United States of America

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

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

The United States has a national antimicrobial resistance (AMR) plan for the surveillance, detection and reporting of priority AMR pathogens. The "National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), 2020-2025," released in October 2020, builds on the first National Action Plan that was released in March 2015, implementing the 'National strategy for combating antibiotic-resistant bacteria', in response to 'Executive Order 13676: Combating antibiotic-resistant bacteria' of September 2014. [1, 2, 3, 4] The 2020 Plan outlines activities the Government will undertake to reduce the impact of AMR in the country and maintains the five goals established under the 2015 Plan, which address surveillance, detection and reporting of priority AMR pathogens, aiming to strengthen and expand surveillance efforts. The objectives for surveillance and detection work to include both resistance testing and genetic characterisation of pathogens and extending the Centers for Disease Control and Prevention's "AR Lab Network". [1] The 2020 and 2015 Plan and the 2014 strategy introduce a One Health approach to the country's AMR work. [1, 2, 3] The 2016 Joint External Evaluation of IHR Core Capacities of the US notes that the National Antimicrobial Resistance Monitoring System (NARMS) has been operating since 1996, aggregating and reporting on national AMR surveillance data. [4]

[1] U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation. October 2020. "National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), 2020-2025." [https://aspe.hhs.gov/pdf-report/carb-plan-2020-2025]. Accessed 13 December 2020.
[2] The White House. March 2015. "National action plan for combating antibiotic-resistant bacteria." [https://www.cdc.gov/drugresistance/pdf/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf]. Accessed 13 December 2020.
[3] The White House. September 2014. "National Strategy for Combating Antibiotic-Resistant Bacteria." [https://www.cdc.gov/drugresistance/pdf/carb_national_strategy.pdf]. Accessed 13 December 2020.
[4] The White House. 18 September 2014. "Executive Order – Combatting antibiotic-resistant bacteria." [https://obamawhitehouse.archives.gov/the-press-office/2014/09/18/executive-order-combating-antibiotic-resistant-bacteria]. Accessed 13 December 2020.
[5] World Health Organisation (WHO). 2017. "Joint external evaluation of IHR core capacities of the United States of America – Mission report: June 2016." Geneva: World Health Organisation. [http://apps.who.int/iris/bitstream/10665/254701/1/WHO-WHE-CPI-2017.13-eng.pdf?ua=1&ua=1]. 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: 2

The United States' national laboratory system tests for all 7+1 priority AMR pathogens. The 2016 Joint External Evaluation of IHR Core Capacities of the US states that the Centers for Disease Control and Prevention (CDC) laboratory serves as the national civilian AMR reference laboratory for detection of the World Health Organisation (WHO) priority AMR pathogens, while the Department of Defense Multidrug-resistant Organism Repository and Surveillance Network plays this role for the military. [1] The CDC has several AMR tracking networks. One is the Emerging Infections Program (EIP), which monitors AMR in a network of public health-academic-hospital collaborations in 10 states. This includes Active Bacteria Core (ABC) surveillance, which monitors S. pneumoniae and S. aureus; and the Multi-site Gram-negative Surveillance Initiative (MuGSI), under the EIP's Healthcare-Associated Infections Community Interface (HAIC), which monitors seven carbapenem-resistant organisms including E. coli and K. pneumoniae. [2, 3, 4] A second is the National Antimicrobial Resistance Monitoring System (NARMS), which monitors salmonella, shigella and E. coli transmitted through food (testing bacteria from humans, animals and meats). A third is the National Healthcare Safety Network (NHSN), which collects data directly from healthcare settings on healthcare-associated infections and AMR, and monitors S. aureus. A fourth is the Gonococcal Isolate Surveillance Program (GISP), which collects data from sexually-transmitted disease clinics in around 28 cities, and monitors N. gonorrhoeae. A fifth is the National Tuberculosis Surveillance System (NTSS), which monitors M. tuberculosis (TB). [2] Established in 2016, the CDC's Antibiotic Resistance Laboratory Network (AR Lab Network) covers 50 states, 5 cities and Puerto Rico. It has seven regional laboratories and a National TB Center. [5] Designation of local sentinel sites appears to be down to individual states, but the CDC invests in state capacity and the 2020 national AMR action plan includes objectives around increased reporting. [6, 7, 8]

