. [<https://www.maff.go.jp/>]. Accessed 14 December 2020.

[4] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 14 December 2020.

[5] Ministry of Health, Labor and Welfare (MHLW). "Zoonotic Disease". [<https://www.mhlw.go.jp/file/06-Seisakujouhou-10900000-Kenkoukyoku/0000074885.pdf>]. Accessed 14 December 2020.

[6] Japanese Law Translation Database System. Act No. 57 of 30 May 2003. "Act on the Protection of Personal Information". [<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=19&y=4&co=01&ia=03&ja=04&ky=%E5%80%8B%E4%BA%BA%E6%83%85%E5%A0%B1&page=56>]. Accessed 14 January 2021.

1.2.2c

Does the country conduct surveillance of zoonotic disease in wildlife (e.g., wild animals, insects, other disease vectors)?

Yes = 1, No = 0

Current Year Score: 1

There is publicly available evidence that Japan conducts surveillance of zoonotic disease in wildlife (e.g. wild animals, insects, other disease vectors, etc.). The National Action Plan for Pandemic Influenza and New Infectious Diseases, released on 7 June 2013, states that "the national government should gather information concerning influenza viruses infecting birds and pigs

and share and accumulate information thus obtained through cooperation between relevant ministries and agencies". [1] The Ministry of the Environment conducts surveillance of wild birds for zoonotic disease on an ongoing basis. The surveillance program proposed for 2021 includes identification of policy needs as well as zoonotic disease risk assessment and monitoring. [2] The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that "it may be necessary to enhance the involvement of the Ministry of the Environment in the surveillance of zoonotic diseases in wildlife". [3]

[1] Cabinet Secretariat. "National Action Plan for Pandemic Influenza and New Infectious Diseases". 7 June 2013.

[https://www.cas.go.jp/jp/seisaku/ful/keikaku/pdf/national%20action%20plan.pdf]. Accessed 14 January 2021.

[2] Ministry of the Environment. September 2020. "Fiscal 2021 budget". [https://www.env.go.jp/guide/budget/r03/r03juten-sesakushu/2-3_01.pdf]. Accessed 14 December 2020.

[3] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/]. Accessed 14 December 2020.

1.2.3 International reporting of animal disease outbreaks

1.2.3a

Has the country submitted a report to OIE on the incidence of human cases of zoonotic disease for the last calendar year?

Yes = 1 , No = 0

Current Year Score: 0

2019

OIE WAHIS database

1.2.4 Animal health workforce

1.2.4a

Number of veterinarians per 100,000 people

Input number

Current Year Score: 31.45

2018

OIE WAHIS database

1.2.4b

Number of veterinary para-professionals per 100,000 people

Input number

Current Year Score: -

No data available

OIE WAHIS database

1.2.5 Private sector and zoonotic

1.2.5a

Does the national plan on zoonotic disease or other legislation, regulations, or plans include mechanisms for working with the private sector in controlling or responding to zoonoses?

Yes = 1 , No = 0

Current Year Score: 0

There is no publicly available evidence that a national plan on zoonotic disease or other legislation, regulation or plan include mechanisms for working with the private sector in controlling or responding to zoonoses. The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) and World Organization for Animal Health (OIE) PVS Evaluation Report released in October 2016, do not include findings on participation from the private sector. [1, 2] The Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases ("Infectious Diseases Control Law") (Act No. 114 of 2 October 1998) does not contain provisions about working with the private sector. [3] There is no evidence available from the websites of the Ministry of Health, Labor and Welfare or the Ministry of Agriculture, Forestry and Fisheries. [4, 5]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 14 December 2020.

[2] World Organization for Animal Health (OIE). October 2016. "PVS Evaluation Report Japan". [https://www.oie.int/fileadmin/Home/eng/Support_to_OIE_Members/docs/pdf/20180727_Final_OIE_JAPAN_PVS_REPORT.pdf]. Accessed 14 December 2020.

[3] Japanese Law Translation Database System. Act No. 114 of 2 October 1998. "Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases".

[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=28&y=7&co=01&ia=03&ja=04&ky=act+on+the+prevention+of+infectious+diseases+and+medical+care+for+patients+with&page=10>]. Accessed 14 December 2020.

[4] Ministry of Health, Labor and Welfare (MHLW). "Zoonotic Disease".

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/kenkou/kekkaku-kansenshou18/index.html]. Accessed 14 December 2020.

[5] Ministry of Agriculture, Forestry and Fisheries. [<https://www.maff.go.jp/>]. Accessed 14 December 2020.

1.3 BIOSECURITY

1.3.1 Whole-of- government biosecurity systems

1.3.1a

Does the country have in place a record, updated within the past five years, of the facilities in which especially dangerous pathogens and toxins are stored or processed, including details on inventories and inventory management systems of those facilities?

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence that Japan has in place a record, updated within the past 5 years of the facilities in which especially dangerous pathogens and toxins are stored or processed, including details on inventories and inventory management systems of those facilities. Although Japan reports to the United Nations Office at Geneva (UNOG) every year in compliance with Confidence Building Measures, there is no information on inventory management included in the reports. As per the report covering data for 2020, Japan has three P4 laboratories, 17 P3 laboratories and their supporting laboratories at the Murayama Annex research complex of the National Institute of Infectious Diseases (NIID). The declaration describes the scope and general description of activities as "laboratory diagnosis of viral hemorrhagic fever such as Lassa, Marburg and Ebola diseases." The Institute of Physical and Chemical Research (RIKEN)'s Tsukuba Campus is identified as a data exchange partner institute. The declaration does not provide further details on inventories and inventory management systems. [1] The NIID's Murayama Annex research complex was designated as the country's only Biosafety Level 4 (BSL-4) facility in 2015. A series of agreements and consultations with the Ministry of Health, Labor and Welfare (MHLW) have been held on the BSL-4 status of the facility since 2019. [2] The latest update from the MHLW was issued on 11 December 2020 to provide information on a plan to relocate the NIID's BSL-4 facility. [3] The World Health Organization Consultative Meeting on High/Maximum Containment (Biosafety Level 4) Laboratories Networking held in December 2017 in Lyon, France updated the status of BSL-4 facilities in Japan, citing the existing facility of the NIID and a planned high-containment facility at Nagasaki University. The meeting report states that "the National Institute of Infectious Diseases Laboratory is committed to playing a role in controlling, combating and managing infections associated with highly pathogenic agents in Japan and abroad." [4] In July 2019, the MHLW designated South American hemorrhagic fever, Ebola, Lassa fever, Crimean-Congo hemorrhagic fever, and Marburg hemorrhagic fever as pathogens that can be imported into the NIID's BSL-4 facility. [5] Nature reported on 14 October 2019 that Japan imported Ebola and Marburg virus, Lassa virus, and the viruses that cause South American hemorrhagic fever and Crimean-Congo hemorrhagic fever in September 2019. According to Nature, "the viruses' arrival represents the first time that pathogens rated BSL-4, the most dangerous rating, have been allowed to enter the NIID, the only facility in the country operating at that level." [6] The VERTIC BWC Legislation Database has no relevant information. [7] The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) does not include evidence of pathogen inventory management. [8]

- [1] United Nations Office at Geneva. BWC Electronic Confidence Building Measures Portal. 28 April 2020. "Japan". [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_japan.pdf]. Accessed 14 December 2020.
- [2] Ministry of Health and Welfare (MHLW). August 2020. "On Review of National Institute of Infectious Diseases Murayama Annex research complex BSL-4". [<https://www.niid.go.jp/niid/images/meeting/murayama-c/mc21-05.pdf>].
- [3] Ministry of Health and Welfare (MHLW). 11 December 2020. "On Review of National Institute of Infectious Diseases Murayama Annex research complex BSL-4 facility". [https://www.mhlw.go.jp/stf/shingi/other-kousei_408914_00010.html]. Accessed 14 December 2020.
- [4] World Health Organization (WHO). 13-15 December 2017. "Consultative Meeting on High/Maximum Containment (Biosafety Level 4) Laboratories Networking Meeting report". [[https://www.who.int/publications/i/item/who-consultative-meeting-high-maximum-containment-\(-biosafety-level-4\)-laboratories-networking-venue](https://www.who.int/publications/i/item/who-consultative-meeting-high-maximum-containment-(-biosafety-level-4)-laboratories-networking-venue)]. Accessed 14 December 2020.
- [5] Ministry of Health and Welfare (MHLW). July 2019. "Press Release". [https://www.mhlw.go.jp/stf/newpage_05651.html]. Accessed 14 December 2020.
- [6] Nature. 14 October 2019. "Why Japan imported Ebola ahead of the 2020 Olympics". [<https://www.nature.com/articles/d41586-019-03103-4>]. Accessed 14 December 2020.
- [7] Verification Research, Training and Information Center (VERTIC). BWC Legislation Database. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/j/>]. Accessed 14 January 2021.
- [8] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 14 January 2021.

1.3.1b

Does the country have in place legislation and/or regulations related to biosecurity which address requirements such as physical containment, operation practices, failure reporting systems, and/or cybersecurity of facilities in which especially dangerous pathogens and toxins are stored or processed?

Yes = 1 , No = 0

Current Year Score: 1

Japan has in place regulations related to biosecurity which address requirements such as physical containment, operation practices, failure reporting systems of facilities in which especially dangerous pathogens and toxins are stored or processed.

The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that there is a legal framework available to regulate possession of infectious pathogens. [1]

The Ministry of Health, Labor and Welfare provides relevant regulations including facility standards, operational procedures, transportation protocol and emergency response manuals. "Regulations on Control of Designated Pathogens Under the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases" provides rules and protocols on biosecurity of class I/II/III/IV pathogens, including physical containment, operation practices, and failure reporting systems of facilities in which especially dangerous pathogens and toxins are stored or processed. [2]

Japan reports to the United Nations Office at Geneva (UNOG) every year in compliance with "Confidence Building Measures." As per the report covering data for 2020, Japan has three P4 laboratories, 17 P3 Laboratories and their supporting laboratories at the Murayama Annex research complex of the National Institute of Infectious Diseases (NIID). The declaration describes the scope and general description of activities as "laboratory diagnosis of viral hemorrhagic fever such as Lassa, Marburg and Ebola diseases." The declaration does not provide further details about biosecurity requirements. [3] There is no further information available from the VERTIC Biological Weapons Convention Legislation Database. [4]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 15 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). "Regulations on Control of Designated Pathogens Under the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases". [https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/kekaku-kansenshou17/03.html]. Accessed 15 December 2020.

[3] United Nations Office at Geneva. BWC Electronic Confidence Building Measures Portal. 28 April 2020. "Japan". [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_japan.pdf]. Accessed 15 December 2020.

[4] Verification Research, Training and Information Center (VERTIC). "BWC Legislation Database". [<http://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/j/>]. Accessed 15 December 2020.

1.3.1c

Is there an established agency (or agencies) responsible for the enforcement of biosecurity legislation and regulations?

Yes = 1 , No = 0

Current Year Score: 1

The Ministry of Health, Labor and Welfare (MHLW) is responsible for the enforcement of biosecurity legislation and regulations. The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that the Ministry of Health, Labor and Welfare prohibits the possession of class I pathogens and permits possession of class II pathogens. [1] Article 9 of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 2 October 1998) states: "(1) The Minister of Health, Labor and Welfare must formulate the basic guideline for promoting the prevention of Infectious Diseases in an integrated manner (hereinafter referred to as the "Basic Guideline")." The Basic Guideline includes " (vii) matters concerning systems for the examination of Pathogens, etc. and the improvement of examination capabilities; (x) matters concerning the securing of the systems to properly treat Specified Pathogens, etc." [2] Compliance with "Regulations on Control of Designated Pathogens Under the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases," enforced by the MHLW, is mandatory for class II/II/IV pathogens. Permits are required for possession of class II pathogens, while notification is needed for class III pathogens. [3] Japan reports to the United Nations Office at Geneva (UNOG) every year in compliance with "Confidence Building Measures." As per the report covering data for 2020, Japan has three P4 laboratories, 17 P3 Laboratories and their supporting laboratories at the Murayama Annex research complex of the National Institute of Infectious Diseases (NIID). The declaration describes the scope and general description of activities as "laboratory diagnosis of viral hemorrhagic fever such as Lassa, Marburg and Ebola diseases." The Murayama Annex facility is under the jurisdiction of the Ministry of Health, Labor and Welfare. [4]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 15 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). "Regulations on Control of Designated Pathogens Under the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases". [https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/kekkaku-kansenshou17/03.html]. Accessed 15 December 2020.

[3] Japanese Law Translation Database System. Act No. 114 of 2 October 1998. "Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases". [<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=28&y=7&co=01&ia=03&ja=04&ky=act+on+the+prevention+of+infectious+diseases+and+medical+care+for+patients+with&page=10>]. Accessed 15 December 2020.

[4] United Nations Office at Geneva. BWC Electronic Confidence Building Measures Portal. 28 April 2020. "Japan". [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_japan.pdf]. Accessed 15 December 2020.

1.3.1d

Is there public evidence that shows that the country has taken action to consolidate its inventories of especially dangerous pathogens and toxins into a minimum number of facilities?

Yes = 1, No = 0

Current Year Score: 0

There is no public evidence that shows that Japan has taken action to consolidate its inventories of especially dangerous pathogens and toxins into a minimum number of facilities. The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that "Japan regulates the number of facilities that can possess high-risk pathogens to minimize risk" with no reference to inventory consolidation. [1] Compliance with "Regulations on Control of Designated Pathogens Under the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases," enforced by the Ministry of Health, Labor and Welfare, is mandatory for class II/II/IV pathogens. Permits are required for possession of class II pathogens, while notification is needed for class III pathogens. [2] Japan reports to the United Nations Office at Geneva (UNOG) every year in compliance with "Confidence Building Measures." As per the report

covering data for 2020, Japan has three P4 laboratories, 17 P3 Laboratories and their supporting laboratories at the Murayama Annex research complex of the National Institute of Infectious Diseases (NIID). The declaration describes the scope and general description of activities as "laboratory diagnosis of viral hemorrhagic fever such as Lassa, Marburg and Ebola diseases." The report has no mention of inventory control. [3] No additional information is available from the Ministry of Agriculture, Forestry and Fisheries or the Ministry of Defense. [4, 5] The Verification, Research, Training and Information Center (VERTIC) Biological Weapons Convention (BWC) Legislation Database has no relevant information. [6]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 15 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). "Regulations on Control of Designated Pathogens Under the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases". [https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/kekkaku-kansenshou17/03.html]. Accessed 15 December 2020.

[3] United Nations Office at Geneva. BWC Electronic Confidence Building Measures Portal. 28 April 2020. "Japan". [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_japan.pdf]. Accessed 15 December 2020.

[4] Ministry of Agriculture, Forestry and Fisheries. [<http://www.maff.go.jp>]. Accessed 15 December 2020.

[5] Ministry of Defense. [<https://www.mod.go.jp/>]. Accessed 15 December 2020.

[6] Verification Research, Training and Information Center (VERTIC). BWC Legislation Database. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/j/>]. Accessed 14 January 2021.

1.3.1e

Is there public evidence of in-country capacity to conduct Polymerase Chain Reaction (PCR)–based diagnostic testing for anthrax and/or Ebola, which would preclude culturing a live pathogen?

Yes = 1 , No = 0

Current Year Score: 1

There is public evidence of in-country capacity to conduct Polymerase Chain Reaction (PCR)-based diagnostic testing for Ebola and anthrax in Japan. The National Institute of Infectious Diseases (NIID) has a diagnostic system that uses real-time PCR testing to detect Ebola. [1] The NIID has a testing manual for conducting PCR testing for anthrax. [2]

[1] Ministry of Health, Labor and Welfare (MHLW). "Ebola hemorrhagic fever testing". [<https://www.mhlw.go.jp/file/05-Shingikai-10901000-Kenkoukyoku-Soumuka/0000101827.pdf>]. Accessed 15 December 2020.

[2] National Institute of Infectious Diseases (NIID). March 2012. "Anthrax Testing Manual". [https://www.niid.go.jp/niid/images/lab-manual/anthrax_%2020120608-2.pdf]. Accessed 15 December 2020.

1.3.2 Biosecurity training and practices

1.3.2a

Does the country require biosecurity training, using a standardized, required approach, such as through a common curriculum or a train-the-trainer program, for personnel working in facilities housing or working with especially dangerous pathogens, toxins, or biological materials with pandemic potential?

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence that Japan requires biosecurity training, using a standardized, required approach, for personnel working in facilities housing or working with especially dangerous pathogens, toxins, or biological materials with pandemic potential. The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that there are legal requirements for annual training, which covers "handling and management of pathogens, and prevention of infectious disease outbreaks". [1] The Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 2 October 1998) has a provision on education and training without descriptions of training. Article 56-21 states: "Holders of Specified Class I Pathogens, etc. and Permitted Holders of Class II Pathogens, etc. must familiarize the persons who enter the Laboratory for Handling Class I Pathogens, etc. or the Laboratory for Handling Class II Pathogens, etc. with the rules for prevention of outbreaks of Infectious Diseases, and provide necessary education and training to those persons to prevent the outbreak or spread of an Infectious Disease caused by the relevant Pathogens, etc., pursuant to the provisions of Order of the Ministry of Health, Labor and Welfare." [2] The Ministry of Health, Labor and Welfare requires training and education for all facilities handling class I/II pathogens. However, there are no rules for mandatory curriculums or required hours. [3] Japan reports to the United Nations Office at Geneva (UNOG) every year in compliance with "Confidence Building Measures." As per the report covering data for 2020, Japan has three P4 laboratories, 17 P3 Laboratories and their supporting laboratories at the Murayama Annex research complex of the National Institute of Infectious Diseases (NIID). The declaration describes the scope and general description of activities as "laboratory diagnosis of viral hemorrhagic fever such as Lassa, Marburg and Ebola diseases." The declaration does not provide details on biosecurity training. [4] No additional information is available from the Ministry of Agriculture, Forestry and Fisheries or the Ministry of Defense. [5, 6] There is no further information available from the Biological Weapons Convention (BWC) Legislation Database. [7] The Verification, Research, Training and Information Center (VERTIC) BWC Legislation Database has no relevant information. [8]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 15 December 2020.

[2] Japanese Law Translation Database System. Act No. 114 of 2 October 1998. "Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases".

[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=28&y=7&co=01&ia=03&ja=04&ky=act+on+the+prevention+of+infectious+diseases+and+medical+care+for+patients+with&page=10>]. Accessed 15 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW). "Regulations on Control of Designated Pathogens Under the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases".

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/kekkaku-kansenshou17/03.html]. Accessed 15 December 2020.

[4] United Nations Office at Geneva. BWC Electronic Confidence Building Measures Portal. 28 April 2020. "Japan".

[https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_japan.pdf]. Accessed 15 December 2020.

[5] Ministry of Agriculture, Forestry and Fisheries. [<http://www.maff.go.jp>]. Accessed 15 December 2020.

[6] Ministry of Defense. [<https://www.mod.go.jp/>]. Accessed 15 December 2020.

[7] United Nations Office at Geneva. BWC Electronic Confidence Building Measures Portal. 28 April 2020. "Japan".

[https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_japan.pdf]. Accessed 15 December 2020.

[8] Verification Research, Training and Information Center (VERTIC). BWC Legislation Database.

[<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/j/>]. Accessed 14 January 2021.

1.3.3 Personnel vetting: regulating access to sensitive locations

1.3.3a

Do regulations or licensing conditions specify that security and other personnel with access to especially dangerous pathogens, toxins, or biological materials with pandemic potential are subject to the following checks: drug testing, background checks, and psychological or mental fitness checks?

Personnel are subject to all three of these checks = 3, Personnel are subject to two of these checks = 2, Personnel are subject to one of these checks = 1, Personnel are not subject to any of these checks = 0

Current Year Score: 0

There is no publicly available evidence that regulations or licensing conditions exist to specify that security and other personnel with access to especially dangerous pathogens, toxins, or biological materials with pandemic potential are subject to drug testing, background checks, and psychological or mental fitness checks. The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that there are legal requirements for annual training, which covers "handling and management of pathogens, and prevention of infectious disease outbreaks". [1] The Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 2 October 1998) has a provision on education and training with no mention of personnel vetting. Article 56-21 states: "Holders of Specified Class I Pathogens, etc. and Permitted Holders of Class II Pathogens, etc. must familiarize the persons who enter the Laboratory for Handling Class I Pathogens, etc. or the Laboratory for Handling Class II Pathogens, etc. with the rules for prevention of outbreaks of Infectious Diseases, and provide necessary education and training to those persons to prevent the outbreak or spread of an Infectious Disease caused by the relevant Pathogens, etc., pursuant to the provisions of Order of the Ministry of Health, Labor and Welfare." [2] The Ministry of Health, Labor and Welfare's "Regulations on Control of Designated Pathogens Under the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases" does not include such evidence. [3] Japan reports to the United Nations Office at Geneva (UNOG) every year in compliance with "Confidence Building Measures." As per the report covering data for 2020, Japan has three P4 laboratories, 17 P3 Laboratories and their supporting laboratories at the Murayama Annex research complex of the National Institute of Infectious Diseases (NIID). The declaration describes the scope and general description of activities as "laboratory diagnosis of viral hemorrhagic fever such as Lassa, Marburg and Ebola diseases." The declaration does not provide details on personnel vetting. [4] No additional information is available from the Ministry of Agriculture, Forestry and Fisheries or the Ministry of Defense. [5, 6] There is no further information available from the Biological Weapons Convention (BWC) Legislation Database. [7] Nagasaki University's November 2017 update on its plan to establish Japan's second Biosafety Level 4 (BSL-4) laboratory cites personnel training and vetting among planned biosecurity requirements without details. [8] The Verification, Research, Training and Information Center (VERTIC) BWC Legislation Database has no relevant information.[9]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 15 December 2020.

[2] Japanese Law Translation Database System. Act No. 114 of 2 October 1998. "Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases".

[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=28&y=7&co=01&ia=03&ja=04&ky=act+on+the+prevention+of+infectious+diseases+and+medical+care+for+patients+with&page=10>]. Accessed 15 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW). "Regulations on Control of Designated Pathogens Under the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases".

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/kekkaku-kansenshou17/03.html]. Accessed 15 December 2020.

[4] United Nations Office at Geneva. BWC Electronic Confidence Building Measures Portal. 28 April 2020. "Japan".

[https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_japan.pdf]. Accessed 15 December 2020.

- [5] Ministry of Agriculture, Forestry and Fisheries. [<http://www.maff.go.jp>]. Accessed 15 December 2020.
- [6] Ministry of Defense. [<https://www.mod.go.jp/>]. Accessed 15 December 2020.
- [7] United Nations Office at Geneva. BWC Electronic Confidence Building Measures Portal. 28 April 2020. "Japan". [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_japan.pdf]. Accessed 15 December 2020.
- [8] Nagasaki University. 13 November 2017. "Recent developments on BSL-4 facility". [https://www.kantei.go.jp/jp/singi/kokusai_kansen/kento_iinkai/dai3/siryu2.pdf]. Accessed 15 December 2020.
- [9] Verification Research, Training and Information Center (VERTIC). BWC Legislation Database. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/j/>]. Accessed 14 January 2021.

1.3.4 Transportation security

1.3.4a

Does the country have publicly available information on national regulations on the safe and secure transport of infectious substances (specifically including Categories A and B)?

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence that Japan has publicly available information on national regulations on the safe and secure transport of infectious substances (Categories A and B). National regulations on the safe and secure transport of infectious substances are available under the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases ("Infectious Diseases Control Law") (Act No. 114 of 2 October 1998), but there is no distinction between Categories A and B in the law. The Infectious Diseases Control Law's regulation of class I/II/III/IV pathogens does not have a direct reference to UN Categories A and B. However, the regulated pathogens include many Category A infectious substances. [1] The Ministry of Health, Labor and Welfare (MHLW) has "Manual for Safe Transport of Specified Pathogens", which provides rules for transport of class I/II/III/IV pathogens specified in the Infectious Diseases Control Law. The manual regulates personnel, vehicles, storage methods, emergency supplies, communications, and pre-start checklists involved in the transport of dangerous pathogens. [2] The MHLW's domestic transport guideline issued in 2015 states that transport rules consistent with UN Categories A and B should apply to infectious substances not falling into class I/II/III/IV. [3] There is no further evidence from the Ministry of Defense, the Ministry of Agriculture, Forestry and Fisheries, or the National Institute of Infectious Diseases. [4, 5, 6]. The Verification, Research, Training and Information Center (VERTIC) Biological Weapons Convention (BWC) Legislation Database has no relevant information. [7]

[1] Japanese Law Translation Database System. Act No. 114 of 2 October 1998. "Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases".