[1] World Health Organisation (WHO). 2017. "Joint external evaluation of IHR core capacities of the United States of America - Mission report: June 2016." Geneva: World Health Organisation. [http://apps.who.int/iris/bitstream/10665/254701/1/WHO-WHE-CPI-2017.13-eng.pdf?ua=1&ua=1]. Accessed 14 December 2020.
[2] Centers for Disease Control and Prevention (CDC). 2013. "Antibiotic resistance threats in the United States 2013." [https://www.cdc.gov/drugresistance/threat-report-2013/pdf/ar-threats-2013-508.pdf], p. 39-40; 107-110. Accessed 14 December 2020.
[3] Centers for Disease Control and Prevention (CDC). 2018. "Emerging Infections Program." [https://www.cdc.gov/ncezid/dpei/eip/index.html]. Accessed 14 December 2020.
[4] Centers for Disease Control and Prevention (CDC). 13 Dec 2018. "Multi-site Gram-negative Surveillance Initiative." [https://www.cdc.gov/hai/eip/mugsi.html]. Accessed 14 December 2020.
[5] Centers for Disease Control and Prevention (CDC). 2020. "About CDC's Antibiotic Resistance Lab Network." [https://www.cdc.gov/drugresistance/laboratories.html]. Accessed 14 December 2020.
[6] Centers for Disease Control and Prevention (CDC). 2018. "What CDC is Doing: Antibiotic Resistance (AR) Solutions Initiative." [https://www.cdc.gov/drugresistance/solutions-initiative/index.html]. Accessed 14 December 2020.
[7] Centers for Disease Control and Prevention (CDC). 2019. "CDC's 2019 AR Investment Map". [https://wwwn.cdc.gov/arinvestments]. Accessed 14 December 2020.
[8] U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation. October 2020. "National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), 2020-2025." [https://aspe.hhs.gov/pdf-report/carb-plan-2020-2025]. Accessed 14 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: 0

There is insufficient evidence that the government of the United States conducts environmental detection or surveillance activities (e.g., in soil, waterways) for antimicrobial residues or AMR organisms. Although the United States conducts some activities involving detection of AMR in the environment, it does not conduct systematic surveillance. The National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS)—an interagency partnership of the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and Department of Agriculture (USDA)—is a public health surveillance system that conducts antibiotic resistance surveillance. [1, 2] However, NARMS does not specifically mention environmental detection or surveillance activities, such as in soil and waterways, for AMR, and there is no mention of AMR surveillance by the CDC's Division of Foodborne, Waterborne, And Environmental Diseases (DFWED). [3] In the 2019-2020 Antimicrobial Resistance Country Self Assessment, the US indicates that there is a "National system of AMR surveillance established for priority foodborne pathogens and/or relevant indicator bacteria...", regarding a national surveillance for AMR in food (animal and plant origin). However, there is no detail specific to AMR surveillance in soil and waterways. [4] The US Department of Agriculture (USDA)'s 2014 AMR action plan does not mention past or planned surveillance for AMR in soil or waterways, though it sets aside a fund for research into the ecology of AMR gene reservoirs in the environment. [5] There is evidence that the US conducts some activities involving the detection of AMR in the environment. According to the 2016 Joint External Evaluation of IHR Core Capacities of the US, the United States Geological Survey (USGS) Michigan Bacteriological Research Laboratory conducts research on antimicrobial resistance (AMR) in the environment, specifically E. coli and salmonella species. [6, 7] In 2018, the National Health and Environmental Effects Research Laboratory (under the US Environmental Protection Agency, USEPA) published research on the prevalence of AMR genes in the country's waterways, based on 1,747 water samples from the USEPA's 2013-2014 National Rivers and Streams Assessment. The researchers proposed the development of a mapping system for waterway conditions, to include AMR prevalence. [8] Under Goal 2, regarding strengthening surveillance efforts, of the country's 2020 National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), Objective 3.4 aims to "establish new capacities for collecting antibiotic resistance data from the environment, including water and soil." This objective includes the target of at least two projects to expand environmental data collection for AMR by 2022, as part of NARMS. [9] Among the major activities listed among 2012 and 2019 accomplishments in the CDC's National Antimicrobial Resistance Monitoring System 2021-2025 Strategic Plan was working with the EPA "to identify a preliminary sampling scheme for environmental water monitoring." [10] In 2018, the CDC co-hosted a forum on AMR in the environment and subsequently published a report Initiatives for Addressing Antimicrobial Resistance in the Environment. [11, 12]

[1] United States Centers for Disease Control and Prevention (CDC). "National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS)." 2020. [https://www.cdc.gov/narms/index.html]. Accessed 14 December 2020.
[2] United States Centers for Disease Control and Prevention (CDC). "National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS) - About NARMS." 2020. [https://www.cdc.gov/narms/about/index.html]. Accessed 14 December 2020.
[3] United States Centers for Disease Control and Prevention (CDC). "Division of Foodborne, Waterborne, And Environmental Diseases (DFWED)." 2020. [https://www.cdc.gov/ncezid/dfwed/index.html]. Accessed 14 December 2020.
[4] World Health Organisation (WHO). 2020. "Global database for antimicrobial resistance country self assessment 2019-2020, United States." [http://amrcountryprogress.org/]. Accessed 14 December 2020.
[5] United States Department of Agriculture (USDA). 2014. "Antimicrobial resistance action plan." [https://www.usda.gov/sites/default/files/documents/usda-antimicrobial-resistance-action-plan.pdf]. Accessed 14 December

2020.
[6] World Health Organisation (WHO). 2017. “Joint external evaluation of IHR core capacities of the United States of America – Mission report: June 2016.” Geneva: World Health Organisation. [http://apps.who.int/iris/bitstream/10665/254701/1/WHO-WHE-CPI-2017.13-eng.pdf?ua=1&ua=1]. Accessed 14 December 2020.
[7] United States Geological Survey (USGS). N.d. “Environmental Health - Michigan Bacteriological Research Laboratory.” [https://www.usgs.gov/science/labs/mbr-lab]. Accessed 14 December 2020.
[8] Hill, R, Keely, S, Brinkman, N, Wheaton, E, Leibowitz, S, Jahne, M, Martin, R and Garland, J. 2018. “The prevalence of antibiotic resistance genes in US waterways and their relationship to water quality and land use indicators”. Annual Meeting of the Society for Freshwater Science, Detroit, MI, May 20 - 24, 2018. [https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=340942&Lab=NHEERL]. Accessed 14 December 2020.
[9] U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation. October 2020. "National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), 2020-2025." [https://aspe.hhs.gov/pdf-report/carb-plan-2020-2025]. Accessed 14 December 2020.
[10] US Centers for Disease Control and Prevention (CDC), US Food and Drug Administration (FDA), US Department of Agriculture (USDA). ND. "National Antimicrobial Resistance Monitoring System 2021-2025 Strategic Plan." [https://www.fda.gov/media/79976/download]. Accessed 14 December 2020.
[11] US Centers for Disease Control and Prevention (CDC). 2020. "Antibiotic / Antimicrobial Resistance (AR / AMR)." 2020. [https://www.cdc.gov/drugresistance/us-activities.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fantibiotic-use%2Fcommunity%2Fprograms-measurement%2Fnational-activities%2Findex.html]. Accessed 14 December 2020.
[12] US Centers for Disease Control and Prevention and UK Science & Innovation Network. 2018. "Initiatives for Addressing Antimicrobial Resistance in the Environment: Current Situation and Challenges." [https://wellcome.ac.uk/sites/default/files/antimicrobial-resistance-environment-report.pdf]. Accessed 14 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: 1

The United States has national regulations in place requiring prescriptions for antibiotic use for humans, however, there is evidence that points to sale of antibiotics without a prescription for use by humans. The 2016 Joint external evaluation of the United States of America: Self-assessment report states that "all but a handful of commercial products that contain antibiotics require a … prescription." [1] Question 7.1 of the US’ self-assessment report on antimicrobial resistance (AMR) for 2019-2020 indicates that "Prescribing practices and appropriate antibiotic use are monitored in a national sample of healthcare settings." [2] Antibiotics are not included on the lists of controlled substances which automatically require prescription under federal law, but the prescription status of specific antibiotics can be found in the database of approved drug products maintained by the Food and Drug Administration (FDA), which regulates use of medicines. [3, 4, 5] The Centers for Disease Control and Prevention (CDC) monitor human antibiotic use by tracking prescriptions. The CDC's latest annual Outpatient Antibiotic Prescription Report report is from 2018. [6] A 2019 scoping review of 31 studies reporting use of antibiotics without a prescription in the US found the prevalance nonprescription antibiotic use varied from 1 percent to 66 percent, depending on population characteristics. [7] A 2009 publication included in the review found 138 unique vendors selling antibiotics to buyers in the US without a prescription. [8]

[1] Department of Health and Human Services. 20 September 2016. “International health regulations - Joint external evaluation of the United States of America: Self-assessment report.” [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 16 December 2020.
[2] World Health Organisation (WHO). 2020. “Global database for antimicrobial resistance country self assessment 2019-2020, United States.” [http://amrcountryprogress.org/]. Accessed 16 December 2020.
[3] Federal Government. 2020. “Electronic Code of Federal Regulations, Title 21, Chapter II, Part 1306, section 1306.11: Requirement of prescription.” [https://www.ecfr.gov/cgi-bin/text-idx?SID=4f4b808a2a5ae2ab99b6b0e32340b428&mc=true&node=se21.9.1306_111&rgn=div8]. Accessed 16 December 2020.
[4] Federal Government. 2020. “Electronic Code of Federal Regulations, Title 21, Chapter II, Part 1308: Schedules of controlled substances.” [https://www.ecfr.gov/cgi-bin/text-idx?SID=a46c17ffca7020c657cbf44626a70bea&mc=true&node=pt21.9.1308&rgn=div5]. Accessed 16 December 2020.
[5] Food and Drug Administration (FDA). 2020. “Drugs@FDA: FDA Approved Drug Products.” [https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm]. Accessed 16 December 2020.
[6] Centers for Disease Control and Prevention (CDC). 2020. “Measuring outpatient antibiotic prescribing.” [https://www.cdc.gov/antibiotic-use/community/programs-measurement/measuring-antibiotic-prescribing.html]. Accessed 16 December 2020.
[7] Grigoryan, L., Germanos, G. et al. 2019. "Use of antibiotics without a prescription in the US population: a scoping review." Annals of internal medicine 171.4: 257-263. [http://medicinainterna.net.pe/sites/default/files/Uso%20de%20antibi%C3%B3ticos%20sin%20receta%20m%C3%A9dica.pdf]. Accessed 26 January 2021.
[8] Mainous, A.G., Everett, C.J., et al. 2009. "Availability of antibiotics for purchase without a prescription on the internet." The Annals of Family Medicine 7.5: 431-435.[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2746509/pdf/0060431.pdf]. Accessed 26 January 2021.