[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=28&y=7&co=01&ia=03&ja=04&ky=act+on+the+prevention+of+infectious+diseases+and+medical+care+for+patients+with&page=10>]. Accessed 15 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). June 2010. "Manual for Safe Transport of Specified Pathogens".

[https://www.mhlw.go.jp/file/06-Seisakujouhou-10900000-Kenkoukyoku/7_01.pdf]. Accessed 15 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW). 2015. "Domestic Transport of Pathogens".

[<https://www.pref.ibaraki.jp/hokenfukushi/yobo/kiki/yobo/kansen/idwr/information/other/documents/yupack01.pdf>]. Accessed 15 December 2020.

[4] Ministry of Defense. [<https://www.mod.go.jp/index.html>]. Accessed 14 January 2021.

[5] Ministry of Agriculture, Forestry and Fisheries. [<https://www.maff.go.jp/index.html>]. Accessed 14 January 2021.

[6] National Institute of Infectious Diseases (NIID). [<https://www.niid.go.jp/niid/ja/>]. Accessed 14 January 2021.

[7] Verification Research, Training and Information Center (VERTIC). BWC Legislation Database.

[<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/j/>]. Accessed 14 January 2021.

1.3.5 Cross-border transfer and end-user screening

1.3.5a

Is there legislation and/or regulations in place to oversee the cross-border transfer and end-user screening of especially dangerous pathogens, toxins, and pathogens with pandemic potential?

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence that Japan has national legislation overseeing the cross-border transfer and end-user screening of especially dangerous pathogens, toxins and pathogens with pandemic potential. The Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases ("Infectious Diseases Control Law") (Act No. 114 of 2 October 1998) regulates the import of designated pathogens, but there is no such provision regulating exports. Article 56-12 requires anyone seeking to import class II pathogens to obtain a permit from the Ministry of Health, Labor and Welfare (MHLW) by furnishing the following information: "(i) the applicant's personal name or entity name and address, and the name of the representative if the applicant is a corporation; (ii) types of Class II Pathogens, etc. to be imported (or the types and quantities if they are Toxins); (iii) purpose of import; (iv) exporter's personal name or entity name and address; (v) period for import; (vi) means of transportation; and (vii) name of the port of import." [1] The Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Act No. 97 of 2003) regulates exports of living modified organisms. The law's definition of "living modified organism" is "an organism that possesses nucleic acid, or a replicated product thereof, obtained through use of the any of the following technologies". There is no mention of pathogen in this law. Article 27 states that "a person who wishes to export living modified organisms shall, as stipulated in the ordinance of the competent ministries, notify the importing country of the names of the types of living modified organisms to be exported, and other matters stipulated in the ordinance of the competent ministries". "Competent ministries" refer to the Ministry of the Environment, the Ministry of Economy, the Ministry of Agriculture, Forestry and Fisheries, and the MHLW. [2] No additional evidence is available from the MHLW, the Ministry of Agriculture, Forestry and Fisheries, or Ministry of Defense. [3, 4, 5] The Verification, Research, Training and Information Center (VERTIC) Biological Weapons Convention (BWC) Legislation Database has no relevant information. [6]

[1] Japanese Law Translation Database System. Act No. 114 of 2 October 1998. "Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases".

[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=28&y=7&co=01&ia=03&ja=04&ky=act+on+the+prevention+of+infectious+diseases+and+medical+care+for+patients+with&page=10>]. Accessed 15 December 2020.

[2] Japanese Law Translation Database System. Act No. 97 of 2003. "Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms".

[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=26&y=12&co=01&ia=03&ja=04&ky=living+modified&page=9>]. Accessed 15 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW). "Regulations on Control of Designated Pathogens Under the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases".

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/kekkaku-kansenshou17/03.html]. Accessed 15 December 2020.

[4] Ministry of Agriculture, Forestry and Fisheries. [<http://www.maff.go.jp>]. Accessed 15 December 2020.

[5] Ministry of Defense. [<https://www.mod.go.jp/>]. Accessed 15 December 2020.

[6] Verification Research, Training and Information Center (VERTIC). BWC Legislation Database.

[<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/j/>]. Accessed 14 January 2021.

1.4 BIOSAFETY

1.4.1 Whole-of-government biosafety systems

1.4.1a

Does the country have in place national biosafety legislation and/or regulations?

Yes = 1 , No = 0

Current Year Score: 1

There is public evidence that Japan has in place national biosafety regulations. The National Institute of Infectious Diseases (NIID) has "Regulations on Safe Management of Pathogens, Etc.", which are based on biosafety standards of the World Health Organization (WHO), the Organization for Economic Cooperation and Development, and the US Centers for Disease Control and Prevention. These regulations set biosafety standards, institutional safeguards, and health monitoring requirements. The NIID cites the WHO's "Laboratory Biosafety Manual (3rd Edition) and "Biorisk Management: Laboratory Biosecurity Guidance" among references for "Regulations on Safe Management of Pathogens, Etc.". [1] The Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Act No. 97 of 18 June 2003) represents Japan's compliance with the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. The law regulates the domestic use as well as export and import of living modified organisms. [2] Japan is a state party to the Biological Weapons Convention (BWC), which comprehensively prohibits the development, production, stockpiling, acquisition and retention of biological and toxin weapons. [3] Japan reports to the United Nations Office at Geneva (UNOG) every year in compliance with "Confidence Building Measures." As per the report covering data for 2020, Japan has three P4 laboratories, 17 P3 Laboratories and their supporting laboratories at the Murayama Annex research complex of the National Institute of Infectious Diseases (NIID). The declaration describes the scope and general description of activities as "laboratory diagnosis of viral hemorrhagic fever such as Lassa, Marburg and Ebola diseases." The declaration does not include details on biosafety. [4] There is no further information available from the Biological Weapons Convention (BWC) Legislation Database. [5]

[1] National Institute of Infectious Diseases (NIID). 1 April 2020. "Regulations on Safe Management of Pathogens, Etc.".

[https://www.niid.go.jp/niid/images/biosafe/kanrikitei3/Kanrikitei3_20200401.pdf]. Accessed 16 December 2020.

[2] Japanese Law Translation Database System. Act No. 97 of 2003. "Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms".

[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=26&y=12&co=01&ia=03&ja=04&ky=living+modified&page=9>]. Accessed 16 December 2020.

[3] Delegation of Japan to the Conference on Disarmament. 20 November 2018. "Biological Weapons Convention".

[https://www.disarm.emb-japan.go.jp/itpr_ja/BWC_info.html]. Accessed 16 December 2020.

[4] United Nations Office at Geneva. BWC Electronic Confidence Building Measures Portal. 28 April 2020. "Japan".

[https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_japan.pdf]. Accessed 15 December 2020.

[5] Verification Research, Training and Information Center (VERTIC). "BWC Legislation Database".

[<http://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/j/>]. Accessed 15 December 2020.

1.4.1b

Is there an established agency responsible for the enforcement of biosafety legislation and regulations?

Yes = 1, No = 0

Current Year Score: 1

Japan has an established agency responsible for the enforcement of biosafety legislation and regulations.

The Ministry of Health, Labor and Welfare (MHLW) and the Ministry of Agriculture, Forestry and Fisheries have jurisdiction over the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 2 October 1998) and the Act on Domestic Animal Infectious Diseases Control (Act No. 166 of 31 May 1951), respectively. [1, 2]

The National Institute of Infectious Diseases (NIID) under the MHLW is responsible for the enforcement of "Regulations on Safe Management of Pathogens, Etc.". [3]

Japan reports to the United Nations Office at Geneva (UNOG) every year in compliance with "Confidence Building Measures." As per the report covering data for 2020, Japan has three P4 laboratories, 17 P3 Laboratories and their supporting laboratories at the Murayama Annex research complex of the National Institute of Infectious Diseases (NIID). The declaration describes the scope and general description of activities as "laboratory diagnosis of viral hemorrhagic fever such as Lassa, Marburg and Ebola diseases." The declaration does not include details on biosafety. [4]

[1] Japanese Law Translation Database System. Act No. 114 of 2 October 1998. "Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases".

[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=28&y=7&co=01&ia=03&ja=04&ky=act+on+the+prevention+of+infectious+diseases+and+medical+care+for+patients+with&page=10>]. Accessed 18 December 2020.

[2] Japanese Law Translation Database System. Act No. 166 of 31 May 1951. "Act on Domestic Animal Infectious Diseases Control".

[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=0&y=0&co=01&ia=03&ja=04&ky=animal+infectious&page=20>]. Accessed 18 December 2020.

[3] National Institute of Infectious Diseases (NIID). 1 April 2020. "Regulations on Safe Management of Pathogens, Etc.". [https://www.niid.go.jp/niid/images/biosafe/kanrikitei3/Kanrikitei3_20200401.pdf]. Accessed 18 December 2020.

[4] United Nations Office at Geneva. BWC Electronic Confidence Building Measures Portal. 28 April 2020. "Japan". [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_japan.pdf]. Accessed 18 December 2020.

1.4.2 Biosafety training and practices

1.4.2a

Does the country require biosafety training, using a standardized, required approach, such as through a common curriculum or a train-the-trainer program, for personnel working in facilities housing or working with especially dangerous pathogens, toxins, or biological materials with pandemic potential?

Yes = 1, No = 0

Current Year Score: 0

There is insufficient evidence that Japan requires biosafety training, using a standardized, required approach, such as through a common curriculum or a train-the-trainer program, for personnel working in facilities housing or working with especially dangerous pathogens, toxins, or biological materials with pandemic potential. The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that there are legal requirements for annual training,

which covers "handling and management of pathogens, and prevention of infectious disease outbreaks". [1] The Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 2 October 1998) has a provision on education and training without descriptions of training. Article 56-21 states: "Holders of Specified Class I Pathogens, etc. and Permitted Holders of Class II Pathogens, etc. must familiarize the persons who enter the Laboratory for Handling Class I Pathogens, etc. or the Laboratory for Handling Class II Pathogens, etc. with the rules for prevention of outbreaks of Infectious Diseases, and provide necessary education and training to those persons to prevent the outbreak or spread of an Infectious Disease caused by the relevant Pathogens, etc., pursuant to the provisions of Order of the Ministry of Health, Labor and Welfare." [2] The Ministry of Health, Labor and Welfare requires training and education for all facilities handling class I/II pathogens. However, there are no rules for mandatory curriculums or required hours. [3] Japan reports to the United Nations Office at Geneva (UNOG) every year in compliance with "Confidence Building Measures." As per the report covering data for 2020, Japan has three P4 laboratories, 17 P3 Laboratories and their supporting laboratories at the Murayama Annex research complex of the National Institute of Infectious Diseases (NIID). The declaration describes the scope and general description of activities as "laboratory diagnosis of viral hemorrhagic fever such as Lassa, Marburg and Ebola diseases." The declaration does not provide details on biosafety training. [4] No additional information is available from the Ministry of Agriculture, Forestry and Fisheries. [5] There is no further information available from the Biological Weapons Convention (BWC) Legislation Database. [6] The Verification, Research, Training and Information Center (VERTIC) Biological Weapons Convention (BWC) Legislation Database has no relevant information. [7]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 18 December 2020.

[2] Japanese Law Translation Database System. Act No. 114 of 2 October 1998. "Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases". [<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=28&y=7&co=01&ia=03&ja=04&ky=act+on+the+prevention+of+infectious+diseases+and+medical+care+for+patients+with&page=10>]. Accessed 18 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW). "Regulations on Control of Designated Pathogens Under the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases ". [https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/kekkaku-kansenshou17/03.html]. Accessed 18 December 2020.

[4] United Nations Office at Geneva. BWC Electronic Confidence Building Measures Portal. 28 April 2020. "Japan". [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_japan.pdf]. Accessed 18 December 2020.

[5] Ministry of Agriculture, Forestry and Fisheries. [<http://www.maff.go.jp>]. Accessed 18 December 2020.

[6] United Nations Office at Geneva. 2018. BWC Electronic Confidence Building Measures Portal. "Japan". [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_japan.pdf]. Accessed 18 December 2020.

[7] Verification Research, Training and Information Center (VERTIC). BWC Legislation Database. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/j/>]. Accessed 14 January 2021.

1.5 DUAL-USE RESEARCH AND CULTURE OF RESPONSIBLE SCIENCE

1.5.1 Oversight of research with especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research

1.5.1a

Is there publicly available evidence that the country has conducted an assessment to determine whether ongoing research is occurring on especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research?

Yes = 1 , No = 0

Current Year Score: 0

There is no publicly available evidence that Japan has conducted an assessment to determine whether ongoing research is occurring on especially dangerous pathogens, toxins, pathogens with pandemic potential, and/or other dual-use research. The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that "no mechanisms currently exist for oversight of dual-use research". [1] The Ministry of Health, Labor and Welfare, the Ministry of Agriculture, Forestry and Fisheries, the Ministry of Defense, or the National Institute of Infectious Diseases does not have publicly available evidence. [2, 3, 4, 5] The Science Council of Japan, an independent organization representing the Japanese scientists community, has the "Code of Conduct for Scientists," which addresses scientists' engagement with dual-use research. The 2013 revision of the Code of Conduct for Scientists states added the following provision: "(Dual Use of Scientific Research Outcomes) 6. Scientists shall recognize that there exist possibilities that their research results, contrary to their own intentions, may be used for destructive actions, and shall select appropriate means and methods as allowed by society in conducting research and publicizing the results". [6] Japan reports to the United Nations Office at Geneva (UNOG) every year in compliance with "Confidence Building Measures." As per the report covering data for 2020, Japan has three P4 laboratories, 17 P3 Laboratories and their supporting laboratories at the Murayama Annex research complex of the National Institute of Infectious Diseases (NIID). The Institute of Physical and Chemical Research (RIKEN)'s Tsukuba Campus is identified as a data exchange partner institute. The declaration describes the scope and general description of activities as "laboratory diagnosis of viral hemorrhagic fever such as Lassa, Marburg and Ebola diseases." The declaration cites ongoing "national biological defense research and development programs," which includes "medicine, immunology, molecular biology, bio-engineering" research at the National Defense Medical College. This part of the declaration contains a list of publicly available papers and reports resulting from the work at the National Defense Medical College, published during the previous 12 months. [7] The government of Japan has commitment to pursue dual-use research. The "National Defense Program Guidelines for FY 2019 and Beyond" report, released on 18 December 2018, states that the Ministry of Defense and the Self-Defense Forces "will work to actively leverage potentially dual-use, advanced commercial technologies through such efforts as: technology exchange with relevant domestic and overseas entities; enhanced collaboration with relevant ministries and agencies; and use of the 'Innovative Science & Technology Initiative for Security' program." [8] The Verification, Research, Training and Information Center (VERTIC) Biological Weapons Convention (BWC) Legislation Database has no relevant information. [9]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 19 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 19 December 2020.

[3] Ministry of Agriculture, Forestry and Fisheries. [<http://www.maff.go.jp>]. Accessed 19 December 2020.

[4] Ministry of Defense. [<https://www.mod.go.jp/>]. Accessed 19 December 2020.

[5] National Institute of Infectious Diseases (NIID). [<https://www.niid.go.jp/niid/ja/>]. Accessed 19 December 2020.

[6] Science Council of Japan. 25 January 2013. "Statement: Code of Conduct for Scientists -Revised Version". [http://www.scj.go.jp/en/report/Code_of_Conduct_for_Scientists-Revised_version.pdf]. Accessed 19 December 2020.

[7] United Nations Office at Geneva. BWC Electronic Confidence Building Measures Portal. 28 April 2020. "Japan". [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_japan.pdf]. Accessed 19 December 2020.

[8] Ministry of National Defense. 18 December 2018. "National Defense Program Guidelines for FY 2019 and Beyond". [https://www.mod.go.jp/j/approach/agenda/guideline/2019/pdf/20181218_e.pdf]. Accessed 19 December 2020.

[9] Verification Research, Training and Information Center (VERTIC). BWC Legislation Database. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/j/>]. Accessed 14 January 2021.

1.5.1b

Is there legislation and/or regulation requiring oversight of research with especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research?

Yes = 1, No = 0

Current Year Score: 0

There is insufficient evidence that Japan has a national policy that requires oversight of dual-use research, such as research with especially dangerous pathogens, toxins, and/or pathogens with pandemic potential. The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that "no mechanisms currently exist for oversight of dual-use research". [1] The Ministry of Health, Labor and Welfare, the Ministry of Agriculture, Forestry and Fisheries, the Ministry of Defense, and the National Institute of Infectious Diseases websites do not have publicly available evidence. [2, 3, 4, 5] The Science Council of Japan, an independent organization representing the Japanese scientists community, has the "Code of Conduct for Scientists," which addresses scientists' engagement with dual-use research. The 2013 revision of the Code of Conduct for Scientists states added the following provision: "(Dual Use of Scientific Research Outcomes) 6. Scientists shall recognize that there exist possibilities that their research results, contrary to their own intentions, may be used for destructive actions, and shall select appropriate means and methods as allowed by society in conducting research and publicizing the results". [6] Japan reports to the United Nations Office at Geneva (UNOG) every year in compliance with "Confidence Building Measures." As per the report covering data for 2020, Japan has three P4 laboratories, 17 P3 Laboratories and their supporting laboratories at the Murayama Annex research complex of the National Institute of Infectious Diseases (NIID). The Institute of Physical and Chemical Research (RIKEN)'s Tsukuba Campus is identified as a data exchange partner institute. The declaration describes the scope and general description of activities as "laboratory diagnosis of viral hemorrhagic fever such as Lassa, Marburg and Ebola diseases." The declaration cites ongoing "national biological defense research and development programs," which includes "medicine, immunology, molecular biology, bio-engineering" research at the National Defense Medical College. This part of the declaration contains a list of publicly available papers and reports resulting from the work at the National Defense Medical College, published during the previous 12 months. [7] The government of Japan has commitment to pursue dual-use research. The "National Defense Program Guidelines for FY 2019 and Beyond" report, released on 18 December 2018, states that the Ministry of Defense and the Self-Defense Forces "will work to actively leverage potentially dual-use, advanced commercial technologies through such efforts as: technology exchange with relevant domestic and overseas entities; enhanced collaboration with relevant ministries and agencies; and use of the 'Innovative Science & Technology Initiative for Security' program." [8] The Verification, Research, Training and Information Center (VERTIC) Biological Weapons Convention (BWC) Legislation Database has no relevant information. [9]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 19 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 19 December 2020.

[3] Ministry of Agriculture, Forestry and Fisheries. [<http://www.maff.go.jp>]. Accessed 19 December 2020.

[4] Ministry of Defense. [<https://www.mod.go.jp/>]. Accessed 19 December 2020.

[5] National Institute of Infectious Diseases (NIID). [<https://www.niid.go.jp/niid/ja/>]. Accessed 19 December 2020.

[6] Science Council of Japan. 25 January 2013. "Statement: Code of Conduct for Scientists -Revised Version". [http://www.scj.go.jp/en/report/Code_of_Conduct_for_Scientists-Revised_version.pdf]. Accessed 19 December 2020.

[7] United Nations Office at Geneva. BWC Electronic Confidence Building Measures Portal. 28 April 2020. "Japan". [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_japan.pdf]. Accessed 19 December 2020.

[8] Ministry of National Defense. 18 December 2018. "National Defense Program Guidelines for FY 2019 and Beyond". [https://www.mod.go.jp/j/approach/agenda/guideline/2019/pdf/20181218_e.pdf]. Accessed 19 December 2020.

[9] Verification Research, Training and Information Center (VERTIC). "BWC Legislation Database".

[<http://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/j/>]. Accessed 19 December 2020.

1.5.1c

Is there an agency responsible for oversight of research with especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research?

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence that Japan has an agency responsible for oversight of research with especially dangerous pathogens, pathogens with pandemic potential, and/or other dual-use research. The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that "no mechanisms currently exist for oversight of dual-use research". [1] The Ministry of Health, Labor and Welfare, the Ministry of Agriculture, Forestry and Fisheries, the Ministry of Defense, or the National Institute of Infectious Diseases does not have publicly available evidence. [2, 3, 4, 5] The Science Council of Japan, an independent organization representing the Japanese scientists community, has the "Code of Conduct for Scientists," which addresses scientists' engagement with dual-use research. The 2013 revision of the Code of Conduct for Scientists states added the following provision: "(Dual Use of Scientific Research Outcomes) 6. Scientists shall recognize that there exist possibilities that their research results, contrary to their own intentions, may be used for destructive actions, and shall select appropriate means and methods as allowed by society in conducting research and publicizing the results". [6] Japan reports to the United Nations Office at Geneva (UNOG) every year in compliance with "Confidence Building Measures." As per the report covering data for 2020, Japan has three P4 laboratories, 17 P3 Laboratories and their supporting laboratories at the Murayama Annex research complex of the National Institute of Infectious Diseases (NIID). The Institute of Physical and Chemical Research (RIKEN)'s Tsukuba Campus is identified as a data exchange partner institute. The declaration describes the scope and general description of activities as "laboratory diagnosis of viral hemorrhagic fever such as Lassa, Marburg and Ebola diseases." The declaration cites ongoing "national biological defense research and development programs," which includes "medicine, immunology, molecular biology, bio-engineering" research at the National Defense Medical College. This part of the declaration contains a list of publicly available papers and reports resulting from the work at the National Defense Medical College, published during the previous 12 months. [7] The government of Japan has commitment to pursue dual-use research. The "National Defense Program Guidelines for FY 2019 and Beyond" report, released on 18 December 2018, states that the Ministry of Defense and the Self-Defense Forces "will work to actively leverage potentially dual-use, advanced commercial technologies through such efforts as: technology exchange with relevant domestic and overseas entities; enhanced collaboration with relevant ministries and agencies; and use of the 'Innovative Science & Technology Initiative for Security' program." [8] The Verification, Research, Training and Information Center (VERTIC) Biological Weapons Convention (BWC) Legislation Database has no relevant information. [9]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 19 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 19 December 2020.

[3] Ministry of Agriculture, Forestry and Fisheries. [<http://www.maff.go.jp>]. Accessed 19 December 2020.

[4] Ministry of Defense. [<https://www.mod.go.jp/>]. Accessed 19 December 2020.

[5] National Institute of Infectious Diseases (NIID). [<https://www.niid.go.jp/niid/ja/>]. Accessed 19 December 2020.

[6] Science Council of Japan. 25 January 2013. "Statement: Code of Conduct for Scientists -Revised Version". [http://www.scj.go.jp/en/report/Code_of_Conduct_for_Scientists-Revised_version.pdf]. Accessed 19 December 2020.

[7] United Nations Office at Geneva. BWC Electronic Confidence Building Measures Portal. 28 April 2020. "Japan".

[https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_japan.pdf]. Accessed 19 December 2020.

[8] Ministry of National Defense. 18 December 2018. "National Defense Program Guidelines for FY 2019 and Beyond".
[https://www.mod.go.jp/j/approach/agenda/guideline/2019/pdf/20181218_e.pdf]. Accessed 19 December 2020.

[9] Verification Research, Training and Information Center (VERTIC). BWC Legislation Database.
[<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/j/>]. Accessed 14 January 2021.

1.5.2 Screening guidance for providers of genetic material

1.5.2a

Is there legislation and/or regulation requiring the screening of synthesized DNA (deoxyribonucleic acid) against lists of known pathogens and toxins before it is sold?