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: 1

The United States has national legislation or guidance in place requiring prescriptions for antibiotic use for animals, however, there is evidence that points to sale of antibiotics without a prescription for use for animals. The Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) regulates the use of medicine in animals. [1] The Animal Drug Availability Act (ADAA) of 1996 introduced a category of animal drugs, in addition to the categories of over-the-counter and prescription, called veterinary feed directive (VFD), which allows an animal owner or caretaker to obtain and use a drug on or in animal feed if a written order has been issued by a veterinarian. [2, 3] The FDA maintains an up-to-date list of VFD drugs. [4] In 2015, FDA amended the VFD section of the ADAA, with a final rule published in the Federal Register effective on October 1, 2015, that further details the conditions of VFDs, such as expiration dates and recordkeeping requirements. [5, 6, 7] As of 2017, the FDA reported that all antimicrobial drugs affected by the VFD final rule and outlined in the Guidance for Industry (GFI) #213 have either aligned or their approvals have been voluntarily withdrawn. [6] VFD compliance is enforced by the FDA's Office of Regulatory Affairs and state feed regulatory programs, and with the Feed Manufacturing Compliance Program. [8, 9] A 2020 study—"the first to document the availability of antibiotics on websites for veterinary use"—used English and Spanish search terms and found that "veterinary antibiotics are easily available for purchase online without a prescription." Of the vendors found using English search terms, 57 percent operated in the US and 55 percent did not require a prescription; also of the searches carried out in English, 43 percent had sales restricted to national delivers, though it was not indicated what percentage of vendors delivered to the US. [10]

[1] US Food and Drug Administration (FDA). 2020. "Center for Veterinary Medicine (CVM)." [https://www.fda.gov/about-fda/fda-organization/center-veterinary-medicine]. Accessed 18 December 2020.
[2] US Food and Drug Administration (FDA). 2020. "Animal Drug Availability Act of 1996." [https://www.fda.gov/animal-veterinary/guidance-regulations/animal-drug-availability-act-1996]. Accessed 18 December 2020.
[3] US Food and Drug Administration (FDA). 2019. "Frequently Asked Questions about Animal Drugs." [https://www.fda.gov/animal-veterinary/safety-health/frequently-asked-questions-about-animal-drugs#difference]. Accessed 18 December 2020.
[4] US Food and Drug Administration (FDA). 2020."Drugs with Veterinary Feed Directive (VFD) Marketing Status." [https://www.fda.gov/animal-veterinary/development-approval-process/drugs-veterinary-feed-directive-vfd-marketing-status]. Accessed 18 December 2020.
[5] US Food and Drug Administration (FDA). 2020."Veterinary Feed Directive (VFD)." [https://www.fda.gov/animal-veterinary/development-approval-process/veterinary-feed-directive-vfd]. Accessed 18 December 2020.
[6] US Food and Drug Administration (FDA). 2020."FACT SHEET: Veterinary Feed Directive Final Rule and Next Steps." [https://www.fda.gov/animal-veterinary/development-approval-process/fact-sheet-veterinary-feed-directive-final-rule-and-next-steps]. Accessed 18 December 2020.
[7] US Federal Register. "Veterinary Feed Directive - A Rule by the Food and Drug Administration on 06/03/2015." [https://www.federalregister.gov/documents/2015/06/03/2015-13393/veterinary-feed-directive]. Accessed 18 December 2020.
[8] US Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM). 2018. "Supporting Antimicrobial Stewardship in Veterinary Settings: Goals for Fiscal Years 2019-2023." [https://www.fda.gov/media/115776/download]. Accessed 18 December 2020.
[9] US Food and Drug Administration (FDA). 29 August 2019. "FDA Publishes Assessment of Compliance with Veterinary Feed Directive Final Rule." [https://www.fda.gov/animal-veterinary/cvm-updates/fda-publishes-assessment-compliance-veterinary-feed-directive-final-rule]. Accessed 18 December 2020.
[10] Garcia, J.F., Diez, M.J., et al. 2020. "The online sale of antibiotics for veterinary use." Animals 10.3: 503. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7143797/pdf/animals-10-00503.pdf]. Accessed 26 January 2021.