Yes = 1, No = 0

Current Year Score: 0

There is insufficient evidence that Japan has national legislation and regulations requiring the screening of synthesized DNA. There is no information on whether synthesized DNA is passed through a code reader before it is sold. The Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Act No. 97 of 2003) regulates "Type 1" and "Type 2" use of living modified organisms (LMOs). Article 28 specifies export labelling requirements for LMOs as follows: "Living modified organisms must not be exported unless the format use of those living modified organisms and other particulars stipulated by Order of the competent ministries are labelled on the living modified organisms or their packaging, container or consignment invoice, as stipulated by Order of the competent ministries". [1] Type 2 use of LMOs include development of live vaccines for animals (Ministry of Agriculture, Forestry and Fisheries), use of viruses for gene therapy (Ministry of Health, Labor and Welfare), use in gene recombination experiments (Ministry of Education, Culture, Sports, Science and Technology), and production of industrial enzymes (Ministry of Economy, Trade and Industry). Type 1 use is not specified, and it is determined by the Ministry of the Environment and other relevant ministries, depending on the purpose and usage of LMOs. The ministries with jurisdiction over LMO use require screening and approval for each case of LMO use. It is unclear whether this screening involves DNA or known pathogens. [2] Japan reports to the United Nations Office at Geneva (UNOG) every year in compliance with "Confidence Building Measures." As per the report covering data for 2020, Japan has three P4 laboratories, 17 P3 Laboratories and their supporting laboratories at the Murayama Annex research complex of the National Institute of Infectious Diseases (NIID). The Institute of Physical and Chemical Research (RIKEN)'s Tsukuba Campus is identified as a data exchange partner institute. The declaration describes the scope and general description of activities as "laboratory diagnosis of viral hemorrhagic fever such as Lassa, Marburg and Ebola diseases." The declaration contains no information on the screening of synthesized DNA. [3] The Verification, Research, Training and Information Center (VERTIC) Biological Weapons Convention (BWC) Legislation Database has no relevant information. [4]

[1] Japanese Law Translation Database System. Act No. 97 of 2003. "Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms".

[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=26&y=12&co=01&ia=03&ja=04&ky=living+modified&page=9>]. Accessed 19 December 2020.

[2] Ministry of the Environment. "Biosafety Regulations in Japan".

[http://www.biodic.go.jp/bch/english/cartagena/s_04.html]. Accessed 19 December 2020.

[3] United Nations Office at Geneva. BWC Electronic Confidence Building Measures Portal. 28 April 2020. "Japan".

[https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_japan.pdf]. Accessed 19 December 2020.

[4] Verification Research, Training and Information Center (VERTIC). BWC Legislation Database.

[<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/j/>]. Accessed 14 January

2021.

1.6 IMMUNIZATION

1.6.1 Vaccination rates

1.6.1a

Immunization rate (measles/MCV2)

Immunization rate (measles/MCV2), 95% or greater = 2, 80-94.9% = 1, Less than 80%, or no data = 0

Current Year Score: 1

2019

World Health Organization

1.6.1b

Are official foot-and-mouth disease (FMD) vaccination figures for livestock publicly available through the OIE database?

Yes = 1, No = 0

Current Year Score: 1

2020

OIE WAHIS database

Category 2: Early detection and reporting for epidemics of potential international concern

2.1 LABORATORY SYSTEMS STRENGTH AND QUALITY

2.1.1 Laboratory testing for detection of priority diseases

2.1.1a

Does the national laboratory system have the capacity to conduct diagnostic tests for at least 5 of the 10 WHO-defined core tests?

Evidence they can conduct 5 of the 10 core tests and these tests are named = 2, Evidence they can conduct 5 of the 10 core tests and the tests are not named = 1, No evidence they can conduct 5 of the 10 core tests = 0

Current Year Score: 2

The national laboratory system has the capacity to conduct diagnostic tests for at least 5 of the 10 World Health Organization (WHO)-defined core tests, although there is no publicly available information about the four country-specific tests or

whether Japan has publicly defined them.

The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that Japan has in place a nationwide laboratory network that provides "access to diagnostic tests for notifiable diseases including 10 core tests for priority diseases of major national public health concern." The JEE further states: "Japanese citizens and residents have access to diagnostic tests for notifiable diseases including 10 core tests for priority diseases of major national public health concern. These tests include Middle East respiratory syndrome coronavirus (MERS-CoV) polymerase chain reaction (PCR), Measles PCR, SFTS PCR, Influenza PCR, Carbapenem-resistant Enterobacteriaceae (CRE) PCR, tuberculosis microscopy, poliovirus culture, human immunodeficiency virus (HIV) serology, Salmonella species culture, and Plasmodium species rapid diagnostic tests (RDT)". The JEE does not state which of these tests are country-defined tests. [1]

The National Institute of Infectious Diseases (NIID)'s laboratory manuals for pathogen detection cover class I/II/III/IV/V infectious diseases as well as specially designated diseases, as specified under the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 2 October 1998). The NIID's testing capacity includes polymerase chain reaction (PCR) testing for influenza virus (flu); serology for HIV; virus culture for poliovirus (polio); microscopy for mycobacterium tuberculosis (tuberculosis/TB); rapid diagnostic testing for plasmodium spp. (malaria); and bacterial culture for Salmonella enteritidis serotype Typhi (typhoid). [2]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 19 December 2020.

[2] National Institute of Infectious Diseases (NIID). "Laboratory manuals for pathogen detection". [<https://www.niid.go.jp/niid/ja/laboratory-test.html#class0>]. Accessed 19 December 2020.

2.1.1b

Is there a national plan, strategy or similar document for conducting testing during a public health emergency, which includes considerations for testing for novel pathogens, scaling capacity, and defining goals for testing?

Yes, there is evidence of a plan, and it includes considerations for testing for novel pathogens, scaling capacity, and defining goals for testing = 2, Yes, there is evidence of a plan, but there is insufficient evidence that it includes considerations for testing for novel pathogens, scaling capacity, and defining goals for testing = 1, No evidence of a plan = 0

Current Year Score: 1

There is evidence of a national strategy for deploying testing specific to Covid-19, but there is no evidence of plans which can be used for multiple disease outbreaks.

The Ministry of Health, Labor and Welfare (MHLW) issued updated information on the Covid-19 testing regime on 22 July 2020 with a view to scaling capacity for handling a subsequent wave of infections nationwide. Defined goals for testing include expansion of outsourcing to private test providers and securing of a reagent supply. [1]

The National Institute of Infectious Diseases (NIID) issued a PCR-based testing manual for Covid-19 on 5 February 2020. The NIID's testing manual does not contain provisions on scaling capacity or defining goals for testing. [2] There is no further evidence from the Ministry of Agriculture, Forestry. [3]

[1] Ministry of Health, Labor and Welfare (MHLW). 22 July 2020. [<https://www.mhlw.go.jp/content/000692982.pdf>]. Accessed 14 January 2021.

[2] National Institute of Infectious Diseases (NIID). 19 March 2020. "Laboratory manuals for pathogen detection".

[<https://www.niid.go.jp/niid/images/lab-manual/2019-nCoV20200319.pdf>]. Accessed 19 December 2020.

[3] Ministry of Agriculture, Forestry and Fisheries. [<https://www.maff.go.jp/index.html>]. Accessed 14 January 2021.

2.1.2 Laboratory quality systems

2.1.2a

Is there a national laboratory that serves as a reference facility which is accredited (e.g., International Organization for Standardization [ISO] 15189:2003, U.S. Clinical Laboratory Improvement Amendments [CLIA])?

Yes = 1 , No = 0

Current Year Score: 0

There is no publicly available evidence that the National Institute of Infectious Diseases (NIID), which operates national reference laboratories, has been accredited. [1] The Ministry of Health, Labor and Welfare or the Ministry of Agriculture, Forestry and Fisheries do not have publicly available evidence. [2, 3] The Japan Accreditation Board provides International Organization for Standardization (ISO) 15189 certification for medical laboratories under a mutual recognition agreement with the Asia Pacific Laboratory Accreditation Cooperation. The NIID is not among the accredited institutions. [4]

[1] National Institute of Infectious Diseases (NIID). [<https://www.niid.go.jp/niid/ja/>]. Accessed 19 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 19 December 2020.

[3] Ministry of Agriculture, Forestry and Fisheries. [<http://www.maff.go.jp>]. Accessed 19 December 2020.

[4] Japan Accreditation Board. "Medical Laboratories". [https://www.jab.or.jp/en/accredited_bodies/]. Accessed 20 December 2020.

2.1.2b

Is there a national laboratory that serves as a reference facility which is subject to external quality assurance review?

Yes = 1 , No = 0

Current Year Score: 0

There is no publicly available evidence that the National Institute of Infectious Diseases (NIID) is subject to external quality assurance review as a national reference facility. [1] The Ministry of Health, Labor and Welfare or the Ministry of Agriculture, Forestry and Fisheries does not have publicly available evidence. [2, 3]. The NIID is subject to the ISO 17025 competence requirements for testing and collaboration laboratories consistent with the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme and to Official Medicines Control Laboratory certification by the Ministry of Health, Labor and Welfare and the Pharmaceuticals and Medical Devices Agency. [4]

[1] National Institute of Infectious Diseases (NIID). [<https://www.niid.go.jp/niid/ja/>]. Accessed 19 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 19 December 2020.

[3] Ministry of Agriculture, Forestry and Fisheries. [<http://www.maff.go.jp>]. Accessed 19 December 2020.

[4] National Institute of Infectious Diseases (NIID). "Quality Assurance".

[<https://www.niid.go.jp/niid/images/annual/h30/201814.pdf>]. Accessed 19 December 2020.

2.2 LABORATORY SUPPLY CHAINS

2.2.1 Specimen referral and transport system

2.2.1a

Is there a nationwide specimen transport system?

Yes = 1 , No = 0

Current Year Score: 1

Japan has a nationwide specimen transport system. The Joint External Evaluation (JEE) of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that a specimen transportation system exists under the Manual for Safe Transport of Specified Pathogens, which is consistent with World Health Organization (WHO) guidance on regulations for the transport of infectious substances. [1] The country also scores a 5 on JEE question D.1.2, indicating it has a system in place to transport specimens from at least 80% of the country. [1] The Ministry of Health, Labor and Welfare's "Manual for Safe Transport of Specified Pathogens", under which the specimen transportation system is funded, contained detailed instructions on ground/air/maritime transportation of class I/II/III/IV pathogens from one place to another throughout the country, including from the site of collection to a laboratory for testing. [1,2] The manual describes loading methods, container and equipment criteria, and communications and vehicle crew requirements. The manual does not provide distinction between public and private means of transportation. No operational details are available as to geographic coverage or transportation providers. [2]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 19 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). June 2010. "Manual for Safe Transport of Specified Pathogens". [https://www.mhlw.go.jp/file/06-Seisakujouhou-10900000-Kenkoukyoku/7_01.pdf]. Accessed 19 December 2020.

2.2.2 Laboratory cooperation and coordination

2.2.2a

Is there a plan in place to rapidly authorize or license laboratories to supplement the capacity of the national public health laboratory system to scale-up testing during an outbreak?

Yes = 2 , Yes, but there is evidence of gaps in implementation = 1 , No = 0

Current Year Score: 2

There is evidence that Japan has a plan in place to rapidly authorize or license laboratories to supplement the capacity of the national public health laboratory system to scale-up testing during an outbreak. The Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 2 October 1998) provides a legal basis for the Ministry of Health, Labor and Welfare (MHLW) to implement testing scale-up plans during an outbreak. Article 38 states: (1) Designated Medical Institutions for Specified Infectious Diseases are to be designated by the Minister of Health, Labor and Welfare, subject to the consent of the establisher of the respective medical institution, and further subject to consultations with the prefectural governor who has jurisdiction over the location of the medical institution. (2) The Designated Medical Institutions for Class I Infectious Diseases, Designated Medical Institutions for Class II Infectious Diseases, and Designated Medical Institutions for Tuberculosis are to be designated by a prefectural governor, subject to the consent of the establisher of the respective medical institution, which is to be selected from the hospitals (or the hospitals or clinics (including those specified by Cabinet Order referred to in Article 6, paragraph (16)) or the pharmacies, with regard to the Designated Medical

Institutions for Tuberculosis) conforming to the standards specified by the Minister of Health, Labor and Welfare. (3) Pursuant to the provisions specified by the Minister of Health, Labor and Welfare, the Designated Medical Institutions for Infectious Diseases must take charge of the medical services for patients with infectious diseases and persons with symptoms of New Infectious Diseases for which the prefectural government bears expenses in accordance with the provisions of the preceding two Articles." [1] On 25 February 2020, the MHLW issued a notice allowing local governments to add new laboratories or outsource to private laboratories under contract for Covid-19 testing based on the National Institute of Infectious Diseases' laboratory manuals for pathogen detection. [2] On 16 September 2020 the MHLW issued a further notice to local governments on putting in place contingency testing scale-up plans involving available area institutions. [3] According to MHLW data, 4.63m PCR tests were conducted between 18 February and 17 December, including 2.57m tests conducted by private laboratories. [4] There is no further evidence from the Ministry of Agriculture, Forestry and Fisheries or the National Institute of Infectious Diseases. [5, 6]

[1] Japanese Law Translation Database System. Act No. 114 of 2 October 1998. "Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases".

[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=28&y=7&co=01&ia=03&ja=04&ky=act+on+the+prevention+of+infectious+diseases+and+medical+care+for+patients+with&page=10>]. Accessed 19 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). 25 February 2020. [<https://www.mhlw.go.jp/content/000600570.pdf>]. Accessed 19 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW). 16 September 2020.

[<https://www.fdma.go.jp/laws/tutatsu/items/0916jimurennraku.pdf>]. Accessed 19 December 2020.

[4] Ministry of Health, Labor and Welfare (MHLW). 17 December 2020.

[<https://www.mhlw.go.jp/content/10906000/000707617.pdf>]. Accessed 19 December 2020.

[5] Ministry of Agriculture, Forestry and Fisheries. [<https://www.maff.go.jp/index.html>]. Accessed 14 January 2021.

[6] National Institute of Infectious Diseases (NIID). [<https://www.niid.go.jp/niid/ja/>]. Accessed 14 January 2021.

2.3 REAL-TIME SURVEILLANCE AND REPORTING

2.3.1 Indicator and event-based surveillance and reporting systems

2.3.1a

Is there evidence that the country is conducting ongoing event-based surveillance and analysis for infectious disease?

Yes, there is evidence of ongoing event-based surveillance and evidence that the data is being analyzed on a daily basis = 2,

Yes, there is evidence of ongoing event-based surveillance, but no evidence that the data are being analyzed on a daily basis

= 1, No = 0

Current Year Score: 2

Japan has an event-based surveillance unit (EBS) that conducts ongoing surveillance and analyzes data on a daily basis. The infectious disease surveillance system set up under the National Institute of Infectious Diseases (NIID) is an EBS unit responsible for outbreak detection based on laboratory surveillance and patient reporting. The National Epidemiological Surveillance of Infectious Diseases (NESID) operated by the NIID's Infectious Disease Surveillance Center collects reports on suspected cases from sentinel sites on an ongoing basis. [1, 2] The Joint External Evaluation (JEE) of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that the country's infectious disease surveillance system includes an EBS. According to the JEE, "Japan has an extensive infectious disease surveillance system that includes indicator-based surveillance (IBS), event-based surveillance (EBS), sentinel surveillance, syndromic surveillance, and dedicated surveillance for emergency events or special circumstances". The JEE also states: "EBS of informal data sources such as media, local non-governmental organizations, as well as WHO notifications are conducted by the NIID daily...On a daily basis, all surveillance

data are reviewed by the surveillance team at the NIID, and when necessary, risk assessments are conducted for certain situations." [3]

[1] National Institute of Infectious Diseases (NIID). February 2018. "Infectious Disease Surveillance System in Japan".

[https://www.niid.go.jp/niid/images/epi/nesid/nesid_en.pdf]. Accessed 19 December 2020.

[2] National Institute of Infectious Diseases (NIID). "Infectious Disease Surveillance Center".

[https://www.niid.go.jp/niid/ja/from-idsc.html]. Accessed 19 December 2020.

[3] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/]. Accessed 19 December 2020.

2.3.1b

Is there publicly available evidence that the country reported a potential public health emergency of international concern (PHEIC) to the WHO within the last two years?

Yes = 1, No = 0

Current Year Score: 1

There is publicly available evidence that Japan reported a potential public health emergency of international concern (PHEIC) to the WHO within the last two years. Japan reported novel coronavirus outbreaks to the WHO in January 2020. This reporting happened before 30 January 2020 when the WHO announced Covid-19 as a potential PHEIC. [1] There was no PHEIC report filed by Japan in 2019. [2]

[1] World Health Organization (WHO). 2020. "Daily outbreak news". [https://www.who.int/csr/don/archive/year/2020/en/]. Accessed 19 December 2020.

[2] World Health Organization (WHO). 2019. "Daily outbreak news". [https://www.who.int/csr/don/archive/year/2019/en/]. Accessed 19 December 2020.

2.3.2 Interoperable, interconnected, electronic real-time reporting systems

2.3.2a

Does the government operate an electronic reporting surveillance system at both the national and the sub-national level?

Yes = 1, No = 0

Current Year Score: 1

The government operates an electronic reporting surveillance system at both the national and sub-national level. An online platform for reporting detected pathogens exists as part of the National Institute of Infectious Diseases (NIID)'s National Epidemiological Surveillance of Infectious Diseases (NESID) system, which covers all sources under the jurisdiction of the national government and local governments. The NIID describes the system as a "centralized data management system" for "information concerning infectious diseases in Japan," which is "collected and published, and occurrence and trends are assessed, based on reporting from physicians and veterinarians". [1] The building blocks of the NESID reporting system are 4Local public health centers enter data into the nationwide electronic surveillance system, which enables data to be shared throughout the system. [2]

[1] National Institute of Infectious Diseases (NIID). February 2018. "Infectious Disease Surveillance System in Japan".

[https://www.niid.go.jp/niid/images/epi/nesid/nesid_en.pdf]. Accessed 19 December 2020.

[2] National Institute of Infectious Diseases (NIID). "Infectious Disease Surveillance Center". [https://www.niid.go.jp/niid/ja/from-idsc.html]. Accessed 19 December 2020.

2.3.2b

Does the electronic reporting surveillance system collect ongoing or real-time laboratory data?

Yes = 1, No = 0

Current Year Score: 1

The laboratory-based surveillance system collects ongoing laboratory data from a network of public health facilities on a real-time or weekly basis. Under the National Epidemiological Surveillance of Infectious Diseases (NESID) system, laboratory data from medical facilities and patient sentinel sites are relayed through public health centers and public health institutes to the central infectious disease surveillance center at the National Institute of Infectious Diseases. Submissions of specimens are mandated as part of the active epidemiological investigation under the laboratory-based surveillance system for infectious diseases including pandemic influenza. The Infectious Disease Surveillance Center operates a platform for ongoing electronic reporting: Infectious Disease Weekly Report. Infectious Agents Surveillance Report. [1, 2] The Ministry of Health, Labor and Welfare launched "Health Center Real-Time Information-Sharing System on Covid-19 (HER-SYS)" in May 2020. HER-SYS digitalizes the entire information flow of patient testing and data reporting and sharing. [2]

[1] National Institute of Infectious Diseases (NIID). February 2018. "Infectious Disease Surveillance System in Japan". [https://www.niid.go.jp/niid/images/epi/nesid/nesid_en.pdf]. Accessed 19 December 2020.

[2] National Institute of Infectious Diseases (NIID). "Infectious Disease Surveillance Center". [https://www.niid.go.jp/niid/ja/from-idsc.html]. Accessed 19 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW). May 2020. "Health Center Real-Time Information-Sharing System on Covid-19 (HER-SYS)". [https://www.mhlw.go.jp/content/10900000/000678061.pdf]. Accessed 19 December 2020.

2.4 SURVEILLANCE DATA ACCESSIBILITY AND TRANSPARENCY

2.4.1 Coverage and use of electronic health records

2.4.1a

Are electronic health records commonly in use?

Electronic health records are commonly in use = 2, Electronic health records are not commonly in use, but there is evidence they are used = 1, No evidence electronic health records are in use = 0

Current Year Score: 1

There is insufficient evidence that electronic health records are commonly in use in Japan. However, there is evidence that EHRs are in use for an increasing number of hospitals in Japan. The Ministry of Health, Labor and Welfare (MHLW)'s latest data show that the EHR adoption rate increased from 14.2% in 2008 to 46.7% in 2017 for hospital nationwide. The adoption rate is higher for larger hospitals. In 2017, 85.4% of hospitals with 400 or more beds used EHRs. The ratio was 64.9% for hospitals with 200-399 beds, 37% for hospitals with fewer than 200 beds, 41.6% for clinics. [1] Standardization is a high priority for the MHLW's ongoing initiative for digitalizing healthcare information. [2] According to the Japanese Association of Healthcare Information Systems Industry's annual survey, the number of hospitals using electronic health records reached 3,221, or 38.3% of all hospitals, in 2018, increased from 2,903 or 34.4% in 2017. [3]

[1] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/content/10800000/000482158.pdf>]. Accessed 19 December 2020.

[2] Standardized Structured Medical Information eXchange. [http://www.ss-mix.org/cons/ssmix2_about.html]. Accessed 19 December 2020.

[3] Japanese Association of Healthcare Information Systems Industry. 23 August 2019. "Medical Information System Adoption Survey". [https://www.jahis.jp/action/id=57?contents_type=23]. Accessed 22 December 2018.

2.4.1b

Does the national public health system have access to electronic health records of individuals in their country?

Yes = 1, No = 0

Current Year Score: 1

There is evidence that the national public health system has access to electronic health records (EHR) of individuals in Japan. There are exceptions from the requirement for obtaining prior consent for access to personal information, as provided by the Act on the Protection of Personal Information (Act No. 57 of 30 May 2003), which include "cases in which there is a special need to enhance public hygiene or promote fostering healthy children, and when it is difficult to obtain a principal's consent." [1] Japan's universal healthcare system is based on the government provider's review of all health records to determine the validity of claims. According to the World Health Organization's "Japan Health System Review" released in 2018, Japan's national database of health insurance reimbursement claims filed by healthcare providers covers "diagnoses, age, sex, procedures and drugs provided, volume and tariff." However, there is no mention of electronic health records as a component of the national database. [2]. The Health Insurance Claims Review & Reimbursement Services, which collects and reviews all healthcare claims, does not mention access to electronic health records as part of its standard operating procedure. [3]. The government's plan to incorporate a standardized EHR system into the national public health system and facilitate online verification of patient information received cabinet approval on 21 June 2019. [4]

[1] Japanese Law Translation Database System. Act No. 57 of 30 May 2003. "Act on the Protection of Personal Information". [<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=19&y=4&co=01&ia=03&ja=04&ky=%E5%80%8B%E4%BA%BA%E6%83%85%E5%A0%B1&page=56>]. Accessed 15 January 2021.

[2] World Health Organization (WHO). 2018. "Japan Health System Review" [<https://apps.who.int/iris/bitstream/handle/10665/259941/9789290226260-eng.pdf?sequence=1&isAllowed=y>]. Accessed 19 December 2020.

[3] Health Insurance Claims Review & Reimbursement Services. "Evaluation and Reimbursement Workflow". [http://www.ssk.or.jp/seikyushiharai/gyomuflow/gyomuflow_01.html]. Accessed 19 December 2020.

[4] Cabinet Secretariat. 21 June 2019.

[https://www.kantei.go.jp/jp/singi/kenkouiryou/jisedai_kiban/iryoujyoho_sistem/dai1/sankou2.pdf]. Accessed 30 December 2018.

2.4.1c

Are there data standards to ensure data is comparable (e.g., ISO standards)?

Yes = 1, No = 0

Current Year Score: 1

Japan has data standards to ensure data is comparable (e.g., ISO standards).

The Ministry of Health, Labor and Welfare (MHLW) provides a set of data standards to ensure some types of data are

comparable, including ISO 22077-1:2015, which specifies how medical waveforms, such as electrocardiogram, electroencephalogram, spirometry waveform, etc., are described for interoperability among healthcare information systems. [1] There are private-sector data standards in place to ensure data is comparable in Japan. The Japanese Association of Healthcare Information Systems Industry (JAHIS) oversees standardization of electronic health records. JAHIS standards cover medical data including digital images for production, storage, authentication, and interchange. JAHIS standards are frequently updated to keep up with changes in healthcare industry practices and technologies. [2] The MHLW adopts the "JAHIS Protocol for Prescription Data Communication" and the "JAHIS Protocol for Clinical. Laboratory Data Communication." [1, 3, 4]

[1] Ministry of Health, Labor and Welfare (MHLW).

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/iryuu/johoka/index.html]. Accessed 19 December 2020.

[2] Japanese Association of Healthcare Information Systems Industry (JAHIS). [<https://www.jahis.jp/>]. Accessed 19 December 2020.

[3] JAHIS. "JAHIS Protocol for Prescription Data". [<https://www.jahis.jp/standard/detail/id=564>]. Accessed 19 December 2020.

[4] JAHIS. "JAHIS Protocol for Clinical. Laboratory Data Communication". [<https://www.jahis.jp/standard/detail/id=180>]. Accessed 19 December 2020.

2.4.2 Data integration between human, animal, and environmental health sectors

2.4.2a

Is there evidence of established mechanisms at the relevant ministries responsible for animal, human, and wildlife surveillance to share data (e.g., through mosquito surveillance, brucellosis surveillance)?

Yes = 1 , No = 0

Current Year Score: 1

There is evidence that an established mechanism of data sharing exists to cover relevant ministries responsible for animal, human and wildlife surveillance. The Joint External Evaluation (JEE) of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that "an information sharing system has been established" to share information among the Ministry of Agriculture, Forestry and Fisheries, the Ministry of the Environment, and other relevant ministries and agencies in case of detection of a suspected case of highly pathogenic avian influenza in poultry and wild birds. The JEE also notes that "there is currently no process for regular information sharing for zoonotic diseases other than avian influenza. However, information can be shared ad-hoc upon identification or suspicion of a zoonotic disease of significant public health concern". [1] However, there is no mention of involvement by the Ministry of Health, Labor and Welfare. [1] The World Organization for Animal Health (OIE) Performance of Veterinary Services (PVS) Evaluation Report, released in October 2016, states that "external coordination with other ministries and agencies operates effectively" among the Ministry of Agriculture, Forestry and Fisheries (animal health), the Ministry of Health, Labor and Welfare (animal food safety), the Ministry of the Environment (wildlife and animal welfare), and other commissions and centers. [2] The Ministry of Health, Labor and Welfare holds annual symposiums on "one health" issues. The latest symposium was held on 8 February in Tokyo. [3] No further evidence is available from the Ministry of Agriculture, Forestry and Fisheries or the Ministry of the Environment. [4, 5].

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 19 December 2020.

[2] World Organization for Animal Health (OIE). October 2016. "PVS Evaluation Report Japan".

[http://www.oie.int/fileadmin/Home/eng/Support_to_OIE_Members/docs/pdf/20180727_Final_OIE_JAPAN_PVS_REPORT.p

df]. Accessed 19 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000172990.html>]. Accessed 16 February 2019.

[4] Ministry of Agriculture, Forestry and Fisheries. [<http://www.maff.go.jp/index.html>]. Accessed 19 December 2020.

[5] Ministry of the Environment. [<https://www.env.go.jp/index.html>]. Accessed 19 December 2020.

2.4.3 Transparency of surveillance data

2.4.3a

Does the country make de-identified health surveillance data on infectious diseases publicly available via reports (or other format) on government websites (such as the Ministry of Health, Ministry of Agriculture, or similar)?

Yes = 1, No = 0

Current Year Score: 1

Japan makes de-identified health surveillance data on disease outbreaks publicly available via reports on a weekly basis.

Article 16 and Article 44 of the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 2 October 1998) require the Ministry of Health, Labor and Welfare (MHLW) to propagate de-identified health surveillance data by publishing "in newspapers, by broadcasting via the Internet, or by any other appropriate means". [1] The Infectious Disease Surveillance Center of the National Institute of Infectious Diseases publishes "Infectious Diseases Weekly Report" on its website. [2] The MHLW releases de-identified health surveillance data on Covid-19 on a daily basis on its website. [3]

[1] Japanese Law Translation Database System. Act No. 114 of 2 October 1998. "Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases".

[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=28&y=7&co=01&ia=03&ja=04&ky=act+on+the+prevention+of+infectious+diseases+and+medical+care+for+patients+with&page=10>]. Accessed 19 December 2020.

[2] National Institute of Infectious Diseases (NIID). "Infectious Disease Surveillance Center".

[<https://www.niid.go.jp/niid/ja/from-idsc.html>]. Accessed 19 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW).

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000164708_00001.html]. Accessed 19 December 2020.

2.4.3b

Does the country make de-identified COVID-19 surveillance data (including details such as daily case count, mortality rate, etc) available via daily reports (or other formats) on government websites (such as the Ministry of Health, or similar)?

Yes = 1, No = 0

Current Year Score: 1

Japan makes de-identified Covid-19 surveillance data (including details such as daily case count, mortality rate, etc.) available via daily reports (or other formats) on government websites (such as the Ministry of Health, or similar). The Ministry of Health, Labor and Welfare (MHLW) releases de-identified health surveillance data on Covid-19 on a daily basis on its website. Daily updates cover the number of positive cases, the number of people tested, the number of hospitalizations, the number of deaths, and the number of severely cases. [1]

[1] Ministry of Health, Labor and Welfare (MHLW).

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000164708_00001.html]. Accessed 19 December 2020.

2.4.4 Ethical considerations during surveillance

2.4.4a

Is there legislation and/or regulations that safeguard the confidentiality of identifiable health information for individuals, such as that generated through health surveillance activities?

Yes = 1 , No = 0

Current Year Score: 1

There is evidence that Japan has laws, regulations or guidelines that specifically safeguard the confidentiality of identifiable health information for individuals. Japan's revised 'Act on the Protection of Personal Information (APPI)' (Act No. 57 of 2003 as amended in 2015) first came into effect on 30 May 2017. Most recently, it was amended and passed in June 2020. Under the APPI, "each ministry provides, jointly with the PPC or individually, guideline(s), Q&As, and commentaries with regard to the relevant business sector". The APPI includes general guidelines as well as guidelines for transfers to third parties in foreign countries, for Checking and Recording on Transfers to Third Parties, for Anonymized Information, and for Data Leakages. [1] As such, there is further evidence that Japan's Ministry of Health, Labor and Welfare ('MHLW') has issued guidance for data protections. These include "Guidance for the Appropriate Handling of Personal Information by Medical or Care-related Service Providers; Guidance concerning Safety Management of Medical Information Systems; Ethical Guidelines concerning Medical Research Targeting Humans; Ethical Guidelines concerning Analysis and Research of the Human Genome and Genes; Guidelines concerning Gene Therapy Clinical Research; and Ethical Guidelines concerning Research of Assisted Reproduction Technologies that Produce Fertilized Embryos". [1]

[1] One Trust Data Guidance. July 2002. "Japan - Data Protection Overview". [<https://www.dataguidance.com/notes/japan-data-protection-overview>] Accessed June 3, 2021.

2.4.4b

Is there legislation and/or regulations safeguarding the confidentiality of identifiable health information for individuals, such as that generated through health surveillance activities, include mention of protections from cyber attacks (e.g., ransomware)?

Yes = 1 , No = 0

Current Year Score: 1

There is evidence that Japan has legislation and/or regulations safeguarding the confidentiality of identifiable health information for individuals, such as that generated through health surveillance activities, including protections from cyber attacks (e.g., ransomware).

Japan's revised 'Act on the Protection of Personal Information (APPI)' (Act No. 57 of 2003 as amended in 2015) first came into effect on 30 May 2017. Most recently, it was amended and passed in June 2020. Under the APPI, "each ministry provides, jointly with the Personal Information Protection Commission (PPC), the regulatory body established pursuant to the APPI responsible for overseeing compliance with the APPI and relevant ministers, or individually, guideline(s), Q&As, and commentaries with regard to the relevant business sector". [1]

The APPI includes general guidelines as well as guidelines for transfers to third parties in foreign countries, for Checking and

Recording on Transfers to Third Parties, for Anonymized Information, and for Data Leakages. [1] As such, there is further evidence that Japan's Ministry of Health, Labor and Welfare (MHLW) has issued guidance for data protections. These include "Guidance for the Appropriate Handling of Personal Information by Medical or Care-related Service Providers; Guidance concerning Safety Management of Medical Information Systems; Ethical Guidelines concerning Medical Research Targeting Humans; Ethical Guidelines concerning Analysis and Research of the Human Genome and Genes; Guidelines concerning Gene Therapy Clinical Research; and Ethical Guidelines concerning Research of Assisted Reproduction Technologies that Produce Fertilized Embryos". [1]

These General Guidelines by the PPC provide high-level examples of security measures including technological security measures such as system access and authorization access control, prevention of unauthorized access, and review of system vulnerabilities. [1]

[1] One Trust Data Guidance. July 2002. "Japan - Data Protection Overview". [<https://www.dataguidance.com/notes/japan-data-protection-overview>] Accessed June 3, 2021.

2.4.5 International data sharing

2.4.5a

Has the government made a commitment via public statements, legislation and/or a cooperative agreement to share surveillance data during a public health emergency with other countries in the region?

Yes, commitments have been made to share data for more than one disease = 2, Yes, commitments have been made to share data only for one disease = 1, No = 0

Current Year Score: 0

There is insufficient evidence that the government of Japan has cooperative agreements to share surveillance data during a public health emergency with other countries in the region for one or more than one diseases.

The National Institute of Infectious Diseases (NIID) and its South Korean counterpart Korea Centers for Disease Control and Prevention (now Korea Disease Control and Prevention Agency) signed the "Joint Announcement on the Cooperation Between National Institute of Infectious Diseases, Japan And Korea Centers for Diseases Control, and Prevention, the Republic of Korea" on 28 April 1991. The agreement covers information sharing on infectious diseases. [1] However, it does not explicitly include sharing at the times of emergency.

The NIID and the Chinese Center for Disease Control and Prevention signed the "Memorandum of Collaboration on Infectious Diseases Between National Institute of Infectious Diseases, Japan And Chinese Center for Disease Control and Prevention, the People's Republic of China" on 23 August 1991. The agreement includes infectious disease data sharing. [2] The NIID has similar cooperation agreements with Taiwan, India, Indonesia, Vietnam and Mongolia. [3]

[1] National Institute of Infectious Diseases (NIID). 28 April 1991. "Joint Announcement on the Cooperation Between National Institute of Infectious Diseases, Japan And Korea Centers for Diseases Control, and Prevention, the Republic of Korea". [<https://www.niid.go.jp/niid/images/inter/inter1/kcdc.pdf>].

[2] National Institute of Infectious Diseases (NIID). 23 August 1991. "Memorandum of Collaboration on Infectious Diseases Between National Institute of Infectious Diseases, Japan And Chinese Center for Disease Control and Prevention, the People's Republic of China". [<https://www.niid.go.jp/niid/images/inter/inter1/ccdc.pdf>]. Accessed 19 December 2020.

[3] National Institute of Infectious Diseases (NIID). "International Cooperation".

[<https://www.niid.go.jp/niid/ja/international/mou.html>]. Accessed 19 December 2020.

2.5 CASE-BASED INVESTIGATION

2.5.1 Case investigation and contact tracing

2.5.1a

Is there a national system in place to provide support at the sub-national level (e.g. training, metrics standardization and/or financial resources) to conduct contact tracing in the event of a public health emergency?

Yes, there is evidence that the national government supports sub-national systems to prepare for future public health emergencies = 2, Yes, there is evidence that the national government supports sub-national systems, but only in response to active public health emergencies = 1, No = 0

Current Year Score: 1

There is some evidence that Japan has a national system for providing support at the sub-national level (e.g. training, metrics standardization and/or financial resources) to conduct contact tracing, but only in response to active public health emergencies (covid-19).

Evidence of contract tracing in the policy context does not exist outside the current response to Covid-19. The central government provided ¥3trn (US\$29bn) for local governments' Covid-19 pandemic programs, including contact tracing, in 2020. [1] The Ministry of Health, Labor and Welfare (MHLW) launched the Covid-19 Contact Confirming Application (COCOA) contract tracing app for nationwide rollout in June 2020. [2] There is no evidence of training or metrics standardization. [3] The National Institute of Infectious Diseases provided field epidemiological support for local governments handling cluster outbreaks by dispatching teams of epidemiological investigators. [4]

[1] Cabinet Secretariat. [<https://www.kantei.go.jp/jp/singi/tiiki/rinjikoufukin/index.html>]. Accessed 19 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). 19 June 2020. [<https://www.mhlw.go.jp/content/000646559.pdf>]. Accessed 19 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW).

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000164708_00001.html]. Accessed 19 December 2020.

[4] National Institute of Infectious Diseases (NIID). 17 July 2020. [<https://www.niid.go.jp/niid/ja/jissekijpn/9744-fetp.html>]. Accessed 20 December 2020.

2.5.1b

Does the country provide wraparound services to enable infected people and their contacts to self-isolate or quarantine as recommended, particularly economic support (paycheck, job security) and medical attention?

Yes, both economic support and medical attention are provided = 2, Yes, but only economic support or medical attention is provided = 1, No = 0

Current Year Score: 2

The government of Japan provides wraparound services to enable infected people and their contacts to self-isolate as recommended, particularly economic support (paycheck, job security) and medical attention, throughout the country.

The Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response (Act No. 31 of 2012) contains provisions on economic support during a state of public health emergency, including reimbursements of

expenses related to the enforcement of emergency measures. The law also provides fiscal support and financial assistance for people affected by a state of emergency. Article 65 states: "Expenses incurred in connection with measures enforced in accordance with regulations under the law as new infectious diseases emergency measures shall be borne by authorities responsible for their enforcement." [1]

The Ministry of Health, Labor and Welfare (MHLW) has a Covid-19 program that provides benefits to workers at small and medium enterprises who do not receive paid leave from their employers during their absence from work due to Covid-19. [2] The MHLW has a similar program specific to pregnant female workers. This program subsidizes employers that allow pregnant female workers to take paid leave at the doctor's recommendation as a precaution against infection. [3]

[1] Ministry of Internal Affairs and Communications. Act No. 31 of 2012. "Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response". [<https://elaws.e-gov.go.jp/document?lawid=424AC0000000031>]. Accessed 15 January 2021.

[2] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/stf/kyugyoshienkin.html>]. Accessed 20 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW). [https://www.mhlw.go.jp/stf/newpage_11686.html]. Accessed 20 December 2020.

2.5.1c

Does the country make de-identified data on contact tracing efforts for COVID-19 (including the percentage of new cases from identified contacts) available via daily reports (or other format) on government websites (such as the Ministry of Health, or similar)?

Yes = 1 , No = 0

Current Year Score: 0

The government of Japan does not make de-identified data on contact tracing efforts for Covid-19 (including the percentage of new cases from identified contacts) available via daily reports (or other format) on government websites (such as the Ministry of Health, or similar). The Ministry of Health, Labor and Welfare (MHLW) does not release such data but allows local governments to make cluster outbreak data public on their websites. The MHLW provides guidelines that restrict the scope of open information on local Covid-19 outbreaks, including contact histories. The percentage of new cases from identified contacts is not included. [1, 2] For example, the Shinjuku City of Tokyo Metropolis publishes de-identified contact tracing data on cluster outbreaks as they occur on its website. [3]

[1] Ministry of Health, Labor and Welfare (MHLW).

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000164708_00001.html]. Accessed 20 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). 28 July 2020. [<https://www.mhlw.go.jp/content/000652973.pdf>]. Accessed

[3] Shinjuku City, Tokyo. [https://www.city.shinjuku.lg.jp/kusei/cln202002_kns01.html]. Accessed 20 December 2020.

2.5.2 Point of entry management

2.5.2a

Is there a joint plan or cooperative agreement between the public health system and border control authorities to identify suspected and potential cases in international travelers and trace and quarantine their contacts in the event of a public health emergency?

Yes, plan(s)/agreement(s) are in place to prepare for future public health emergencies = 2, Yes, but plan(s)/agreement(s) are in place only in response to active public health emergencies = 1, No = 0

Current Year Score: 1

There is evidence that Japan has a joint plan or cooperative agreement between the public health system and border control authorities to identify suspected and potential cases in international travelers and trace and quarantine their contacts but only in response to active emergency (covid-19).

No evidence of such a policy arrangement exists outside the current government response to Covid-19. The Ministry of Justice, which has jurisdiction over border controls, enforces entry restrictions as follows: "Regarding Covid-19 (novel coronavirus), which is spreading throughout the world, based on Cabinet approval on January 31, 2020 and the announcement by the Novel Coronavirus Response Headquarters, and so on for the time being, the Ministry of Justice considers foreign nationals who hold the record for staying in the countries / regions listed in attached table 1 within 14 days before the day of application for landing to be foreign nationals who fall under Article 5, paragraph (1), item (xiv) of the Immigration Control (See note 1) and Refugee Recognition Act (hereinafter referred to as the "Immigration Control Act") and unless there are special exceptional circumstances, the foreign national will be subject to denial of landing." [1]

The Ministry of Justice issued an update on denial of landing to prevent the spread of Covid-19 on 13 January 2021 with a blanket ban on entry into Japan by foreign nationals "unless there are special exceptional circumstances". [2] The Ministry of Health, Labor and Welfare provides 14-day quarantine restrictions for international travelers otherwise allowed to enter the country. Quarantined travelers must stay at a place designated at the point of entry and are subjected to health checks by local public health centers during quarantine. [3] There is no evidence available from the National Institute of Infectious Diseases. [4]

[1] Ministry of Justice. 1 November 2020. "Regarding denial of landing to prevent the spread of Covid-19". [<http://www.moj.go.jp/content/001332786.pdf>]. Accessed 20 December 2020.

[2] Ministry of Justice. 13 January 2021. "Regarding denial of landing to prevent the spread of Covid-19". [<http://www.moj.go.jp/isa/content/001338898.pdf>]. Accessed 23 January 2021.

[3] Ministry of Health, Labor and Welfare (MHLW). 17 November 2020. [https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/covid19_qa_kanrenkigyuu_00001.html]. Accessed 20 December 2020.

[4] National Institute of Infectious Diseases (NIID). [<https://www.niid.go.jp/niid/ja/>]. Accessed 15 January 2021.

2.6 EPIDEMIOLOGY WORKFORCE

2.6.1 Applied epidemiology training program, such as the field epidemiology training program, for public health professionals and veterinarians (e.g., Field Epidemiology Training Program [FETP] and Field Epidemiology Training Program for Veterinarians [FETPV])

2.6.1a

Does the country meet one of the following criteria?

- Applied epidemiology training program (such as FETP) is available in country
- Resources are provided by the government to send citizens to another country to participate in applied epidemiology training programs (such as FETP)

Needs to meet at least one of the criteria to be scored a 1 on this measure. , Yes for both = 1 , Yes for one = 1 , No for both = 0

Current Year Score: 1

There is evidence that Field Epidemiology Training Program (FETP) is available in Japan, but there is no documented evidence that resources are provided by the government to send citizens to another country to participate in FETP. The Joint External Evaluation (JEE) of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that the National Institute of Infectious Diseases (NIID) has a two-year national field epidemiology training program. The JEE cites a lack of "international visibility" including partnerships with international organizations. [1] The NIID's Field Epidemiology Training Program Japan (FETP-J) curriculum covers field epidemiological investigation, surveillance, and risk assessment. Foreign experts are invited to teach short-term courses. The next FETP-J program is offered for April 2021-March 2023. [2] No further evidence is available from the Ministry of Health, Labor and Welfare, the US Centers for Disease Control and Prevention, or the Training Programs in Epidemiology and Public Health Interventions Network. [3, 4, 5]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 20 December 2020.

[2] National Institute of Infectious Diseases (NIID). "Field Epidemiology Training Program Japan (FETP-J)". [<https://www.niid.go.jp/niid/ja/fetp.html>]. Accessed 20 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 20 December 2020.

[4] US Centers for Disease Control and Prevention. "Field Epidemiology Training Program (FETP)".

[<https://www.cdc.gov/globalhealth/healthprotection/fetp/index.htm>]. Accessed 20 December 2020.

[5] Training Programs in Epidemiology and Public Health Interventions Network (TEPHINET). [<https://www.tephinet.org/>]. Accessed 20 December 2020.

2.6.1b

Are the available field epidemiology training programs explicitly inclusive of animal health professionals or is there a specific animal health field epidemiology training program offered (such as FETPV)?

Yes = 1 , No = 0

Current Year Score: 1

In Japan, the Field Epidemiology Training Program (FETP) is explicitly inclusive of animal health professionals. The National Institute of Infectious Diseases' Field Epidemiology Training Program Japan (FETP-J) specifically includes veterinarians among target participants. A biennial one-week course is offered by Michael Bell, Deputy Director of the Division of Healthcare Quality Promotion at the National Center for Emerging and Zoonotic Infectious Diseases of the US Centers for Disease Control and Prevention. Risk assessment courses cover zoonotic diseases such as Ebola, MERS, and H7N9. [1] The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) cites the need to "enhance field epidemiological skills among veterinarians by increasing the participation of veterinarians" in FETP. [2]

[1] National Institute of Infectious Diseases (NIID). "Field Epidemiology Training Program Japan (FETP-J)". [<https://www.niid.go.jp/niid/ja/fetp.html>]. Accessed 20 December 2020.

[2] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 20 December 2020.

2.6.2 Epidemiology workforce capacity

2.6.2a

Is there public evidence that the country has at least 1 trained field epidemiologist per 200,000 people?

Yes = 1 , No = 0

Current Year Score: 0

2020

Completed JEE assessments; Economist Impact analyst qualitative assessment based on official national sources, which vary by country

Category 3: Rapid response to and mitigation of the spread of an epidemic

3.1 EMERGENCY PREPAREDNESS AND RESPONSE PLANNING

3.1.1 National public health emergency preparedness and response plan

3.1.1a

Does the country have an overarching national public health emergency response plan in place which addresses planning for multiple communicable diseases with epidemic or pandemic potential?

Evidence that there is a plan in place, and the plan is publicly available = 2, Evidence that the plan is in place, but the plan is not publicly available OR, Disease-specific plans are in place, but there is no evidence of an overarching plan = 1, No evidence that such a plan or plans are in place = 0

Current Year Score: 2

Japan has an overarching national public health emergency response plan in place which addresses planning for multiple communicable diseases with pandemic potential. The Joint External Evaluation (JEE) of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that the Ministry of Health, Labor and Welfare (MHLW)'s "Basic Guidelines for Health Risk and Crisis Management" provides a basis for "activation of the public health emergency operations follows guidelines and procedures". [1] As Japan's overarching national public health emergency response plan, the "Basic Guidelines for Health Risk and Crisis Management" addresses health emergencies caused by pharmaceuticals, infectious diseases or food. There is no reference to specific types of infectious diseases. The guidelines hold the MHLW responsible for prevention, containment, and medical treatment efforts associated with a public health crisis caused by health risk factors such as infectious diseases. [2] The JEE also cites the existence of the "National Action Plan for Pandemic Influenza and New Infectious Diseases". [1] The "National Action Plan for Pandemic Influenza and New Infectious Diseases," released in June 2013, provides government measures for pre-outbreak preparedness and emergency response in different phases of an outbreak under the Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response (Act No. 31 of 2012). The plan targets pandemic influenza and unspecified new infectious diseases. This law augments the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 2 October 1998) with provisions specific to public health emergencies. [3] An amendment has been made to the Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response to add Covid-19 to

new infectious diseases, effective 13 March 2020. [4] The Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response mandates "formulation of action plans by national and municipal governments; stockpiling supplies and goods including medical products and masks; and implementation of border control measures." The law allows the government to declare an "Emergency Situation Regarding Pandemic Influenza and New Infectious Diseases," which triggers emergency actions including "requesting people to refrain from going out; requesting and issuing an order to restrict the use of facilities including schools; requesting and issuing an order to restrict the holding of events; emergency permission for the use of temporary medical facilities; requesting and issuing an order to transport emergency supplies; requesting the sales and the seizure of specified goods; extending the expiration date of driver's license; and provision of loans by public financial institutions, and other measures." [5]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 20 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). "Basic Guidelines for Health Risk and Crisis Management". [<https://www.mhlw.go.jp/general/seido/kousei/kenkou/sisin/index.html>]. Accessed 20 December 2020.