1.2 ZOONOTIC 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 are strategies in the United States that include plans for zoonotic disease. The US briefly addresses zoonotic diseases under its National Health Security Strategy 2019-2022 (NHSS), and the National Center for Emerging and Infectious Zoonotic Diseases (NCEZID) has a national strategy which covers zoonoses. The NHSS, developed by the Department for Health and Human Services (DHHS), ensures a coordinated approach to national health security. [1,2] The current strategy and its associated implementation plan, unlike the previous versions, do not use the term “zoonoses”, but the NHSS notes the need to adopt a One Health approach to collecting situational awareness data across human, animal, plant, and environmental health; and states “We must be prepared for newly emerging and re-emerging infectious diseases (such as pandemic influenza, Ebola virus, and Zika virus) and the potential for these diseases to be animal-related”. [2,3] NCEZID, at the Centers for Disease Control (CDC, under the DHSS), has a National Strategy 2018-2023 identifying priority work to prevent infectious emerging and zoonotic diseases. Its remit includes zoonotic diseases such as Ebola and anthrax, and vector-borne diseases

such as Zika and Lyme disease, with a focus on the risks they present to human health. It sets high-level strategy rather than specific actions. For instance, one measure it calls for to better prevent and control emerging and zoonotic infectious diseases is to: “Strengthen collaborations to prevent spread of zoonotic infections by promoting best practices for environmental health and animal health, including livestock, pets, and wildlife”. [4] In December 2017, the US Centers for Disease Control and Prevention (CDC), US Department of Agriculture (USDA), and US Department of the Interior (DOI) held a One Health Zoonotic Disease Prioritization (OHZDP) workshop to identifiy and prioritize zoonotic diseasess of greatest concern—zoonotic influenza, salmonellosis, West Nile virus, plague, emerging coronaviruses, rabies, brucellosis, and lyme disease—and "to develop plans for implementing and strengthening multisectoral, One Health approaches to address these diseases in the United States." The workshop's recommendations for next steps include a U.S. National One Health Framework publication by 2023. [5]

[1] Department of Health and Human Services. 20 Sep 2016. “International health regulations - Joint external evaluation of the United States of America: Self-assessment report.” [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Acceessed 16 December 2020.
[2] Department of Health and Human Services. 2019. “National Health Security Strategy 2019-2022.” [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/NHSS-Strategy-508.pdf]. Acceessed 16 December 2020.
[3] Department of Health and Human Services. 2019. “National Health Security Strategy: Implementation plan 2019-2022.” [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/2019-2022-nhss-ip-v508.pdf]. Acceessed 16 December 2020.
[4] National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention (CDC). 2012. “National Center for Emerging and Zoonotic Infectious Diseases Strategic Plan 2018-2023.” [https://www.cdc.gov/ncezid/pdf/ncezid-strategic-plan-2018-2023-508.pdf]. Acceessed 16 December 2020.
[5] Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), Department of the Interior (DOI), US Department of Agriculture (USDA). ND. "Prioritizing Zoonotic Diseases for Multisectoral, One Health Collaboration in the United States: Workshop Summary." [https://www.cdc.gov/onehealth/pdfs/us-ohzdp-report-508.pdf]. Acceessed 16 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: 0

There is insufficient evidence that there is national legislation, plans, or equivalent strategy documents for the United States which includes measures for risk identification and reduction for zoonotic disease spillover events from animals to humans. The 2016 Joint external evaluation of the United States of America: Self-assessment report states that there are interagency agreements—including an MOU between the Centers for Diesease Control and Prevention (CDC) and US Department of Agriculture (USDA) and an MOU between CDC and the Department of the Interior (DOI) National Park Service—to collaborate when there is potential for or evidence of zoonotic disease spillover. [1] However, the JEE self-assessment mentions that there is no specific national policy, and multisectoral relationships fulfill the coordination needs prior to and during zoonotic outbreak events. [1] The CDC's National Center for Emerging and Zoonotic Infectious Diseases Strategic Plan 2018-2023 emphasizes collaboration with partners, including federal, state, and local public health departments, though it does not specifically outline plans for zoonotic disease spillover. [2] In December 2017, the CDC, USDA, and DOI held a One Health Zoonotic Disease Prioritization (OHZDP) workshop to identifiy and prioritize zoonotic diseasess of greatest concern—zoonotic influenza, salmonellosis, West Nile virus, plague, emerging coronaviruses, rabies, brucellosis, and lyme disease—including

spillover concerns and "to develop plans for implementing and strengthening multisectoral, One Health approaches to address these diseases in the United States." The workshop's recommendations for next steps include a U.S. National One Health Framework publication by 2023. [3] However, there is no evidence of plan or equivalent strategy that includes measures for risk identification and reduction for spillover as a result of this convening. There is no additional evidence of national legislation, plans, or equivalent strategy documents available through the CDC, USDA, or DOI. [4, 5, 6] According to a January 2021 report from the Brookings Institute, "U.S. policy to prevent the spread of zoonotic diseases remains fragmented and inadequate." [7]

[1] Department of Health and Human Services. 20 September 2016. “International health regulations - Joint external evaluation of the United States of America: Self-assessment report.” [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 22 December 2020.
[2] National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention (CDC). 2012. “National Center for Emerging and Zoonotic Infectious Diseases Strategic Plan 2018-2023.” [https://www.cdc.gov/ncezid/pdf/ncezid-strategic-plan-2018-2023-508.pdf]. Accessed 22 December 2020.
[3] Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), Department of the Interior (DOI), US Department of Agriculture (USDA). ND. "Prioritizing Zoonotic Diseases for Multisectoral, One Health Collaboration in the United States: Workshop Summary." [https://www.cdc.gov/onehealth/pdfs/us-ohzdp-report-508.pdf]. Accessed 22 December 2020.
[4] US Centers for Disease Control and Prevention. 2021. [https://www.cdc.gov/]. Keyword search. Accessed 26 January 2021.
[5] US Department of Agriculture. 2021. [https://www.usda.gov/]. Keyword search. Accessed 26 January 2021.
[6] US Department of the Interior. 2021. [https://www.doi.gov/]. Keyword search. Accessed 26 January 2021.
[7] Felbab-Brown, V. 25 January 2021. "Preventing pandemics through biodiversity conservation and smart wildlife trade regulation." [https://www.brookings.edu/research/preventing-pandemics-through-biodiversity-conservation-and-smart-wildlife-trade-regulation/]. The Brookings Institution. Accessed 21 April 2021.

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

The US has national plans that account for the surveillance and control of multiple zoonotic pathogens of public health concern, though laws are set at the local level. In 2005 the US Department of Agriculture (USDA) published a strategic plan for a National Animal Health Surveillance System (NAHSS), to be led by Veterinary Services (VS) under the Animal and Plant Health Inspection Service (APHIS), USDA. [1] It involves passive and active surveillance and control of notifiable and non-notifiable zoonotic (and other animal) diseases, addressing OIE and federal programmes. [2] In 2017 APHIS published ‘Emerging animal disease preparedness and response plan’ as a strategy for surveillance and response, and in March 2020, the agency published a proposed National List of Reportable Animal Diseases (NLRAD) System Standards. The System Standards list notifiable animal diseases, for instance anthrax, brucellosis and avian influenza, rabies and many others. [3, 4] As of 2016, USDA was working to codify NLRAD in Title 9 of the Code of Federal Regulations (CFR). [5] In April 2020, a proposed rule "to amend the animal disease regulations to provide for a National List of Reportable Animal Diseases, along with reporting responsibilities for animal health professionals that encounter or suspect cases of communicable animal diseases and disease agents" was published in the Federal Register. This proposed rule was opened for comments until June 2020 and was reopened for comment again briefly in August 2020. [6, 7] There is no further information on the status of the proposed rule since the latest comment period and no evidence that NLRAD has been codified in the CFR. [8] Title 9, Chapter

I, Subchapter B of the Code of Federal Regulations covers Cooperative Control and Eradication of Livestock or Poultry Diseases, such as relating to Brucellosis, avian influenza, and pseudorabies. [8] The US Centers for Disease Control and Prevention (CDC) has also published a surveillance strategy for human and animal diseases. This provides national guidance while recognising that surveillance is organised and regulated at the local level. It includes the National Notifiable Diseases Surveillance System (NNDSS), which "enables all levels of public health to share notifiable disease-related health information, which includes zoonoses"; and the CDC One Health Zoonotic Disease Prioritization Tool, which "has the goal of identifying zoonotic diseases or pathogens of greatest concern so … resources can be effectively focused." [5, 9, 10] The current list of nationally-notifiable infectious diseases (including zoonoses) is published online by the CDC. It includes zoonoses such as anthrax, brucellosis, novel influenza A virus infections, human and animal rabies, and many others. [11]