[3] Cabinet Secretariat. 7 June 2013. "National Action Plan for Pandemic Influenza and New Infectious Diseases". [<https://www.cas.go.jp/jp/seisaku/ful/keikaku/pdf/national%20action%20plan.pdf>]. Accessed 20 December 2020.

[4] Fire and Disaster Management Agency. 16 March 2020.

[<https://www.fdma.go.jp/laws/tutatsu/items/0316jimurennraku.pdf>]. Accessed 20 December 2020.

[5] Ministry of Health, Labor and Welfare (MHLW). "Overview of the Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response". [<https://www.mhlw.go.jp/content/10900000/000606693.pdf>]. Accessed 20 December 2020.

3.1.1b

If an overarching plan is in place, has it been updated in the last 3 years?

Yes = 1 , No /no plan in place= 0

Current Year Score: 0

There is no evidence that the Ministry of Health, Labor and Welfare's "Basic Guidelines for Health Risk and Crisis Management," which is Japan's overarching national public health emergency response plan, has been updated in the last 3 years. These guidelines were created in March 1997 and updated in March 2001 and October 2013. [1] The Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response (Act No. 31 of 2012), which serves as an overarching contingency plan, was revised on 13 March 2020 to roll out emergency measures to handle the Covid-19 outbreak. [2] The "National Action Plan for Pandemic Influenza and New Infectious Diseases," released in June 2013, was last revised in September 2017 to add changes to medicine stockpile targets and other minor changes. [3]

[1] Ministry of Health, Labor and Welfare (MHLW). "Basic Guidelines for Health Risk and Crisis Management" [<https://www.mhlw.go.jp/general/seido/kousei/kenkou/sisin/index.html>]. Accessed 20 December 2020.

[2] Fire and Disaster Management Agency. 16 March 2020.

[<https://www.fdma.go.jp/laws/tutatsu/items/0316jimurennraku.pdf>]. Accessed 20 December 2020.

[3] Cabinet Secretariat. 7 June 2013. "National Action Plan for Pandemic Influenza and New Infectious Diseases". [<https://www.cas.go.jp/jp/seisaku/ful/keikaku/pdf/national%20action%20plan.pdf>]. Accessed 20 December 2020.

3.1.1c

If an overarching plan is in place, does it include considerations for pediatric and/or other vulnerable populations?

Yes = 1 , No /no plan in place= 0

Current Year Score: 1

The existing overarching plan includes considerations for pediatric and/or other vulnerable populations. The Ministry of Health, Labor and Welfare's "Basic Guidelines for Health Risk and Crisis Management." Which serves as Japan's overarching national plan, includes considerations for pediatric and other vulnerable populations. The "Guidelines for Regional Health Risk and Crisis Management" provided by the Basic Guidelines mandates uninterrupted healthcare provision by authorities in collaboration with the medical and welfare community and schools for people with chronic diseases and mental illnesses, incapacitated people, elderly people, people with disabilities, pregnant women, and children during a health emergency. [1] The "National Action Plan for Pandemic Influenza and New Infectious Diseases," released in June 2013, prioritizes vaccination for the following four categories in an order varying for different pandemic outbreak scenarios: (i) People at high medical risk: people who are deemed to be at high risk of developing a severe case, such as those suffering from respiratory or cardiovascular problems; people suffering from underlying diseases; and pregnant women (ii) Children (including parents of infants aged less than one year old and of children who cannot be vaccinated for physiological reasons) (iii) Adults/youth (iv) Elderly people: people in age groups deemed to be at high risk of developing a severe case (people aged 65 or older)". [2] The Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response (Act No. 31 of 2012) does not include considerations for pediatric and/or other vulnerable populations. [3]

[1] Ministry of Health, Labor and Welfare (MHLW). March 2001. "Guidelines for Regional Health Risk and Crisis Management. [<https://www.mhlw.go.jp/general/seido/kousei/kenkou/guideline/index.html>]. Accessed 20 December 2020.

[2] Cabinet Secretariat. 7 June 2013. "National Action Plan for Pandemic Influenza and New Infectious Diseases". [<https://www.cas.go.jp/jp/seisaku/ful/keikaku/pdf/national%20action%20plan.pdf>]. Accessed 20 December 2020.

[3] Ministry of Internal Affairs and Communications. Act No. 31 of 2012. "Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response". [<https://elaws.e-gov.go.jp/document?lawid=424AC0000000031>]. Accessed 20 December 2020.

3.1.1d

Does the country have a publicly available plan in place specifically for pandemic influenza preparedness that has been updated since 2009?

Yes = 1 , No = 0

Current Year Score: 0

2020

WHO Strategic Partnership for IHR and Health Security (SPH)

3.1.2 Private sector involvement in response planning

3.1.2a

Does the country have a specific mechanism(s) for engaging with the private sector to assist with outbreak emergency preparedness and response?

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence of a specific mechanism that provides engagement with the private sector to assist with outbreak emergency preparedness and response. The Ministry of Health, Labor and Welfare's "Guidelines for Regional Health Risk and Crisis Management" of 2001 mandates collaboration with local medical professionals, universities, research institutes, and tertiary hospitals as well as consultation with outside experts to provide containment measures. However, it has no mention of an organized system of public-private collaboration. [1] The government launched an internet portal to provide centralized data on private enterprises' Covid-19 relief and support programs. Activity categories include communication, telework, healthcare, entertainment, education, telecommunications, welfare, hotels and restaurants, and public service. [2, 3]

[1] Ministry of Health, Labor and Welfare (MHLW). March 2001. "Guidelines for Regional Health Risk and Crisis Management". [<https://www.mhlw.go.jp/general/seido/kousei/kenkou/guideline/index.html>]. Accessed 21 December 2020.

[2] Ministry of Economy, Trade and Industry (METI) [<https://www.meti.go.jp/covid-19/info-service.html>]. Accessed 21 December 2020.

[3] Private Sector Support Information Navigator. [<https://vscovid19.code4japan.org/>]. Accessed 21 December 2020.

3.1.3 Non-pharmaceutical interventions planning

3.1.3a

Does the country have a policy, plan and/or guidelines in place to implement non-pharmaceutical interventions (NPIs) during an epidemic or pandemic?

Yes, a policy, plan and/or guidelines are in place for more than one disease = 2, Yes, but the policy, plan and/or guidelines exist only for one disease = 1, No = 0

Current Year Score: 2

Japan has a policy, plan and guidelines in place to implement non-pharmaceutical interventions (NPIs) during an epidemic or pandemic, for more than one disease.

The Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response (Act No. 31 of 2012) provide non-emergency and emergency preparedness and response measures. Emergency measures include the declaration of a state of emergency as the highest level of emergency response involving NPIs, which include state-at-home requests and restrictions on schools, public facilities and event venues. [1]

Tiered criteria of emergency based on the severity of an outbreak apply to the activation of state of emergency measures. The Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response's minimum criterion for declaring a state of emergency is a domestic outbreak of a novel infectious disease. The government applies more detailed criteria: higher incidence of severe cases relative to influenza and high incidence of cases with unknown or possible transmission routes. [2]

In April 2020, the Novel Coronavirus Response Headquarters declared a state of emergency covering all 47 prefectures. Until it was lifted on 31 May 2020, the state of emergency placed various NPI restrictions such as stay-at-home requests, restrictions on holding events, and restrictions on using facilities. [3] In January 2021, the government reinstated a state of emergency in Tokyo and three surrounding prefectures and seven other outlying prefectures. [4, 5]

[1] Ministry of Internal Affairs and Communications. Act No. 31 of 2012. "Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response". [<https://elaws.e-gov.go.jp/document?lawid=424AC0000000031>]. Accessed 21 December 2020.

- [2] Cabinet Secretariat. [<https://www.cas.go.jp/jp/seisaku/ful/yusikisyakaigi/dai4/siryou1.pdf>]. Accessed 21 December 2020.
- [3] Ministry of Health, Labor and Welfare (MHLW). 25 May 2020. "Basic Policies for Novel Coronavirus Disease Control by the Government of Japan". [<https://www.mhlw.go.jp/content/10900000/000634753.pdf>]. Accessed 21 December 2020.
- [4] Prime Minister's Office. 7 January 2021. [https://www.kantei.go.jp/jp/99_suga/actions/202101/07corona.html]. Accessed 15 January 2021.
- [5] Prime Minister's Office. 13 January 2021. [https://www.kantei.go.jp/jp/99_suga/actions/202101/13corona.html]. Accessed 15 January 2021.

3.2 EXERCISING RESPONSE PLANS

3.2.1 Activating response plans

3.2.1a

Does the country meet one of the following criteria?

- Is there evidence that the country has activated their national emergency response plan for an infectious disease outbreak in the past year?
- Is there evidence that the country has completed a national-level biological threat-focused exercise (either with WHO or separately) in the past year?

Needs to meet at least one of the criteria to be scored a 1 on this measure. , Yes for both = 1 , Yes for one = 1 , No for both = 0

Current Year Score: 1

There is evidence that Japan has activated its national emergency response plan for an infectious disease outbreak in the past year. In April 2020, the government's Novel Coronavirus Response Headquarters declared a state of emergency covering all 47 prefectures. Until it was lifted on 31 May 2020, the state of emergency placed various non-pharmaceutical interventions NPI restrictions such as stay-at-home requests, restrictions on holding events, and restrictions on using facilities. [1] In January 2021, the government reinstated a state of emergency in Tokyo and three surrounding prefectures and seven other outlying prefectures. [2, 3]

The Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response (Act No. 31 of 2012) requires the central and local government to activate "action plans" to enforce a state of emergency. [4] It is not clear whether and how the Ministry of Health, Labor and Welfare activated its "Basic Guidelines for Health Risk and Crisis Management", which serves as Japan's overarching national plan, in conjunction with the state of emergency action plan. [1]

There is no evidence that Japan has completed a national-level biological threat-focused exercise (either with World Health Organization (WHO) or separately) in the past year. No evidence is available from the WHO Japan, Ministry of Health, Labor and Welfare, or Ministry of Agriculture, Forestry and Fisheries websites. [5, 6, 7]

[1] Ministry of Health, Labor and Welfare (MHLW). 25 May 2020. "Basic Policies for Novel Coronavirus Disease Control by the Government of Japan". [<https://www.mhlw.go.jp/content/10900000/000634753.pdf>]. Accessed 21 December 2020.

[2] Prime Minister of Office. 7 January 2021. [https://www.kantei.go.jp/jp/99_suga/actions/202101/07corona.html]. Accessed 15 January 2021.

[3] Prime Minister of Office. 13 January 2021. [https://www.kantei.go.jp/jp/99_suga/actions/202101/13corona.html]. Accessed 15 January 2021.

[4] Ministry of Internal Affairs and Communications. Act No. 31 of 2012. "Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response". [<https://elaws.e-gov.go.jp/document?lawid=424AC0000000031>].

Accessed 20 December 2020.

[5] World Health Organization (WHO). Japan. [<https://www.who.int/japan/news/news-releases>]. Accessed 21 December 2020.

[6] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 21 December 2020.

[7] Ministry of Agriculture, Forestry and Fisheries. [<http://www.maff.go.jp/index.html>]. Accessed 21 December 2020.

3.2.1b

Is there evidence that the country in the past year has identified a list of gaps and best practices in response (either through an infectious disease response or a biological-threat focused exercise) and developed a plan to improve response capabilities?

Yes, the country has developed and published a plan to improve response capacity = 2 , Yes, the country has developed a plan to improve response capacity, but has not published the plan = 1 , No = 0

Current Year Score: 0

There is no evidence that Japan in the past year has undergone an exercise to identify a list of gaps and best practices through either an after-action review (post-emergency response) or a biological threat-focused IHR exercise with the World Health Organization (WHO). The WHO IHR portal and other WHO pages do not include mention of such an exercise. [1]. The Ministry of Health, Labor and Welfare does not have supporting evidence. [2]

[1] World Health Organization (WHO). "After Action Review". [<https://extranet.who.int/sph/after-action-review>]. Accessed 21 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 20 December 2020.

3.2.2 Private sector engagement in exercises

3.2.2a

Is there evidence that the country in the past year has undergone a national-level biological threat-focused exercise that has included private sector representatives?

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence that Japan has, in the past year, undergone a national-level biological threat-focused exercise that has included private sector representatives. There is no evidence from the World Health Organization (WHO), Ministry of Health, Labor and Welfare or National Institute of Infectious Diseases that Japan has completed a national-level biological threat-focused exercise (either with WHO or separately) in the past year. [1, 2, 3] According to the WHO's Simulation Exercise statistics, Japan conducted a tabletop evaluation exercise in October 2019 with the following objectives: Legislation and Financing, Coordination and National IHR Focal Point Functions, Zoonotic Events and The Human-animal Interface, Food Safety, Laboratory, Surveillance, Human Resources, National Health Emergency Framework, Health Service Provision, Risk communications, Points of entry, Chemical events, Radiation emergencies and Other capacity tested. [4] No additional details are available.

[1] World Health Organization (WHO). Japan. [<https://www.who.int/japan/news/news-releases>]. Accessed 21 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 21 December 2020.

[3] National Institute of Infectious Diseases (NIID). [<https://www.niid.go.jp/niid/ja/>]. Accessed 15 January 2021.

[4] World Health Organization (WHO). "Simulation Exercise". [<https://extranet.who.int/sph/simulation-exercise?region=All&country=341>]. Accessed 23 January 2021.

3.3 EMERGENCY RESPONSE OPERATION

3.3.1 Emergency response operation

3.3.1a

Does the country have in place an Emergency Operations Center (EOC)?

Yes = 1 , No = 0

Current Year Score: 0

Japan operates an Emergency Operations Center (EOC) on an ad hoc basis. The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that "although Japan does not have a permanent public health EOC at the national level, emergency response headquarters can be activated as required". The JEE further describes the Japanese EOC as follows: "When an emergency response headquarters is established, terms of reference for different types of crises are available, which specify the relevant organizational structures and the respective roles and responsibilities." [1] The Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response (Act No. 31 of 2012) provides a legal basis for the activation of a dedicated public health EOC in times of a public health emergency. Article 15 mandates the establishment of a cabinet-level "response headquarters" as an ad-hoc EOC to handle an epidemic or pandemic outbreak. [2] The Novel Coronavirus Response Headquarters was launched on 26 March 2020 under the prime minister. [3]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 21 December 2020.

[2] Ministry of Internal Affairs and Communications. Act No. 31 of 2012. "Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response". [<https://elaws.e-gov.go.jp/document?lawid=424AC0000000031>]. Accessed 21 December 2020.

[3] Cabinet Secretariat. 26 March 2020. [<https://corona.go.jp/expert-meeting/pdf/konkyo.pdf>]. Accessed 21 December 2020.

3.3.1b

Is the Emergency Operations Center (EOC) required to conduct a drill for a public health emergency scenario at least once per year or is there evidence that they conduct a drill at least once per year?

Yes = 1 , No = 0

Current Year Score: 1

There is evidence that the Emergency Operations Center conducts a drill at least once per year.

The Joint External Evaluation (JEE) of IHR Core Capacities of Japan mission report (26 February-2 March 2018) notes that the country "conducts a range of emergency response training at both the national and the prefecture level, including on-the-job training and drills." The JEE further states: "Both the Prime Minister's Official Residence and [Ministry of Health, Labor and Welfare] MHLW implement exercises at least twice per year. Emergency assembly drills are conducted, and tabletop exercises are held for pandemic influenza to train decision making and are attended by all Cabinet Ministers including the Prime Minister." [1]

The Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response (Act No. 31 of 2012) requires training drills to take place in organic collaboration between the central government and local governments. The law requires central and local government agencies to conduct drills based on action plans. However, the law does not state how often these drills should be conducted. [2] There is no further evidence from the Ministry of Health, Labor and Welfare or the Prime Minister's Office. [3, 4]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 21 December 2020.

[2] Ministry of Internal Affairs and Communications. Act No. 31 of 2012. "Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response". [<https://elaws.e-gov.go.jp/document?lawid=424AC0000000031>]. Accessed 21 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 23 January 2021.

[4] Prime Minister's Office. [<https://www.kantei.go.jp/>]. Accessed 23 January 2021.

3.3.1c

Is there public evidence to show that the Emergency Operations Center (EOC) has conducted within the last year a coordinated emergency response or emergency response exercise activated within 120 minutes of the identification of the public health emergency/scenario?

Yes = 1, No = 0

Current Year Score: 0

There is no public evidence to show that the Emergency Operations Center (EOC) can conduct, or has conducted within the last year, a coordinated emergency response or emergency response exercise activated within 120 minutes of the identification of the public health emergency/scenario. The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) has no mention of such EOC activity in the past year. [1] The Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response (Act No. 31 of 2012) does not provide a minimum time range for EOC activation. [2] The Novel Coronavirus Response Headquarters was launched on 26 March 2020 as a pandemic EOC under the law, even though Japan filed ex-China novel coronavirus outbreaks to the World Health Organization (WHO) in January 2020. [3, 4] There is no further evidence available from the Ministry of Health, Labor and Welfare. [5]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 21 December 2020.

[2] Ministry of Internal Affairs and Communications. Act No. 31 of 2012. "Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response". [<https://elaws.e-gov.go.jp/document?lawid=424AC0000000031>]. Accessed 21 December 2020.

[3] Cabinet Secretariat. 26 March 2020. [<https://corona.go.jp/expert-meeting/pdf/konkyo.pdf>]. Accessed 21 December 2020.

[4] World Health Organization (WHO). "Daily outbreak news". [<https://www.who.int/csr/don/archive/year/2020/en/>]. Accessed 21 December 2020.

[5] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 21 December 2020.

3.4 LINKING PUBLIC HEALTH AND SECURITY AUTHORITIES

3.4.1 Public health and security authorities are linked for rapid response during a biological event

3.4.1a

Does the country meet one of the following criteria?

- Is there public evidence that public health and national security authorities have carried out an exercise to respond to a potential deliberate biological event (i.e., bioterrorism attack)?
- Are there publicly available standard operating procedures, guidelines, memorandums of understanding (MOUs), or other agreements between the public health and security authorities to respond to a potential deliberate biological event (i.e., bioterrorism attack)?

Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

Current Year Score: 1

There is evidence that public health and national security authorities have carried out an exercise to respond to a potential deliberate biological event (i.e., bioterrorism attack). Japan has a policy mandating collaboration between the public health and security authorities to respond to a potential deliberate biological event. The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that Japan conducts exercises on response to biological terrorism annually as a part of the Civil Protection Exercise. [1] The Cabinet Secretariat's Civil Protection Portal Site states that "the national government implements drills for civil protection and training exercises in cooperation with local governments." "Dispersal of large amounts of biological agents" are included among "emergency response situations" The Civil Protection Law (Act No. 112 of 2004) stipulates the responsibilities of the national and local governments and measures, such as evacuation of residents, relief of evacuated residents, and response to armed attack disasters. Civil protection planning is required for all central government agencies, local governments, and designated public institutions. [2] The Ministry of Defense's "Basic Policy on Response to Biological Weapons," released in January 2002, requires cooperation between security authorities and the Ministry of Health, Labor and Welfare and other related agencies to coordinate response to biological weapons. [3] There is no further evidence from the Ministry of Health, Labor and Welfare or the Prime Minister's Office. [4, 5]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 21 December 2020.

[2] Cabinet Secretariat. "Civil Protection Portal Site". [http://www.kokuminhogo.go.jp/en/pc-index_e.html]. Accessed 21 December 2020.

[3] Ministry of Defense. January 2002. "Basic Policy on Response to Biological Weapons". [<https://www.mod.go.jp/j/approach/defense/seibutu/index.html>]. Accessed 21 December 2020.

[4] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 23 January 2021.

[5] Prime Minister's Office. [<https://www.kantei.go.jp/>]. Accessed 23 January 2021.

3.5 RISK COMMUNICATIONS

3.5.1 Public communication

3.5.1b

Does the risk communication plan (or other legislation, regulation or strategy document used to guide national public health response) outline how messages will reach populations and sectors with different communications needs (eg different languages, location within the country, media reach)?

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence that there is a risk strategy detailing how messages will reach populations and sectors with different communications needs. The Ministry of Internal Affairs and Communications sponsors the rollout of a Covid-19 multilingual risk communication template through its private sector partner, the Council of Local Authorities for International Relations. [1, 2] The Ministry of Health, Labor and Welfare provides multilingual information on Covid-19, including how to access multilingual call centers nationwide, on its website. [3] The Office for Novel Coronavirus Disease Control at the Cabinet Secretariat provides Covid-19 information updates in different languages on its website. [4]

[1] Ministry of Internal Affairs and Communications. 14 February 2020.

[https://www.soumu.go.jp/main_content/000674445.pdf]. Accessed 21 December 2020.

[2] Council of Local Authorities for International Relations.

[<http://www.clair.or.jp/tabunka/portal/info/contents/114517.php>]. Accessed 21 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW). "Covid-19 Multilingual Guide". [<https://www.covid19-info.jp/>]. Accessed 21 December 2020.

[4] Cabinet Secretariat. Office for Novel Coronavirus Disease Control. "Covid-19 Information and Resources".

[<https://corona.go.jp/en/>]. Accessed 21 December 2020.

3.5.1 Risk communication planning

3.5.1a

Does the country have in place, either in the national public health emergency response plan or in other legislation, regulation, or strategy documents, a section detailing a risk communication plan that is specifically intended for use during a public health emergency?

Yes = 1 , No = 0

Current Year Score: 1

A risk communication plan is required under the Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 2 October 1998). Article 16 states: "The Minister of Health, Labor and Welfare and prefectural governors must analyze the information on Infectious Diseases gathered pursuant to the provisions of Article 12 through the preceding Article, and actively publicize the information on the status of outbreaks, the progress, and causes of the Infectious Diseases and the information necessary for the prevention and treatment of the Infectious Diseases in newspapers, by broadcasting via the Internet, or by any other appropriate means." [1] Article 8 of the Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response (Act No. 31 of 2012) also requires information disclosure to businesses and residents. [2] The Ministry of Health, Labor and Welfare's "Guidelines for Regional Health Risk and Crisis Management" specify the use of mass communication channels including the internet as well as emergency hotlines to communicate risk information to the general public. Media relations are centralized into a single

channel to provide coherent risk communications. In-person consultation is also provided to augment mass communication. [3]

[1] Japanese Law Translation Database System. Act No. 114 of 2 October 1998. "Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases".

[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=28&y=7&co=01&ia=03&ja=04&ky=act+on+the+prevention+of+infectious+diseases+and+medical+care+for+patients+with&page=10>]. Accessed 21 December 2020.

[2] Ministry of Internal Affairs and Communications. Act No. 31 of 2012. "Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response". [<https://elaws.e-gov.go.jp/document?lawid=424AC0000000031>]. Accessed 21 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW). March 2001. "Guidelines for Regional Health Risk and Crisis Management". [<https://www.mhlw.go.jp/general/seido/kousei/kenkou/guideline/index.html>]. Accessed 21 December 2020.

3.5.1c

Does the risk communication plan (or other legislation, regulation or strategy document used to guide national public health response) designate a specific position within the government to serve as the primary spokesperson to the public during a public health emergency?

Yes = 1, No = 0

Current Year Score: 1

Risk communication plans designate a specific position within the government to serve as the primary spokesperson to the public during a public health emergency. The Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 2 October 1998) designate the Minister of Health, Labor and Welfare and prefectural governors as primary spokespersons for risk communication during a public health emergency. [1] On 6 March 2020, Nishimura Yasutoshi, Minister of State for Economic and Fiscal Policy, was appointed then Prime Minister Abe Shinzo as minister in charge of Covid-19 and member of the Novel Coronavirus Response Headquarters under the prime minister. [2]

[1] Japanese Law Translation Database System. Act No. 114 of 2 October 1998. "Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases".

[<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=28&y=7&co=01&ia=03&ja=04&ky=act+on+the+prevention+of+infectious+diseases+and+medical+care+for+patients+with&page=10>]. Accessed 21 December 2020.

[2] The Asahi Shimbun. 6 March 2020. [<https://www.asahi.com/articles/ASN3665DYN36ULFA035.html>]. Accessed 21 December 2020.

3.5.2 Public communication

3.5.2a

In the past year, is there evidence that the public health system has actively shared messages via online media platforms (e.g. social media, website) to inform the public about ongoing public health concerns and/or dispel rumors, misinformation or disinformation?

Public health system regularly shares information on health concerns = 2, Public health system shares information only during active emergencies, but does not regularly utilize online media platforms = 1, Public health system does not regularly utilize online media platforms, either during emergencies or otherwise = 0

Current Year Score: 2

There is evidence in the past year, the public health system has actively shared messages via online media platforms (e.g. social media, website) to inform the public about ongoing public health concerns and dispel rumors, misinformation or disinformation. The government utilizes media platforms to regularly inform the public about public health concerns and deliver accurate information. The Ministry of Health, Labor and Welfare (MHLW) provides a range of public health information updates through its website and social media channels, including infectious disease information. [1] The Cabinet Secretariat operates a Covid-19 portal site as the top-level online government platform for delivering pandemic information to the public. Official Twitter and YouTube channels are available. [2] The MHLW operates its own pandemic site and social media channels such as Twitter, Facebook, and Line. [3] Other major government agencies have similar channels of public communication. [4]

[1] Ministry of Health, Labor and Welfare (MHLW).

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/kenkou/kekkaku-kansenshou/index.html]. Accessed 15 January 2021.

[2] Cabinet Secretariat. "Office for Novel Coronavirus Disease Control". [<https://corona.go.jp/>]. Accessed 22 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW).

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000164708_00001.html]. Accessed 22 December 2020.

[4] Ministry of Health, Labor and Welfare (MHLW). [https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/covid-19link.html#h2_free1]. Accessed 22 December 2020.

3.5.2b

Is there evidence that senior leaders (president or ministers) have shared misinformation or disinformation on infectious diseases in the past two years?

No = 1, Yes = 0

Current Year Score: 1

There is no evidence that senior leaders (president or ministers) have shared misinformation or disinformation on infectious diseases in the past two years. The Cabinet Secretariat, which represents the cabinet, has not released any such statement.

[1] Domestic news media have carried no such reports. [2, 3]

[1] Cabinet Secretariat. [<http://www.cas.go.jp/>]. Accessed 22 December 2020.

[2] NHK. [<https://www3.nhk.or.jp/news/>]. Accessed 22 December 2020.

[3] Reuters. [<https://www.reuters.com/>]. Accessed 15 January 2021.

3.6 ACCESS TO COMMUNICATIONS INFRASTRUCTURE

3.6.1 Internet users

3.6.1a

Percentage of households with Internet

Input number

Current Year Score: 84.59

2019

International Telecommunication Union (ITU)

3.6.2 Mobile subscribers

3.6.2a

Mobile-cellular telephone subscriptions per 100 inhabitants

Input number

Current Year Score: 139.2

2019

International Telecommunication Union (ITU)

3.6.3 Female access to a mobile phone

3.6.3a

Percentage point gap between males and females whose home has access to a mobile phone

Input number

Current Year Score: 3.0

2019

Gallup; Economist Impact calculation

3.6.4 Female access to the Internet

3.6.4a

Percentage point gap between males and females whose home has access to the Internet

Input number

Current Year Score: 11.0

2019

Gallup; Economist Impact calculation

3.7 TRADE AND TRAVEL RESTRICTIONS

3.7.1 Trade restrictions

3.7.1a

In the past year, has the country issued a restriction, without international/bilateral support, on the export/import of medical goods (e.g. medicines, oxygen, medical supplies, PPE) due to an infectious disease outbreak?

Yes = 0, No = 1

Current Year Score: 1

There is no evidence that in the past year, Japan has issued a restriction, without international/bilateral support, on the export/import of medical goods (e.g. medicines, oxygen, medical supplies, PPE) due to an infectious disease outbreak. The World Trade Organization's "Export Prohibitions and Restrictions" report, released on 23 April 2020, cites no restriction implemented by Japan. [1] Japan Customs confirms on its website that there have been no pandemic-related import restrictions introduced with regard to masks, disinfectants and other such supplies. [2] There is no evidence of such restrictions from the Ministry of Health, Labor and Welfare, Ministry of Agriculture, Forestry and Fisheries, Ministry of Economy, Trade and Industry, or Ministry of Foreign Affairs. [3, 4, 5, 6]

- [1] World Trade Organization. 23 April 2020. "Export Prohibitions and Restrictions". [https://www.wto.org/english/tratop_e/covid19_e/export_prohibitions_report_e.pdf]. Accessed 22 December 2020.
- [2] Japan Customs. [https://www.customs.go.jp/news/news/faq_mask.htm]. Accessed 22 December 2020.
- [3] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 22 December 2020.
- [4] Ministry of Agriculture, Forestry and Fisheries. [<http://www.maff.go.jp/index.html>]. Accessed 22 December 2020.
- [5] Ministry of Economy, Trade and Industry (METI) [<https://www.meti.go.jp/>]. Accessed 22 December 2020.
- [6] Ministry of Foreign Affairs. [<http://www.mofa.go.kr/www/index.do>]. Accessed 22 December 2020.

3.7.1b

In the past year, has the country issued a restriction, without international/bilateral support, on the export/import of non-medical goods (e.g. food, textiles, etc) due to an infectious disease outbreak?

Yes = 0, No = 1

Current Year Score: 1

There is no evidence that in the past year, Japan has issued a restriction, without international/bilateral support, on the export/import of non-medical goods (e.g. food, textiles, etc.) due to an infectious disease outbreak. The World Trade Organization's "Report on G20 Trade Measures," released on 18 November 2020, cites no such restrictions implemented by Japan during May-October 2020. [1] There is no evidence of such restrictions implemented in the past year from the Ministry of Health, Labor and Welfare, Ministry of Agriculture, Forestry and Fisheries, Ministry of Economy, Trade and Industry, or Ministry of Foreign Affairs. [2, 3, 4, 5]

- [1] World Trade Organization. 18 November 2020. "Report on G20 Trade Measures". [https://www.wto.org/english/news_e/news20_e/report_trdev_nov20_e.pdf]. Accessed 22 December 2020.
- [2] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 22 December 2020.
- [3] Ministry of Agriculture, Forestry and Fisheries. [<http://www.maff.go.jp/index.html>]. Accessed 22 December 2020.
- [4] Ministry of Economy, Trade and Industry (METI) [<https://www.meti.go.jp/>]. Accessed 22 December 2020.
- [5] Ministry of Foreign Affairs. [<http://www.mofa.go.kr/www/index.do>]. Accessed 22 December 2020.

3.7.2 Travel restrictions

3.7.2a

In the past year, has the country implemented a ban, without international/bilateral support, on travelers arriving from a specific country or countries due to an infectious disease outbreak?

Yes = 0, No = 1

Current Year Score: 0

In the past year, Japan has implemented a ban, without international/bilateral support, on travelers arriving from a specific country or countries due to an infectious disease outbreak. The Ministry of Justice, which has jurisdiction over border controls, enforces entry restrictions as follows: "Regarding Covid-19 (novel coronavirus), which is spreading throughout the world, based on Cabinet approval on January 31, 2020 and the announcement by the Novel Coronavirus Response Headquarters, and so on for the time being, the Ministry of Justice considers foreign nationals who hold the record for staying in the countries / regions listed in attached table 1 within 14 days before the day of application for landing to be foreign nationals who fall under Article 5, paragraph (1), item (xiv) of the Immigration Control (See note 1) and Refugee Recognition Act (hereinafter referred to as the "Immigration Control Act") and unless there are special exceptional circumstances, the foreign national will be subject to denial of landing." [1] The Ministry of Foreign Affairs has published the same information as follows: "For the time being, foreign nationals who have stayed in any of the following 152 countries/regions within 14 days prior to the application for landing are denied entry to Japan pursuant to the Article 5, paragraph (1), item (xiv) of Immigration Control and Refugee Recognition Act, unless special exceptional circumstances are found. Note that foreigners (from the countries and regions where the entry bans do not apply) are not denied entry to Japan even when they arrive in Japan via those countries or regions, which are subject to denial of permission to entry, for refueling or transit purpose. Those who entered those countries or regions will, however, be subject to the entry ban." [2]

[1] Ministry of Justice. 1 November 2020. "Regarding denial of landing to prevent the spread of Covid-19".

[<http://www.moj.go.jp/content/001332786.pdf>]. Accessed 22 December 2020.

[2] Ministry of Foreign Affairs. 18 December 2020. "Consular Services Border enforcement measures to prevent the spread of novel coronavirus (Covid-19)". Accessed 22 December 2020.

Category 4: Sufficient and robust health sector to treat the sick and protect health workers

4.1 HEALTH CAPACITY IN CLINICS, HOSPITALS, AND COMMUNITY CARE CENTERS

4.1.1 Available human resources for the broader healthcare system

4.1.1a

Doctors per 100,000 people

Input number

Current Year Score: 241.15

2016

WHO; national sources

4.1.1b

Nurses and midwives per 100,000 people

Input number

Current Year Score: 1215.31

2018

WHO; national sources

4.1.1c

Does the country have a health workforce strategy in place (which has been updated in the past five years) to identify fields where there is an insufficient workforce and strategies to address these shortcomings?

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence that Japan has a public workforce strategy in place to identify fields where there is an insufficient workforce and strategies to address these shortcomings. The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that "there is a shortage of specialists in some areas such as risk communication specialists and social scientists." [1] The Ministry of Health, Labor and Welfare (MHLW)'s "Seventh Medical Care Plan," released 31 March 2017 and last updated on 14 April 2020, requires the MHLW to work with local governments to identify health workforce imbalances between different regions and between different medical fields and provide remedies. The plan provides guidelines on how to set and achieve goals for security the supply of health professionals, including doctors and nurses. [2] The Law to Promote the Securing of Nursing Personnel (Act No. 86 of 1992) provides a legal basis for policies supporting ongoing replenishment and recruitment of nursing specialists. [3] There is no further evidence from the MHLW. [4]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 22 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). 14 April 2020. "Seventh Medical Care Plan". [https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/iryuu/iryuu_keikaku/index.html]. Accessed 22 December 2020.

[3] Ministry of Internal Affairs and Communications. Act No. 86 of 1992. "Law to Promote the Securing of Nursing Personnel". [<https://elaws.e-gov.go.jp/document?lawid=404AC0000000086>]. Accessed 22 December 2020.

[4] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 21 December 2020.

4.1.2 Facilities capacity

4.1.2a

Hospital beds per 100,000 people

Input number

Current Year Score: 1298

2018

WHO/World Bank; national sources

4.1.2b

Does the country have the capacity to isolate patients with highly communicable diseases in a biocontainment patient care unit and/or patient isolation room/unit located within the country?

Yes = 1, No = 0

Current Year Score: 1

Japan maintains the capacity to isolate patients with highly communicable diseases in patient isolation facilities located within the country. The Ministry of Health, Labor and Welfare (MHLW) designates healthcare facilities nationwide to treat infectious disease patients in need of isolation. As of 1 May 2018, four facilities were designated to treat specified infectious diseases patients, and 55 facilities were set aside to treat class I infectious diseases patients. As of 1 April 2018, there were 351 facilities designated to treat class II infectious diseases. [1] The MHLW provides equipment guidelines for these facilities, including positive/negative ventilation/air conditioning units; entrances, ceilings, windows, lightings, appliances, toilets and shower rooms; and PPE storage spaces. [2]

[1] Ministry of Health, Labor and Welfare (MHLW). 1 May 2018. "Healthcare Facilities Designated to Treat Infectious Diseases". [<https://www.mhlw.go.jp/bunya/kenkou/kekkaku-kansenshou15/02-02.html>]. Accessed 22 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). "Designation Criteria for Designated Healthcare Facilities to Treat Class 1 Infectious Diseases". [<https://www.mhlw.go.jp/file/05-Shingikai-10901000-Kenkoukyoku-Soumuka/0000117055.pdf>]. Accessed 22 December 2020.

4.1.2c

Does the country meet one of the following criteria?

- Is there evidence that the country has demonstrated capacity to expand isolation capacity in response to an infectious disease outbreak in the past two years?

- Is there evidence that the country has developed, updated or tested a plan to expand isolation capacity in response to an infectious disease outbreak in the past two years?

Yes = 1, No = 0

Current Year Score: 1

There is evidence that the country has demonstrated capacity to expand isolation capacity in response to an infectious disease outbreak in the past two years.

According to the Ministry of Health, Labor and Welfare, local governments have implemented isolation capacity expansions since June 2020 as part of its Covid-19 pandemic response. The central government provides subsidies for local governments to add isolation capacity up to ¥19.5m (US\$179,300) per bed. [1] The World Health Organization's "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)" shows no evidence that such a mechanism existed before Covid-19 in Japan. [2] There is no evidence from the Ministry of Health, Labor and Welfare that there was a pre-Covid-19 system of ramping up isolation capacity. [3]

[1] Ministry of Health, Labor and Welfare (MHLW). 21 March 2021. [https://www5.cao.go.jp/keizai-shimon/kaigi/minutes/2021/0121/shiryo_05.pdf]. Accessed 17 April 2021.

[2] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 17 April 2021.

[3] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 17 April 2021.

4.2 SUPPLY CHAIN FOR HEALTH SYSTEM AND HEALTHCARE WORKERS

4.2.1 Routine health care and laboratory system supply

4.2.1a

Is there a national procurement protocol in place which can be utilized by the Ministries of Health and Agriculture for the acquisition of laboratory supplies (e.g. equipment, reagents and media) and medical supplies (e.g. equipment, PPE) for routine needs?

Yes for both laboratory and medical supply needs = 2, Yes, but only for one = 1, No = 0

Current Year Score: 2

Japan has a national procurement protocol in place which can be utilized by the government to procure routine laboratory and medical purposes.

The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that "procurement of equipment and reagents for diagnosis is available within the country." [1] The Government Electronic Procurement System (GEPS) is Japan's e-government platform specializing in electronic bidding and contract awards. This platform is utilized by all government agencies and operated under central and ministerial regulatory guidelines. [2] The Ministry of Health, Labor and Welfare and the Ministry of Agriculture, Forestry and Fisheries have their procurement sites linked to GEPS to procure laboratory supplies and medical supplies for routine needs. [3, 4]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 22 December 2020.

[2] Ministry of Internal Affairs and Communications. "Government Electronic Procurement System (GEPS)". [<https://www.geps.go.jp/>]. Accessed 16 January 2021.

[3] Ministry of Health, Labor and Welfare (MHLW). "Procurement Information". [https://www.mhlw.go.jp/shinsei_boshu/choutatsujouhou/]. Accessed 16 January 2021.

[4] Ministry of Agriculture, Forestry and Fisheries. "Procurement Information". [<http://www.maff.go.jp/j/supply/index.html>]. Accessed 16 January 2021.

4.2.2 Stockpiling for emergencies

4.2.2a

Does the country have a stockpile of medical supplies (e.g. MCMs, medicines, vaccines, medical equipment, PPE) for national use during a public health emergency?

Yes = 2, Yes, but there is limited evidence about what the stockpile contains = 1, No = 0

Current Year Score: 2

Japan maintains a stockpile of medical supplies and medical countermeasures (MCM) (i.e. vaccines, therapeutics and diagnostics) for national use during a public health emergency.

The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that "Japan has a national stockpile of medical countermeasures including vaccines, anti-toxins, and medication, which are stored in nine locations across Japan to facilitate timely supply when required." [1]

Article 10 of the Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response (Act No. 31 of 2012) requires the central and local governments to stockpile and maintain medical supplies and medical countermeasures under emergency action plans. Articles 50 and 51 also mandate cooperation among different local governments and public institutions for emergency access to stockpiled medical supplies and medical countermeasures. [2]

The government operates the Gathering Medical Information System on Covid-19 (G-MIS) for online centralized monitoring of response capacities at about 8,000 hospitals nationwide, including the availability of medical supplies. [3] The Ministry of Health, Labor and Welfare's "Disaster Management Plan," last updated in September 2019, contains provisions on the stockpiling of medical countermeasures for emergency access. [4]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 22 December 2020.

[2] Ministry of Internal Affairs and Communications. Act No. 31 of 2012. "Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response". [<https://elaws.e-gov.go.jp/document?lawid=424AC0000000031>]. Accessed 22 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW). "Gathering Medical Information System on Covid-19 (G-MIS)". [https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000121431_00130.html]. Accessed 22 December 2020.

[4] Ministry of Health, Labor and Welfare (MHLW). "Disaster Management Plan". [<https://www.mhlw.go.jp/content/000556282.pdf>]. Accessed 22 December 2020.

4.2.2b

Does the country have a stockpile of laboratory supplies (e.g. reagents, media) for national use during a public health emergency?

Yes = 2, Yes, but there is limited evidence about what the stockpile contains = 1, No = 0

Current Year Score: 0

There is insufficient evidence that Japan has a stockpile of laboratory supplies (e.g. reagents, media) for national use during a public health emergency. The Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response (Act No. 31 of 2012) includes no provision on stockpiling laboratory supplies. [1] Plans for national procurement are under development. The Ministry of Health, Labor and Welfare announced on 2 June 2020 a plan to stockpile Covid-19 antibody test kits. [2] The government's second supplementary budget for 2020 included funding for procurement of reagents and test kits as well as medical supplies such as disinfectants and masks. [3] There is no further evidence from the Ministry of Defense, National Institute of Infectious Diseases, or the Prime Minister's Office. [4, 5, 6]

[1] Ministry of Internal Affairs and Communications. Act No. 31 of 2012. Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response". [<https://elaws.e-gov.go.jp/document?lawid=424AC0000000031>]. Accessed 22 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). 2 June 2020. [<https://www.mhlw.go.jp/content/000636113.pdf>]. Accessed 22 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/wp/yosan/yosan/20hosei/dl/20hosei04.pdf>]. Accessed 22 December 2020.

[4] Ministry of Defense. [<https://www.mod.go.jp/index.html>]. Accessed 16 January 2021.

[5] National Institute of Infectious Diseases (NIID). [<https://www.niid.go.jp/niid/ja/>]. Accessed 16 January 2021.

[6] Prime Minister's Office. [<https://www.kantei.go.jp/>]. Accessed 16 January 2021.

4.2.2c

Is there evidence that the country conducts or requires an annual review of the national stockpile to ensure the supply is sufficient for a public health emergency?

Yes = 1, No = 0

Current Year Score: 0

There is no evidence that Japan conducts or requires an annual review of the national stockpile to ensure the supply is sufficient for a public health emergency.

The World Health Organization's "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)" does not contain evidence of an annual inventory review conducted in Japan. No evidence is available from the Ministry of Health, Labor and Welfare (MHLW), Ministry of Defense, or Pharmaceutical and Medical Devices Agency. [2, 3, 4].

The government operates the Gathering Medical Information System on Covid-19 (G-MIS) for online centralized monitoring of response capacities at about 8,000 hospitals nationwide, including the availability of medical supplies. [5] The MHLW's "Disaster Management Plan," last updated in September 2019, contains provisions on the stockpiling of medical countermeasures for emergency access. [6]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 17 April 2021.

[2] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 17 April 2021.

[3] Ministry of Defense. [<https://www.mod.go.jp/>]. Accessed 17 April 2021.

[4] Pharmaceutical and Medical Devices Agency. [<https://www.pmda.go.jp/index.html>]. Accessed 17 April 2021.

[5] Ministry of Health, Labor and Welfare (MHLW). "Gathering Medical Information System on Covid-19 (G-MIS)". [https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000121431_00130.html]. Accessed 22 December 2020.

[6] Ministry of Health, Labor and Welfare (MHLW). "Disaster Management Plan".

[<https://www.mhlw.go.jp/content/000556282.pdf>]. Accessed 22 December 2020.

4.2.3 Manufacturing and procurement for emergencies

4.2.3a

Does the country meet one of the following criteria?

- Is there evidence of a plan/agreement to leverage domestic manufacturing capacity to produce medical supplies (e.g. MCMs, medicines, vaccines, equipment, PPE) for national use during a public health emergency?

- Is there evidence of a plan/mechanism to procure medical supplies (e.g. MCMs, medicines, vaccines, equipment, PPE) for national use during a public health emergency?

Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

Current Year Score: 0

There is insufficient evidence of a plan/agreement to leverage domestic manufacturing capacity to produce or procure medical supplies (e.g. Medical Countermeasures (MCM), medicines, vaccines, equipment, PPE) for national use during a

public health emergency.

Article 47 of the Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response (Act No. 31 of 2012) requires public sector institutions to provide measures to ensure the manufacturing and sale of medical countermeasures and medical supplies. [1] The Gathering Medical Information System on Covid-19 (G-MIS) provides an online platform for centralized monitoring of response capacities at about 8,000 hospitals nationwide, including the availability of medical supplies. [2]

The Ministry of Economy, Trade and Industry's Covid-19 response website shows joint efforts between the public and private sectors to smooth out the supply of PPE and disinfectants. The website provides updates on production ramp-ups at domestic mask and disinfectant producers. [3] There is no further evidence from the Ministry of Health, Labor and Welfare, Ministry of Economy, Trade and Industry, Ministry of Defense, National Institute of Infectious Diseases, or the Prime Minister's Office. [4, 5, 6, 7, 8]

[1] Ministry of Internal Affairs and Communications. Act No. 31 of 2012. "Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response". [<https://elaws.e-gov.go.jp/document?lawid=424AC0000000031>]. Accessed 22 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). "Gathering Medical Information System on Covid-19 (G-MIS)". [https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000121431_00130.html]. Accessed 22 December 2020.

[3] Ministry of Economy, Trade and Industry (METI). [<https://www.meti.go.jp/covid-19/mask.html>]. Accessed 22 December 2020.

[4] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 21 December 2020.

[5] Ministry of Economy, Trade and Industry (METI). [<https://www.meti.go.jp/>]. Accessed 16 January 2021.

[6] Ministry of Defense. [<https://www.mod.go.jp/index.html>]. Accessed 16 January 2021.

[7] National Institute of Infectious Diseases (NIID). [<https://www.niid.go.jp/niid/ja/>]. Accessed 16 January 2021.

[8] Prime Minister's Office. [<https://www.kantei.go.jp/>]. Accessed 16 January 2021.

4.2.3b

Does the country meet one of the following criteria?

- **Is there evidence of a plan/agreement to leverage domestic manufacturing capacity to produce laboratory supplies (e.g. reagents, media) for national use during a public health emergency?**

- **Is there evidence of a plan/mechanism to procure laboratory supplies (e.g. reagents, media) for national use during a public health emergency?**

Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

Current Year Score: 0

There is no evidence of a plan to leverage domestic manufacturing capacity to produce laboratory supplies (e.g. reagents, media) for national use during a public health emergency. There is no evidence of a mechanism to procure laboratories for national use during a public health emergency.

Article 47 of the Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response (Act No. 31 of 2012) requires public sector institutions to provide measures to ensure the manufacturing and sale of medical countermeasures and medical supplies with no specific mention of laboratory supplies. [1] The Gathering Medical Information System on Covid-19 (G-MIS) provides an online platform for centralized monitoring of response capacities at about 8,000 hospitals nationwide, including the availability of laboratory supplies. [2] The government's second supplementary budget for 2020 included funding for procurement of reagents and test kits. [3] There is no further evidence from the Ministry of Health, Labor and Welfare, Ministry of Economy, Trade and Industry, Ministry of Defense, National

Institute of Infectious Diseases, or the Prime Minister's Office. [4, 5, 6, 7, 8]

[1] Ministry of Internal Affairs and Communications. Act No. 31 of 2012. "Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response". [<https://elaws.e-gov.go.jp/document?lawid=424AC0000000031>]. Accessed 22 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). "Gathering Medical Information System on Covid-19 (G-MIS)". [https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/0000121431_00130.html]. Accessed 22 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/wp/yosan/yosan/20hosei/dl/20hosei04.pdf>]. Accessed 22 December 2020.

[4] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 21 December 2020.

[5] Ministry of Economy, Trade and Industry (METI) [<https://www.meti.go.jp/>]. Accessed 16 January 2021.

[6] Ministry of Defense. [<https://www.mod.go.jp/index.html>]. Accessed 16 January 2021.