[1] US Department of Agriculture (USDA). 16 February 2005. "Strategic plan: National animal health surveillance system." [https://www.aphis.usda.gov/vs/nahss/docs/NAHSS_Strategic_Plan_2005_0216.pdf]. Accessed 21 December 2020.
[2] US Department of Agriculture (USDA). November 2018. "United States National Animal Health Surveillance System: 2017 Surveillance Activity Report." [https://www.aphis.usda.gov/animal_health/monitoring_surveillance/nahss-annual-report.pdf]. Accessed 21 December 2020.
[3] US Department of Agriculture (USDA) Animal and Plant Health Inspection Service Veterinary Services. July 2017. "Emerging Animal Disease Preparedness and Response Plan."[https://www.aphis.usda.gov/animal_health/downloads/emerging-dis-framework-plan.pdf]. Accessed 21 December 2020.
[4] US Department of Agriculture (USDA) Animal and Plant Health Inspection Service Veterinary Services. March 2020. "U.S. National List of Reportable Animal Diseases (NLRAD) System Standards - Proposed."[https://www.aphis.usda.gov/animal_health/monitoring_surveillance/nlrad-system-standards.pdf]. Accessed 21 December 2020.
[5] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 21 December 2020.
[6] Code of Federal Regulations. 2020. "National List of Reportable Animal Diseases - A Proposed Rule by the Animal and Plant Health Inspection Service on 04/02/2020." [https://www.federalregister.gov/documents/2020/04/02/2020-06697/national-list-of-reportable-animal-diseases]. Accessed 21 December 2020.
[7] Code of Federal Regulations. 2020. "National List of Reportable Animal Diseases - A Proposed Rule by the Animal and Plant Health Inspection Service on 08/18/2020." [https://www.federalregister.gov/documents/2020/08/18/2020-17339/national-list-of-reportable-animal-diseases]. Accessed 21 December 2020.
[8] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 9 (Animals and animal products), Chapter I (Animal and Plant Health Inspection Service, Department of Agriculture), Subchapter B: Cooperative control and eradication of livestock and poultry diseases." [https://ecfr.federalregister.gov/current/title-9/chapter-I/subchapter-B]. Accessed 21 December 2020.
[9] Office of Public Health Scientific Services, Centers for Disease Control and Prevention (CDC). September 2018. "Public Health Surveillance: Preparing for the Future." [https://www.cdc.gov/surveillance/pdfs/Surveillance-Series-Bookleth.pdf]. Accessed 21 December 2020.
[10] Centers for Disease Control and Prevention (CDC). 2019. "NNDSS modernisation initiative (NMI): NMI Overview." [https://www.cdc.gov/nmi/overview.html]. Accessed 21 December 2020.
[11] Centers for Disease Control and Prevention (CDC). 2019. "National Notifiable Diseases Surveillance System (NNDSS): 2020 National Notifiable Conditions." [https://wwwn.cdc.gov/nndss/conditions/notifiable/2020/]. Accessed 21 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

Although the US has a unit dedicated to zoonotic disease which collaborates with other departments (equivalent to ministries), it does not function across departments. The unit is the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), established in 2010 under the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHSS). [1, 2] NCEZID is home to the One Health Office, which facilitates collaboration and information-sharing across human, animal and environmental health sectors. [3] The One Health Office has partnerships with the Agency for International Development (USAID); the Department of Interior; the National Oceanic and Atmospheric Administration's Oceans and Human Health Initiative; the Department of Agriculture (USDA); as well as various international and professional organisations, including the National Association of State Public Health Veterinarians (NASPHV). [4, 5, 6] The USDA also has a One Health Joint Working Group, a forum for coordination among USDA agencies on One Health issues including zoonoses. [6,7] It operates a web portal on One Health approaches to zoonotic threats. [8]

[1] National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). 2017. "Who we are." [https://www.cdc.gov/ncezid/who-we-are/index.html]. Accessed 22 December 2020.
[2] National Center for Emerging and Zoonotic Infectious Diseases. 2012. "National Center for Emerging and Zoonotic Infectious Diseases Strategic Plan 2018-2023." [https://www.cdc.gov/ncezid/pdf/ncezid-strategic-plan-2018-2023-508.pdf]. Accessed 22 December 2020.
[3] National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). 2016. "One Health Office." [https://www.cdc.gov/ncezid/who-we-are/ncezid-divisions/oho.html]. Accessed 22 December 2020.
[4] National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). 2019. "One Health/Related links/Highlighted partnerships." [https://www.cdc.gov/onehealth/related.html]. Accessed 22 December 2020.
[5] National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). 2017. "One Health/Domestic activities." [https://www.cdc.gov/onehealth/domestic-activities/index.html]. Accessed 22 December 2020.
[6] US Department of Agriculture (USDA). 2016. "USDA "One Health" approach fact sheet, June 2016." [https://www.usda.gov/sites/default/files/documents/fact-sheet-one-health-06-16-2016.pdf]. Accessed 22 December 2020.
[7] US Department of Agriculture (USDA). 11 April 2017. "USDA embraces One Health approach for solving problems associated with antimicrobial resistance." [https://www.usda.gov/media/blog/2015/11/16/usda-embraces-one-health-approach-solving-problems-associated-antimicrobial]. Accessed 22 December 2020.
[8] US Department of Agriculture (USDA). 21 February 2017. "USDA launches a one stop shop for its "One Health" approach to zoonotic threats." [https://www.usda.gov/media/blog/2016/06/29/usda-launches-one-stop-shop-its-one-health-approach-zoonotic-threats]. Accessed 22 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