[7] National Institute of Infectious Diseases (NIID). [<https://www.niid.go.jp/niid/ja/>]. Accessed 16 January 2021.

[8] Prime Minister's Office. [<https://www.kantei.go.jp/>]. Accessed 16 January 2021.

4.3 MEDICAL COUNTERMEASURES AND PERSONNEL DEPLOYMENT

4.3.1 System for dispensing medical countermeasures (MCM) during a public health emergency

4.3.1a

Does the country have a plan, program, or guidelines in place for dispensing medical countermeasures (MCM) for national use during a public health emergency (i.e., antibiotics, vaccines, therapeutics and diagnostics)?

Yes = 1, No = 0

Current Year Score: 0

There is insufficient evidence that Japan has a plan in place for dispensing medical countermeasures for national use during a public health emergency. The Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response Act (Act No. 31 of 2012) requires central and local governments to organize emergency transport and delivery of emergency medical countermeasures and supplies. Article 64 requires the Ministry of Health, Labor and Welfare (MHLW) to provide medical countermeasures and supplies for free or at reduced prices. [1] The MHLW's "Disaster Management Plan," updated in September 2019, requires prefectural governments to maintain a system of transporting and distributing medical countermeasures to activate for emergency supply. Under the plan, local governments are required to keep a sufficient level of inventory for emergency purposes and maintain manpower to transport and distribute medical countermeasures. However, the plan provides no further detail on such preparedness. [2] There is no further evidence from the MHLW, Ministry of Economy, Trade and Industry, Ministry of Defense, National Institute of Infectious Diseases, or the Prime Minister's Office. [3, 4, 5, 6, 7]

[1] Ministry of Internal Affairs and Communications. Act No. 31 of 2012. "Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response". [<https://elaws.e-gov.go.jp/document?lawid=424AC0000000031>]. Accessed 23 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). "Disaster Management Plan". [<https://www.mhlw.go.jp/content/000556282.pdf>]. Accessed 23 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 21 December 2020.

[3] Ministry of Economy, Trade and Industry (METI) [<https://www.meti.go.jp/>]. Accessed 16 January 2021.

[4] Ministry of Defense. [<https://www.mod.go.jp/index.html>]. Accessed 16 January 2021.

[5] National Institute of Infectious Diseases (NIID). [<https://www.niid.go.jp/niid/ja/>]. Accessed 16 January 2021.

[6] Prime Minister's Office. [<https://www.kantei.go.jp/>]. Accessed 16 January 2021.

4.3.2 System for receiving foreign health personnel during a public health emergency

4.3.2a

Is there a public plan in place to receive health personnel from other countries to respond to a public health emergency?

Yes = 1, No = 0

Current Year Score: 0

There is insufficient evidence that Japan has a public plan in place to receive health personnel from other countries to respond to a public health emergency.

The Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018) states that "Japan has further enhanced its legal framework to not only dispatch personnel but also to facilitate the process of receiving foreign medical teams". However, the report also states that "[a]lthough Japan has the capacity to manage most public health emergencies, Japan may still benefit from further testing and optimizing newly developed guidelines for receiving medical and public health personnel from abroad in the event of a major public health emergency." [1]

The Cabinet Office's "Basic Plan for Disaster Management" of 2018 includes criteria for acceptance of international aid (personnel, supplies, and financial donations) and sharing of information with international stakeholders as a component of disaster management. However, it does not include specific details on how the government will facilitate the arrival of foreign personnel, such as considerations for visas, language skills, etc. [2] The Ministry of Defense's disaster response does not address the need for foreign personnel. [3] The Ministry of Health, Labor and Welfare (MHLW)'s "Disaster Management Plan," updated in September 2019, simply states that the MHLW should make a decision quickly on whether to request international personnel assistance as part of its public health emergency response. [4]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 22 December 2020.

[2] Cabinet Office. June 2018. "Basic Plan for Disaster Management".

[http://www.bousai.go.jp/taisaku/keikaku/pdf/kihon_basic_plan180629.pdf]. Accessed 23 December 2020.

[3] Ministry of Defense. "Defense of Japan 2020". [https://www.mod.go.jp/e/publ/w_paper/index.html]. Accessed 23 December 2020.

[4] Ministry of Health, Labor and Welfare (MHLW). "Disaster Management Plan".

[<https://www.mhlw.go.jp/content/000556282.pdf>]. Accessed 23 December 2020.

4.4 HEALTHCARE ACCESS

4.4.1 Access to healthcare

4.4.1a

Does the constitution explicitly guarantee citizens' right to medical care?

Guaranteed free = 4, Guaranteed right = 3, Aspirational or subject to progressive realization = 2, Guaranteed for some groups, not universally = 1, No specific provision = 0

Current Year Score: 0

2020

World Policy Analysis Center

4.4.1b

Access to skilled birth attendants (% of population)

Input number

Current Year Score: 99.9

2015

WHO/World Bank/United Nations Children's Fund (UNICEF)

4.4.1c

Out-of-pocket health expenditures per capita, purchasing power parity (PPP; current international \$)

Input number

Current Year Score: 586.3

2017

WHO Global Health Expenditure database

4.4.2 Paid medical leave

4.4.2a

Are workers guaranteed paid sick leave?

Paid sick leave = 2, Unpaid sick leave = 1, No sick leave = 0

Current Year Score: 2

2020

World Policy Analysis Center

4.4.3 Healthcare worker access to healthcare

4.4.3a

Has the government issued legislation, a policy, or a public statement committing to provide prioritized healthcare services to healthcare workers who become sick as a result of responding to a public health emergency?

Yes = 1, No = 0

Current Year Score: 0

There is no evidence that the government has issued a statement committing to provide prioritized healthcare services to healthcare workers who become sick as a result of responding to a public health emergency. On 11 December 2020, the government's Covid-19 taskforce issued a statement prioritizing vaccination of healthcare workers, along with people with underlying conditions. [1] However, the Ministry of Health, Labor and Welfare's H1N1 vaccination policy in 2009 did not give consideration to prioritizing vaccination of healthcare workers. [2] There is no further evidence of this from the Ministry of Health, Labor and Welfare, Ministry of Economy, Trade and Industry, Ministry of Defense, National Institute of Infectious Diseases, or the Prime Minister's Office. [3, 4, 5, 6, 7]

[1] Cabinet Secretariat. 11 December 2020. [https://www.cas.go.jp/jp/seisaku/ful/bunkakai/corona_vaccine_2.pdf]. Accessed 23 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). 13 October 2009. [<https://www.mhlw.go.jp/kinkyu/kenkou/influenza/dl/infu091013-01.pdf>]. Accessed 23 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 21 December 2020.

[4] Ministry of Economy, Trade and Industry (METI) [<https://www.meti.go.jp/>]. Accessed 16 January 2021.

[5] Ministry of Defense. [<https://www.mod.go.jp/index.html>]. Accessed 16 January 2021.

[6] National Institute of Infectious Diseases (NIID). [<https://www.niid.go.jp/niid/ja/>]. Accessed 16 January 2021.

[7] Prime Minister's Office. [<https://www.kantei.go.jp/>]. Accessed 16 January 2021.

4.5 COMMUNICATIONS WITH HEALTHCARE WORKERS DURING A PUBLIC HEALTH EMERGENCY

4.5.1 Communication with healthcare workers

4.5.1a

Is there a system in place for public health officials and healthcare workers to communicate during a public health emergency?

Yes = 1, No = 0

Current Year Score: 0

There is insufficient evidence that there is a system in place for public health officials and healthcare workers to communicate during a public health emergency.

The Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response (Act No. 31 of 2012) does not contain provisions on communication between public health officials and healthcare workers. [1]

The Ministry of Health, Labor and Welfare (MHLW) and the Cabinet Secretariat's IT Office have launched an online centralized communication platform called Gathering Medical Information System on Covid-19 (G-MIS) to collect information on the operational status of hospitals, the availability of hospital capacity, and the procurement of medical equipment (e.g. ventilators) and medical supplies (e.g. PPE) from medical institutions nationwide (about 8,000 hospitals). Through the system, frontline health workers file reports and inquiries, and public health officials provide guidance and feedback. [2]

The Ministry of Economy, Trade and Industry's Covid-19 website provides critical updates for health workers, including the availability of PPE and ventilators. [3] There is no further evidence from the MHLW, National Institute of Infectious Diseases, or the Prime Minister's Office. [4, 5, 6]

[1] Ministry of Internal Affairs and Communications. Act No. 31 of 2012. "Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response". [<https://elaws.e-gov.go.jp/document?lawid=424AC0000000031>]. Accessed 22 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). "Gathering Medical Information System on Covid-19 (G-MIS)". [<https://www.mhlw.go.jp/content/10900000/000678071.pdf>]. Accessed 23 December 2020.

[3] Ministry of Economy, Trade and Industry (METI) [<https://www.meti.go.jp/covid-19/mask.html>]. Accessed 23 December 2020.

[4] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 21 December 2020.

[5] National Institute of Infectious Diseases (NIID). [<https://www.niid.go.jp/niid/ja/>]. Accessed 16 January 2021.

[6] Prime Minister's Office. [<https://www.kantei.go.jp/>]. Accessed 16 January 2021.

4.5.1b

Does the system for public health officials and healthcare workers to communicate during an emergency encompass healthcare workers in both the public and private sector?

Yes = 1, No = 0

Current Year Score: 0

There is insufficient evidence that there is a system in place for public health officials and healthcare workers to communicate during a public health emergency that encompasses workers in both the private and public sector.

The Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response (Act No. 31 of 2012) does not contain provisions on communication between public health officials and healthcare workers. [1]

The Ministry of Health, Labor and Welfare and the Cabinet Secretariat's IT Office have launched an online centralized communication platform called Gathering Medical Information System on Covid-19 (G-MIS) to collect information on the operational status of hospitals, the availability of hospital capacity, and the procurement of medical equipment (e.g. ventilators) and medical supplies (e.g. PPE) from medical institutions nationwide (about 8,000 hospitals). Through the system, frontline health workers file reports and inquiries, and public health officials provide guidance and feedback. [2]

The Ministry of Economy, Trade and Industry's Covid-19 website provides critical updates for health workers, including the availability of PPE and ventilators. [3] There is no further evidence from the Ministry of Health, Labor and Welfare, National Institute of Infectious Diseases, or the Prime Minister's Office. [4, 5, 6]

[1] Ministry of Internal Affairs and Communications. Act No. 31 of 2012. "Act on Special Measures for Pandemic Influenza and New Infectious Diseases Preparedness and Response". [<https://elaws.e-gov.go.jp/document?lawid=424AC0000000031>]. Accessed 22 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). "Gathering Medical Information System on Covid-19 (G-MIS)". [<https://www.mhlw.go.jp/content/10900000/000678071.pdf>]. Accessed 23 December 2020.

[3] Ministry of Economy, Trade and Industry (METI) [<https://www.meti.go.jp/covid-19/mask.html>]. Accessed 23 December 2020.

[4] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 21 December 2020.

[5] National Institute of Infectious Diseases (NIID). [<https://www.niid.go.jp/niid/ja/>]. Accessed 16 January 2021.

[6] Prime Minister's Office. [<https://www.kantei.go.jp/>]. Accessed 16 January 2021.

4.6 INFECTION CONTROL PRACTICES AND AVAILABILITY OF EQUIPMENT

4.6.1 Healthcare associated infection (HCAI) prevention and control programs

4.6.1a

Is there evidence that the national public health system is monitoring for and tracking the number of healthcare associated infections (HCAI) that take place in healthcare facilities?

Yes = 1 , No = 0

Current Year Score: 1

There is evidence that the national public health system is monitoring for and tracking the number of healthcare-associated infections (HCAI) that take place in healthcare facilities.

The Japan Nosocomial Infections Surveillance (JANIS), established in 2000, is a dedicated medical surveillance agency monitoring and tracking the incidence and prevalence of nosocomial infections and antimicrobial-resistant bacteria in medical settings. Its surveillance activity is conducted by the clinical laboratory division, antimicrobial-resistant bacterial infection (ARBI) division, intensive care unit (ICU) division, surgical site infection division, and neonatal intensive care unit division. [1] Its "Annual Open Report 2019" contains HCAI data based on submissions from 2,075 facilities. [2]

[1] Ministry of Health, Labor and Welfare (MHLW). "Japan Nosocomial Infections Surveillance (JANIS)".

[<https://janis.mhlw.go.jp/english/index.asp>]. Accessed 23 December 2020.

[2] JANIS. 2019. "Annual Open Report".

[https://janis.mhlw.go.jp/english/report/open_report/2019/3/1/ken_Open_Report_Eng_201900_clsi2012.pdf]. Accessed 23 December 2020.

4.7 CAPACITY TO TEST AND APPROVE NEW MEDICAL COUNTERMEASURES

4.7.1 Regulatory process for conducting clinical trials of unregistered interventions

4.7.1a

Is there a national requirement for ethical review (e.g., from an ethics committee or via Institutional Review Board approval) before beginning a clinical trial?

Yes = 1 , No = 0

Current Year Score: 1

There is a national requirement for ethical review before beginning a clinical trial. The Law on Clinical Studies (Act No. 16 of 2017) requires intervention by a certified institutional review board in a clinical trial. [1] The Ministry of Health, Labor and Welfare (MHLW) issued "Ethical Guidelines for Medical and Health Research Involving Human Subjects" in December 2014 to set out "fundamental requirements to be observed by any of those concerned in medical and health research involving human subjects". The guideline requires clinical research projects to obtain prior approval from an ethical review committee. [2] The Pharmaceuticals and Medical Devices Agency, which reviews new drugs and medical devices for approval or

disapproval by the MHLW, conducts Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) assessments on whether clinical trials meet ethical and scientific standards. [3]

[1] Ministry of Internal Affairs and Communications. Act No. 16 of 2017. "Law on Clinical Studies". [<https://elaws.e-gov.go.jp/document?lawid=429AC0000000016>]. Accessed 23 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). 22 December 2014. "Ethical Guidelines for Medical and Health Research Involving Human Subjects". [<https://www.mhlw.go.jp/file/06-Seisakujouhou-10600000-Daijinkanboukouseikagakuka/0000080278.pdf>]. Accessed 23 December 2020.

[3] Pharmaceuticals and Medical Devices Agency (PMDA). "GLP / GCP / GPSP Compliance Assessments". [<https://www.pmda.go.jp/english/review-services/glp-gcp-gpsp/0001.html>]. Accessed 23 December 2020.

4.7.1b

Is there an expedited process for approving clinical trials for unregistered medical countermeasures (MCM) to treat ongoing epidemics?

Yes = 1 , No = 0

Current Year Score: 1

There is an expedited process for approving clinical trials for unregistered medical countermeasures (MCM). The current system of approving clinical trials for unregistered MCM on a fast-track basis applies to innovative drugs and medical devices. The Ministry of Health, Labor and Welfare (MHLW)'s "Strategy of SAKIGAKE" ("sakigake" means forerunner) provides the basis for approving clinical trials for unregistered MCM. The strategy includes a scheme for rapid authorization of unapproved drugs to expedite the "practical application of unapproved/off-label use of drugs for serious and life-threatening diseases". [1] A deliberation council on unapproved drugs/off-label use, established under the MHLW, reviews applications for expedited approval of drugs that meet "high therapeutic needs" or "SAKIGAKE" requirements. [2] As of 19 June 2020, 24 drugs and 13 regenerative medical products have been granted Sakigake designation in Japan, according to the Pharmaceuticals and Medical Devices Agency. [3]

[1] Ministry of Health, Labor and Welfare (MHLW). "Strategy of SAKIGAKE". [<https://www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/140729-01.html>]. Accessed 16 January 2021.

[2] Ministry of Health, Labor and Welfare (MHLW). [https://www.mhlw.go.jp/stf/shingi/other-iyaku_128701.html]. Accessed 16 January 2021.

[3] Pharmaceuticals and Medical Devices Agency (PMDA). [<https://www.pmda.go.jp/review-services/drug-reviews/0003.html>]. Accessed 16 January 2021.

4.7.2 Regulatory process for approving medical countermeasures

4.7.2a

Is there a government agency responsible for approving new medical countermeasures (MCM) for humans?

Yes = 1 , No = 0

Current Year Score: 1

The Pharmaceuticals and Medical Devices Agency (PMDA) is the government agency responsible for reviewing new medical countermeasures for humans and making approval/disapproval recommendations to the Ministry of Health, Labor and Welfare (MHLW). Actual decisions are issued by the MHLW. [1] The PMDA handles regulatory reviews of drugs, medical

devices and regenerative medical products. In fiscal 2019 (April 2019-March 2020), the PMDA approved 127 drugs. [2]

[1] Pharmaceuticals and Medical Devices Agency (PMDA). [<https://www.pmda.go.jp/index.html>]. Accessed 23 December 2020.

[2] Pharmaceuticals and Medical Devices Agency (PMDA). [<https://www.pmda.go.jp/files/000235290.pdf>]. Accessed 23 December 2020.

4.7.2b

Is there an expedited process for approving medical countermeasures (MCM) for human use during public health emergencies?

Yes = 1, No = 0

Current Year Score: 1

Japan has legislation that provides an expedited process for approving medical countermeasures for human use during public health emergencies. The Joint External Evaluation of IHR core capacities of Japan, conducted 26 February - 2 March 2018, states that "the Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices also allows the Ministry of Health, Labor and Welfare (MHLW) to grant conditional approval in exceptional circumstances for selling or manufacturing unregistered products in the context of a public health emergency." [1]

The Act on the Prevention of Infectious Diseases and Medical Care for Patients with Infectious Diseases (Act No. 114 of 2 October 1998) provides a legal basis for "special approval" of medical countermeasures for emergency reasons. Article 14-3 states: "(1) If an item that an applicant for approval prescribed in Article 14 intends to market falls under both of the following items as pharmaceuticals specified by Cabinet Order, the MHLW may, notwithstanding of the provisions of paragraphs (2), (5), (6) and (8) of the same Article, grant approval for such item prescribed in the same Article after obtaining opinions from the Pharmaceutical Affairs and Food Sanitation Council:

- (i) pharmaceuticals for any urgent needs in the prevention of the spread of disease or other health hazards that may pose serious effects on the lives and health of the general public, and for which no proper method is available other than the use of such pharmaceuticals;
- (ii) with respect to use, pharmaceuticals that are authorized to be sold, provided, stored or displayed for the purpose of sale or provision thereof in a foreign country (limited to countries specified by Cabinet Order as those having a marketing approval system or other systems recognized as being of an equivalent level to that of Japan in terms of quality, efficacy, and safety to be secured for the pharmaceuticals)." [2]

On 7 May 2020, the MHLW granted special approval to the Remdesivir Covid-19 treatment drug developed by Gilead Sciences (US), based on a same-day review by the Pharmaceutical Affairs and Food Sanitation Council. [3]

[1] World Health Organization (WHO). 2018. "Joint External Evaluation of IHR Core Capacities of Japan mission report (26 February-2 March 2018)". [<https://www.who.int/ihr/publications/WHO-WHE-CPI-REP-2018.23/en/>]. Accessed 23 December 2020.

[2] Japanese Law Translation Database System. Act No. 145 of 10 August 1960. "Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices". [<http://www.japaneselawtranslation.go.jp/law/detail/?ft=1&re=2&dn=1&x=27&y=11&co=01&ia=03&ja=04&ky=act+on+securing+quality%2C+efficacy+and+safety+of+products+including+pharmaceuticals&page=13>]. Accessed 23 December 2020.

[3] Ministry of Health, Labor and Welfare (MHLW). 7 May 2020. [<https://www.mhlw.go.jp/content/000628076.pdf>]. Accessed 23 December 2020.

Category 5: Commitments to improving national capacity, financing plans to address gaps, and adhering to global norms

5.1 INTERNATIONAL HEALTH REGULATIONS (IHR) REPORTING COMPLIANCE AND DISASTER RISK REDUCTION

5.1.1 Official IHR reporting

5.1.1a

Has the country submitted IHR reports to the WHO for the previous calendar year?

Yes = 1 , No = 0

Current Year Score: 1

2020

World Health Organization

5.1.2 Integration of health into disaster risk reduction

5.1.2a

Are epidemics and pandemics integrated into the national risk reduction strategy or is there a standalone national disaster risk reduction strategy for epidemics and pandemics?

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that Japan has a standalone national disaster risk reduction strategy for epidemics and pandemics or a national risk reduction strategy that incorporates pandemics. The Ministry of Health, Labor and Welfare (MHLW)'s "Disaster Management Plan," updated in September 2019, contains epidemic risk reduction measures in the event of an earthquake disaster. [1] There is no evidence of a national pandemic disaster risk reduction strategy from the MHLW, the National Institute of Infectious Diseases, or the Prime Minister's Office. [2, 3, 4]

[1] Ministry of Health, Labor and Welfare (MHLW). "Disaster Management Plan".

[<https://www.mhlw.go.jp/content/000556282.pdf>]. Accessed 23 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/index.html>]. Accessed 21 December 2020.

[3] National Institute of Infectious Diseases (NIID). [<https://www.niid.go.jp/niid/ja/>]. Accessed 16 January 2021.

[4] Prime Minister's Office. [<https://www.kantei.go.jp/>]. Accessed 16 January 2021.

5.2 CROSS-BORDER AGREEMENTS ON PUBLIC HEALTH AND ANIMAL HEALTH EMERGENCY RESPONSE

5.2.1 Cross-border agreements

5.2.1a

Does the country have cross-border agreements, protocols, or MOUs with neighboring countries, or as part of a regional group, with regards to public health emergencies?

Yes = 2, Yes, but there is evidence of gaps in implementation = 1, No = 0

Current Year Score: 2

Japan has cross-border agreements with neighboring countries with regard to public health emergencies. Japan participates in "Trilateral Cooperation" with China and South Korea to promote a regional agenda, which includes health. The Trilateral Cooperation Secretariat was officially inaugurated in Seoul, South Korea in September 2011. [1] The health ministers of the three East Asian countries signed the "Joint Statement of the Twelfth Tripartite Health Ministers Meeting (THMM)" on 15 December 2019. The annual agreement reiterated the three countries' commitment to "continue to improve rapid information sharing among the three countries, monitor public health threats in the region, and promote capacity building to respond to threats resulting from infectious diseases outbreaks." [2] Japan, China and South Korea signed the "Joint Statement of the Special Video Conference of THMM on Coronavirus Disease 2019 (Covid-19) Response" on 15 May 2020. The three countries agreed to "enhance free, open, transparent and timely sharing of information, data and expertise on prevention, detection, control and response measures, epidemiologic surveillance updates, risk assessment results, epidemiological, clinical, virological, and laboratory characteristics on Covid-19, treatment experience, including diagnostics, pharmaceuticals, vaccine and technical guidelines." [3]

[1] Trilateral Cooperation Secretariat. "Trilateral Cooperation Summary". [<https://www.tcs-asia.org/en/cooperation/summary.php>]. Accessed 16 January 2021.

[2] South Korean Ministry of Health and Welfare. 15 December 2020. "Press Release".

[http://www.mohw.go.kr/react/al/sal0301vw.jsp?PAR_MENU_ID=04&MENU_ID=0403&page=2&CONT_SEQ=351894&SEARCHKEY=TITLE&SEARCHVALUE=%ED%98%91%EB%A0%A5]. Accessed 15 December 2020.

[3] South Korean Ministry of Health and Welfare. 15 May 2020. "Press Release".

[http://www.mohw.go.kr/react/al/sal0301vw.jsp?PAR_MENU_ID=04&MENU_ID=0403&page=2&CONT_SEQ=354566&SEARCHKEY=TITLE&SEARCHVALUE=%ED%98%91%EB%A0%A5]. Accessed 15 December 2020.

5.2.1b

Does the country have cross-border agreements, protocols, or MOUs with neighboring countries, or as part of a regional group, with regards to animal health emergencies?

Yes = 2, Yes, but there is evidence of gaps in implementation = 1, No = 0

Current Year Score: 0

There is insufficient evidence that Japan has cross-border agreements as part of a regional group with regard to response to animal health emergencies.

Japan has cross-border agreements with neighboring countries with regard to animal health emergencies. Japan participates in "Trilateral Cooperation" with China and South Korea to promote a regional agenda, which includes health, agriculture and fishery. [1] The trilateral summit between the leaders of Japan, China and South Korea addresses cooperation issues on

animal disease outbreaks. The Eighth Trilateral Summit held on 24 December 2019 in Chengdu, China produced an agreement on the "Trilateral Cooperation Vision for the Next Decade," which pledged joint efforts to address various issues, including "trans-boundary animal diseases." [2] The Third Japan-China-Korea Trilateral Agricultural Ministers' Meeting (TAMM), held in Beijing, China on 10 November 2018, confirmed the ongoing commitment to "the sharing of animal health information, the surveillance, reporting and epidemiological investigation of diseases, the exchange of virus and other materials, research and development of diagnostic methodology and vaccines and collaborative research on Transboundary Animal Diseases such as avian influenza, foot and mouth disease and African swine fever." [3] The "Memorandum of Cooperation on Response against Transboundary Animal Diseases", signed by the three East Asian countries' agricultural ministers on 13 September 2015 in Tokyo, Japan, proposed trilateral efforts to "enhance and expand cooperative efforts in prevention and control of transboundary animal diseases." [4]

[1] Trilateral Cooperation Secretariat. "Trilateral Cooperation Summary". [<https://www.tcs-asia.org/en/cooperation/summary.php>]. Accessed 16 January 2021.

[2] Xinhua. 24 December 2019. "Full text of China-ROK-Japan Cooperation Vision for the Next Decade". [http://www.xinhuanet.com/english/2019-12/24/c_138655249.htm]. Accessed 15 December 2020.

[3] Trilateral Cooperation Secretariat. November 2018. "Third Japan-China-Korea Trilateral Agricultural Ministers' Meeting". [https://www.maff.go.jp/j/kokusai/kokusei/kanren_sesaku/attach/pdf/cjk_3-1.pdf]. Accessed 15 December 2020.

[4] Ministry of Agriculture, Forestry and Fisheries. 13 September 2015. "Memorandum of Cooperation on Response against Transboundary Animal Diseases". [https://www.maff.go.jp/j/kokusai/kokusei/kanren_sesaku/attach/pdf/cjk_2-4.pdf]. Accessed 15 December 2020.

5.3 INTERNATIONAL COMMITMENTS

5.3.1 Participation in international agreements

5.3.1a

Does the county have signatory and ratification (or same legal effect) status to the Biological Weapons Convention?

Signed and ratified (or action having the same legal effect) = 2, Signed = 1, Non-compliant or not a member = 0

Current Year Score: 2

2021

Biological Weapons Convention

5.3.1b

Has the country submitted confidence building measures for the Biological Weapons Convention in the past three years?

Yes = 1, No = 0

Current Year Score: 1

2021

Biological Weapons Convention

5.3.1c

Has the state provided the required United Nations Security Council Resolution (UNSCR) 1540 report to the Security Council Committee established pursuant to resolution 1540 (1540 Committee)?

Yes = 1, No = 0

Current Year Score: 1

2021

Biological Weapons Convention

5.3.1d

Extent of United Nations Security Council Resolution (UNSCR) 1540 implementation related to legal frameworks and enforcement for countering biological weapons:

Very good (60+ points) = 4, Good (45–59 points) = 3, Moderate (30–44 points) = 2, Weak (15–29 points) = 1, Very weak (0–14 points) or no matrix exists/country is not party to the BWC = 0

Current Year Score: 4

2021

Biological Weapons Convention

5.3.2 Voluntary memberships

5.3.2a

Does the country meet at least 2 of the following criteria?

- Membership in Global Health Security Agenda (GHSA)
- Membership in the Alliance for Country Assessments for Global Health Security and IHR Implementation (JEE Alliance)
- Membership in the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction (GP)
- Membership in the Australia Group (AG)
- Membership in the Proliferation Security Initiative (PSI)

Needs to meet at least two of the criteria to be scored a 1 on this measure. , Yes for five = 1 , Yes for four = 1 , Yes for three = 1 , Yes for two = 1 , Yes for one = 0 , No for all = 0

Current Year Score: 1

2021

Global Health Security Agenda; JE Alliance; Global Partnership; Australia Group; PSI

5.4 JOINT EXTERNAL EVALUATION (JEE) AND PERFORMANCE OF VETERINARY SERVICES PATHWAY (PVS)

5.4.1 Completion and publication of a Joint External Evaluation (JEE) assessment and gap analysis

5.4.1a

Has the country completed a Joint External Evaluation (JEE) or precursor external evaluation (e.g., GHSA pilot external assessment) and published a full public report in the last five years?

Yes = 1, No = 0

Current Year Score: 1

2021

WHO Strategic Partnership for IHR and Health Security (SPH); Global Health Security Agenda

5.4.1b

Has the country completed and published, within the last five years, either a National Action Plan for Health Security (NAPHS) to address gaps identified through the Joint External Evaluation (JEE) assessment or a national GHSA roadmap that sets milestones for achieving each of the GHSA targets?

Yes = 1, No = 0

Current Year Score: 0

2021

WHO Strategic Partnership for IHR and Health Security (SPH); Global Health Security Agenda

5.4.2 Completion and publication of a Performance of Veterinary Services (PVS) assessment and gap analysis

5.4.2a

Has the country completed and published a Performance of Veterinary Services (PVS) assessment in the last five years?

Yes = 1, No = 0

Current Year Score: 1

2021

OIE PVS assessments

5.4.2b

Has the country completed and published a Performance of Veterinary Services (PVS) gap analysis in the last five years?

Yes = 1, No = 0

Current Year Score: 0

2021

OIE PVS assessments

5.5 FINANCING

5.5.1 National financing for epidemic preparedness

5.5.1a

Is there evidence that the country has allocated national funds to improve capacity to address epidemic threats within the past three years?

Yes = 1 , No = 0

Current Year Score: 1

Japan has allocated national funds to improve capacity to address epidemic threats within the past three years. The Ministry of Health, Labor and Welfare (MHLW)'s fiscal 2021 (April 2021-March 2022) budget plan includes funding for testing and vaccination infrastructure improvement, procurement and stockpiling of medical supplies, and epidemic/pandemic research. [1] The MHLW's fiscal 2020 (April 2020-March 2021) budget programs included vaccine research and development and testing method development. [2]

[1] Ministry of Health and Welfare (MHLW). [<https://www.mhlw.go.jp/wp/yosan/yosan/21syokanyosan/dl/01-01.pdf>]. Accessed 23 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). [<https://www.mhlw.go.jp/wp/yosan/yosan/20syokanyosan/dl/01-01.pdf>]. Accessed 23 December 2020.

5.5.2 Financing under Joint External Evaluation (JEE) and Performance of Veterinary Services (PVS) reports and gap analyses

5.5.2a

Does the Joint External Evaluation (JEE) report, National Action Plan for Health Security (NAPHS), and/or national GHSA roadmap allocate or describe specific funding from the national budget (covering a time-period either in the future or within the past five years) to address the identified gaps?

Yes = 1 , No/country has not conducted a JEE = 0

Current Year Score: 0

2021

WHO Strategic Partnership for IHR and Health Security (SPH); Global Health Security Agenda

5.5.2b

Does the Performance of Veterinary Services (PVS) gap analysis and/or PVS assessment allocate or describe specific funding from the national budget (covering a time-period either in the future or within the past five years) to address the identified gaps?

Yes = 1 , No/country has not conducted a PVS = 0

Current Year Score: 0

2021

OIE PVS assessments

5.5.3 Financing for emergency response

5.5.3a

Is there a publicly identified special emergency public financing mechanism and funds which the country can access in the face of a public health emergency (such as through a dedicated national reserve fund, an established agreement with the World Bank pandemic financing facility/other multilateral emergency funding mechanism, or other pathway identified through a public health or state of emergency act)?

Yes = 1 , No = 0

Current Year Score: 0

There is no publicly identified special emergency public financing mechanism and funds that Japan can access in the face of a public health emergency (such as through a dedicated national reserve fund).

National funding for public health emergency response is provided by the government's regular and supplementary budgets. There is no evidence of a standing facility to provide fiscal funding for public health emergency purposes. [1, 2]. There is no evidence of a public health emergency funding agreement with the World Bank. [3]

[1] Ministry of Health, Labor and Welfare (MHLW). 2021. [<https://www.mhlw.go.jp/wp/yosan/yosan/21syokanyosan/dl/01-01.pdf>]. Accessed 23 December 2020.

[2] Ministry of Health, Labor and Welfare (MHLW). 2020. [<https://www.mhlw.go.jp/wp/yosan/yosan/20syokanyosan/dl/01-01.pdf>]. Accessed 23 December 2020.

[3] World Bank. "Pandemic Financing Facility". [<http://pubdocs.worldbank.org/en/119961516647620597/PEF-Operational-Brief-Dec-2017.pdf>]. Accessed 23 December 2020.

5.5.4 Accountability for commitments made at the international stage for addressing epidemic threats

5.5.4a

Is there evidence that senior leaders (president or ministers), in the past three years, have made a public commitment either to:

- Support other countries to improve capacity to address epidemic threats by providing financing or support?
- Improve the country's domestic capacity to address epidemic threats by expanding financing or requesting support to improve capacity?

Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

Current Year Score: 1

There is evidence that senior leaders have made a public commitment to support other countries to improve capacity to address epidemic threats by providing financing or support in the past three years. In his address to the 75th Session of the United Nations General Assembly on 25 September 2020, Prime Minister Suga Yoshihide said that "Japan is implementing the

Covid-19 Crisis Response Emergency Support Loan of up to ¥500 billion or US\$4.5 billion over the course of two years." [1] Prime Minister Suga has repeatedly stated his government's commitment to improve domestic capacity to address epidemic threats. In his address, he stated, "[W]e must prepare ourselves for future health crises. Japan is committed to expanding its efforts in developing countries to build hospitals as well as to assist strengthening health and medical systems by providing equipment and supporting human resource development. Working with the ASEAN, Japan is supporting the establishment of an ASEAN Center for public health emergencies and emerging diseases. Japan has also been supporting the Africa Centers for Disease Control and Prevention. "At a policy meeting between the government and the ruling party on 18 December 2020, the prime minister said that US\$ 44.1 billion in funding was available for future pandemic response measures including the improvement of public health centers' handling of outbreaks. [2]

[1] Ministry of Foreign Affairs. 26 September 2020. "Address by Prime Minister Suga at the Seventy-Fifth Session of the United Nations General Assembly". [https://www.mofa.go.jp/fp/unp_a/page4e_001095.html]. Accessed 23 December 2020.

[2] Prime Minister's Office. 18 December 2020.

[https://www.kantei.go.jp/jp/99_suga/actions/202012/18yoto_kondankai.html]. Accessed 23 December 2020.

5.5.4b

Is there evidence that the country has, in the past three years, either:

- Provided other countries with financing or technical support to improve capacity to address epidemic threats?
- Requested financing or technical support from donors to improve the country's domestic capacity to address epidemic threats?

Needs to meet at least one of the criteria to be scored a 1 on this measure., Yes for both = 1, Yes for one = 1, No for both = 0

Current Year Score: 1

There is evidence that Japan has provided other countries with financing or technical support to improve capacity to address epidemic threats in the past three years.

The Global Health Security Tracking Dashboard's funder profile for Japan shows that Japan disbursed US\$567.84m between 2014 and 2020. "Funding by core capacity" shows US\$90.93m disbursed for immunization, US\$36.29m for workforce development, US\$22.5m for national laboratory systems, US\$20.97m for medical countermeasures and personnel development, US\$5.94m for preparedness, US\$1.81m for real-time surveillance, and US\$1.45m for emergency response operations. There is no fund "recipient" activity for Japan. [1]

The Japan International Cooperation Agency (JICA)'s funder activity in 2020 includes Covid-19 loans to other countries. Funding to address epidemic threats was also provided in previous years. For example, in August 2019, Japan provided the Republic of Uganda with supplies for preventing Ebola virus outbreaks. [2, 3]

[1] GHS Tracking Dashboard. "Japan: Funder Profile". [<https://tracking.ghscosting.org/details/117/funder>]. Accessed 23 December 2020.

[2] Japan International Cooperation Agency (JICA). "Press Releases". [<https://www.jica.go.jp/english/news/press/index.html>]. Accessed 23 December 2020.

[3] Japan International Cooperation Agency (JICA). 26 August 2019. "Press Release".

[https://www.jica.go.jp/english/news/press/2019/20190826_30_en.html]. Accessed 23 December 2020.

5.5.4c

Is there evidence that the country has fulfilled its full contribution to the WHO within the past two years?

Yes = 1 , No = 0

Current Year Score: 1

2021

Economist Impact analyst qualitative assessment based on official national sources, which vary by country

5.6 COMMITMENT TO SHARING OF GENETIC AND BIOLOGICAL DATA AND SPECIMENS

5.6.1 Commitment to sharing genetic data, clinical specimens, and/or isolated specimens (biological materials) in both emergency and nonemergency research

5.6.1a

Is there a publicly available plan or policy for sharing genetic data, clinical specimens, and/or isolated specimens (biological materials) along with the associated epidemiological data with international organizations and/or other countries that goes beyond influenza?

Yes = 1 , No = 0

Current Year Score: 1

There is evidence showing that a platform exists for sharing genetic data, epidemiological data, clinical specimens, and/or isolated specimens (biological materials) with international organizations and/or other countries that goes beyond influenza through international agreements.

Japan is a member of the Global Health Security Initiative (GHSI), which has developed a "voluntary agreement to facilitate the rapid sharing of non-influenza biological materials among GHSI members during a potential or actual public health emergency." [1,2] Additionally, the Japan Agency for Medical Research and Development (AMED) has a memorandum of cooperation with the US' National Institute of Health on research data sharing between the two agencies. However, it is not clear what types of data are shared under the agreement. The AMED is a member of the Global Research Collaboration for Infectious Disease Preparedness, which facilitates data sharing among members with regard to infectious diseases. [3] The AMED also participates in the International Rare Diseases Research Consortium, the Joint Programming Initiative on Antimicrobial Resistance, the Global Alliance for Genomics and Health, the Clinical Data Interchange Standards Consortium, and the Global Alliance for Chronic Diseases. [4]

[1] Global Health Security Initiative. "GHSI Members". [<http://ghsi.ca/ghsi-members/>]. Accessed 23 December 2020.

[2] Global Health Security Initiative. 17 May 2019. "Nineteenth Ministerial Meeting of the Global Health Security Initiative (GHSI)". [<http://ghsi.ca/ministerial-statements/paris-may-2019/>]. Accessed 23 December 2020.

[3] Japan Agency for Medical Research and Development (AMED). "Collaboration/cooperation with external institutions". [<https://www.amed.go.jp/en/aboutus/collaboration/index.html>]. Accessed 23 December 2020.

[4] Japan Agency for Medical Research and Development (AMED). "Participation in International Alliances and Consortia". [<https://www.amed.go.jp/en/program/list/20/index.html>]. Accessed 16 January 2021.

5.6.1b

Is there public evidence that the country has not shared samples in accordance with the Pandemic Influenza Preparedness (PIP) framework in the past two years?

Yes = 0, No = 1

Current Year Score: 1

There is no public evidence that Japan has not shared samples in accordance with the PIP framework in the past two years. The World Health Organization's Pandemic Influenza Preparedness (PIP) Framework shows no evidence of Japan not sharing samples as such. No evidence is available from major media outlets. [1].

[1] World Health Organization (WHO). "Pandemic Influenza Preparedness (PIP) Framework". [<https://www.who.int/influenza/pip/en/>]. Accessed 23 December 2020.

5.6.1c

Is there public evidence that the country has not shared pandemic pathogen samples during an outbreak in the past two years?

Yes = 0, No = 1

Current Year Score: 1

There is no public evidence that Japan has not shared pandemic pathogen samples during an outbreak in the past two years. The World Health Organization's website has no evidence of Japan not sharing pandemic pathogen samples, including Covid-19 specimens. No evidence is available from major media outlets. [1]

[1] World Health Organization (WHO). "Western Pacific". [<https://www.who.int/westernpacific>]. Accessed 23 December 2020.

Category 6: Overall risk environment and vulnerability to biological threats

6.1 POLITICAL AND SECURITY RISK

6.1.1 Government effectiveness

6.1.1a

Policy formation (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 3

2020

Economist Intelligence

6.1.1b

Quality of bureaucracy (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 3

2020

Economist Intelligence

6.1.1c

Excessive bureaucracy/red tape (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 3

2020

Economist Intelligence

6.1.1d

Vested interests/cronyism (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 2

2020

Economist Intelligence

6.1.1e

Country score on Corruption Perception Index (0-100, where 100=best)

Input number

Current Year Score: 74

2020

Transparency International

6.1.1f

Accountability of public officials (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 3

2020

Economist Intelligence

6.1.1g

Human rights risk (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 3

2020

Economist Intelligence

6.1.2 Orderly transfers of power

6.1.2a

How clear, established, and accepted are constitutional mechanisms for the orderly transfer of power from one government to another?

Very clear, established and accepted = 4, Clear, established and accepted = 3, One of the three criteria (clear, established, accepted) is missing = 2, Two of the three criteria (clear, established, accepted) are missing = 1, Not clear, not established, not accepted = 0

Current Year Score: 4

2021

Economist Intelligence

6.1.3 Risk of social unrest

6.1.3a

What is the risk of disruptive social unrest?

Very low: Social unrest is very unlikely = 4, Low: There is some prospect of social unrest, but disruption would be very limited = 3, Moderate: There is a considerable chance of social unrest, but disruption would be limited = 2, High: Major social unrest is likely, and would cause considerable disruption = 1, Very high: Large-scale social unrest on such a level as to seriously challenge government control of the country is very likely = 0

Current Year Score: 3

2021

Economist Intelligence

6.1.4 Illicit activities by non-state actors

6.1.4a

How likely is it that domestic or foreign terrorists will attack with a frequency or severity that causes substantial disruption?

No threat = 4, Low threat = 3, Moderate threat = 2, High threat = 1, Very high threat = 0

Current Year Score: 3

2021

Economist Intelligence

6.1.4b

What is the level of illicit arms flows within the country?

4 = Very high, 3 = High, 2 = Moderate, 1 = Low, 0 = Very low

Current Year Score: 2

2020

UN Office of Drugs and Crime (UNODC)

6.1.4c

How high is the risk of organized criminal activity to the government or businesses in the country?

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

Current Year Score: 3

2021

Economist Intelligence

6.1.5 Armed conflict

6.1.5a

Is this country presently subject to an armed conflict, or is there at least a moderate risk of such conflict in the future?

No armed conflict exists = 4, Yes; sporadic conflict = 3, Yes; incursional conflict = 2, Yes, low-level insurgency = 1, Yes; territorial conflict = 0

Current Year Score: 4

2021

Economist Intelligence

6.1.6 Government territorial control

6.1.6a

Does the government's authority extend over the full territory of the country?

Yes = 1, No = 0

Current Year Score: 1

2021

Economist Intelligence

6.1.7 International tensions

6.1.7a

Is there a threat that international disputes/tensions could have a negative effect?

No threat = 4, Low threat = 3, Moderate threat = 2, High threat = 1, Very high threat = 0

Current Year Score: 2

2021

Economist Intelligence

6.2 SOCIO-ECONOMIC RESILIENCE

6.2.1 Literacy

6.2.1a

Adult literacy rate, population 15+ years, both sexes (%)

Input number

Current Year Score: 99.9

2008-2018

United Nations Development Programme (UNDP); United Nations Educational, Scientific and Cultural Organization (UNESCO);
The Economist Intelligence Unit

6.2.2 Gender equality

6.2.2a

United Nations Development Programme (UNDP) Gender Inequality Index score

Input number

Current Year Score: 0.9

2018

United Nations Development Programme (UNDP); The Economist Intelligence Unit

6.2.3 Social inclusion

6.2.3a

Poverty headcount ratio at \$1.90 a day (2011 PPP) (% of population)

Input number

Current Year Score: 0.2

2013

World Bank; Economist Impact

6.2.3b

Share of employment in the informal sector

Greater than 50% = 2, Between 25-50% = 1, Less than 25% = 0

Current Year Score: 0

According to an International Labor Organization report released on 30 April 2018, the share of informal employment in total employment was 18.7% in Japan. [1]

[1] International Labor Organization. 30 April 2018. "Women and men in the informal economy: A statistical picture. Third edition". [https://www.ilo.org/global/publications/books/WCMS_626831/lang--en/index.htm]. Accessed 23 December 2020.

6.2.3c

Coverage of social insurance programs (% of population)

Scored in quartiles (0-3, where 3=best)

Current Year Score: 2

2016, or latest available

World Bank; Economist Impact calculations

6.2.4 Public confidence in government

6.2.4a

Level of confidence in public institutions

Input number

Current Year Score: 1

2021

Economist Intelligence Democracy Index

6.2.5 Local media and reporting

6.2.5a

Is media coverage robust? Is there open and free discussion of public issues, with a reasonable diversity of opinions?

Input number

Current Year Score: 1

2021

Economist Intelligence Democracy Index

6.2.6 Inequality

6.2.6a

Gini coefficient

Scored 0-1, where 0=best

Current Year Score: 0.33

Latest available.

World Bank; Economist Impact calculations

6.3 INFRASTRUCTURE ADEQUACY

6.3.1 Adequacy of road network

6.3.1a

What is the risk that the road network will prove inadequate to meet needs?

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

Current Year Score: 3

2021

Economist Intelligence

6.3.2 Adequacy of airports

6.3.2a

What is the risk that air transport will prove inadequate to meet needs?

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

Current Year Score: 3

2021

Economist Intelligence

6.3.3 Adequacy of power network

6.3.3a

What is the risk that power shortages could be disruptive?

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

Current Year Score: 3

2021

Economist Intelligence

6.4 ENVIRONMENTAL RISKS

6.4.1 Urbanization

6.4.1a

Urban population (% of total population)

Input number

Current Year Score: 91.7

2019

World Bank

6.4.2 Land use

6.4.2a

Percentage point change in forest area between 2006–2016

Input number

Current Year Score: -0.04

2008-2018

World Bank; Economist Impact

6.4.3 Natural disaster risk

6.4.3a

What is the risk that the economy will suffer a major disruption owing to a natural disaster?

Very low = 4, Low = 3, Moderate = 2, High = 1, Very high = 0

Current Year Score: 2

2021

Economist Intelligence

6.5 PUBLIC HEALTH VULNERABILITIES

6.5.1 Access to quality healthcare

6.5.1a

Total life expectancy (years)

Input number

Current Year Score: 84.21

2018

United Nations; World Bank, UNICEF; Institute for Health Metrics and Evaluation (IHME); Central Intelligence Agency (CIA)
World Factbook

6.5.1b

Age-standardized NCD mortality rate (per 100 000 population)

Input number

Current Year Score: 235.4

2019

WHO

6.5.1c

Population ages 65 and above (% of total population)

Input number

Current Year Score: 28.0

2019

World Bank

6.5.1d

Prevalence of current tobacco use (% of adults)

Input number

Current Year Score: 21.9

2018

World Bank

6.5.1e

Prevalence of obesity among adults

Input number

Current Year Score: 4.3

2016

WHO

6.5.2 Access to potable water and sanitation

6.5.2a

Percentage of homes with access to at least basic water infrastructure

Input number

Current Year Score: 99

2017

UNICEF; Economist Impact

6.5.2b

Percentage of homes with access to at least basic sanitation facilities

Input number

Current Year Score: 99

2017

UNICEF; Economist Impact

6.5.3 Public healthcare spending levels per capita

6.5.3a

Domestic general government health expenditure per capita, PPP (current international \$)

Input number

Current Year Score: 3787.11

2018

WHO Global Health Expenditure database

6.5.4 Trust in medical and health advice

6.5.4a

Trust medical and health advice from the government

Share of population that trust medical and health advice from the government , More than 80% = 2, Between 60-80%, or no data available = 1, Less than 60% = 0

Current Year Score: 1

2018

Wellcome Trust Global Monitor 2018

6.5.4b

Trust medical and health advice from medical workers

Share of population that trust medical and health advice from health professionals , More than 80% = 2, Between 60-80%, or no data available = 1, Less than 60% = 0

Current Year Score: 2

2018

Wellcome Trust Global Monitor 2018