The United States has a national mechanism for owners of livestock to conduct and report on disease surveillance to a central government agency, though the onus for reporting falls mainly on veterinarians. The US Department of Agriculture

(USDA) operates a National Animal Health Surveillance System (NAHSS), led by Veterinary Services (VS) under the Animal and Plant Health Inspection Service (APHIS). [1] NAHSS involves passive and active surveillance and control of notifiable animal diseases, addressing OIE and federal programmes. [2] Veterinarians play a key role. APHIS states that "it is imperative that [the practitioner] do all that is possible to educate owners, to be aware of unusual clinical signs, to be aware of current disease outbreaks or threats, and to immediately report possible diseases of concern to both Federal and State Animal Health Officials." [3] There is no requirement for the livestock owners to report diseases, but in the US livestock owners need to be in an established veterinarian-client-patient relationship (VCPR) to access any veterinary services or products, requiring the veterinarian to be familiar with the animals. [4] Under the Code of Federal Regulations (CFR) reporting of certain diseases at the state level is mandatory. 9 CFR Part 161.4(f) "requires an accredited veterinarian to immediately report to the Veterinarian-in-Charge and the State Animal Health Official all diagnosed or suspected cases of a communicable animal disease for which APHIS has a control or eradication program in 9 CFR Chapter I, and all diagnosed or suspected cases of any animal disease not known to exist in the United States". [3] Reporting to central government is voluntary. Under the National Animal Health Reporting System (NAHRS), participating state animal health officials submit monthly reports on the voluntary National List of Reportable Animal Diseases (NLRAD) to APHIS. [5, 6] Besides the NAHSS, there is a voluntary, less frequent monitoring system: the National Animal Health Monitoring System (NAHMS). This involves national studies of specific animal commodities or production types, at intervals of five years or more, for which livestock owners complete questionnaires. [7, 8]

[1] US Department of Agriculture (USDA). 16 Feb 2005. "Strategic plan: National animal health surveillance system." [https://www.aphis.usda.gov/vs/nahss/docs/NAHSS_Strategic_Plan_2005_0216.pdf]. Accessed 30 November 2018.
[2] US Department of Agriculture (USDA). 2016. "United States National Animal Health Surveillance System: 2016 surveillance activity report." [https://www.aphis.usda.gov/animal_health/monitoring_surveillance/nahss-annual-report.pdf]. Accessed 30 November 2018.
[3] US Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS). 24 Jul 2017. "Disease surveillance." [https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/nvap/NVAP-Reference-Guide/Disease-Surveillance]. Accessed 30 November 2018.
[4] American Veterinary Medical Association (AVMA). 2020. "VCPR: The veterinarian-client-patient relationship." [https://www.avma.org/KB/Resources/Reference/Pages/VCPR.aspx]. Accessed 30 November 2018.
[5] US Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS). 30 Jan 2018. "National Animal Health Reporting System (NAHRS)." [https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/sa_disease_reporting/ct_usda_aphis_animal_health]. Accessed 30 November 2018.
[6] US Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS). 28 Feb 2018. "Voluntary NLRAD-NAHRS Reportable Disease List." [https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/sa_disease_reporting/voluntary-reportable-disease-list]. Accessed 30 November 2018.
[7] US Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS). 18 Aug 2018. "About NAHMS." [https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/nahms/about]. Accessed 30 November 2018.
[8] US Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS). April 2010. "NAHMS brochure." [https://www.aphis.usda.gov/animal_health/nahms/downloads/NAHMS_brochure.pdf]. Accessed 30 November 2018.

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: 1

The United States has guidelines safeguarding the confidentiality of information generated through animal surveillance activities. The US Department of Agriculture (USDA)'s Animal and Plant Health Inspection Service (APHIS) oversees a National Animal Health Surveillance System (NAHSS) for local surveillance, and a National Animal Health Reporting System (NAHRS) for monthly reporting of NAHSS information to APHIS. According to APHIS: "Confidentiality is a cornerstone of the NAHRS program. Access to the monthly State reports is limited to the submitting State and a small number of designated USDA APHIS Veterinary Services staff who are directly involved in coordinating the NAHRS program. Individual owners are never identified in the information submitted by States as part of NAHRS monthly reporting." [1]

[1] US Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS). 23 June 2020. "About NAHRS." [https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/sa_disease_reporting/ct_about]. Accessed 18 December 2020.

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

The United States conducts disease surveillance in wildlife. The US Geological Service (USGS), under the Department of the Interior (DOI), oversees the health of wildlife in the national park system. The USGS National Wildlife Health Center (NWHC) has diagnostic laboratories for zoonotic diseases in wildlife, which are part of the National Animal Health Laboratory Network (NAHLN). It also maintains a web-based reporting system, Wildlife Health Information Sharing Partnership (WHISPers), for wildlife disease surveillance information. [1] Information is collected opportunistically by multiple state, federal and other agencies, typically on events involving five or more sick or dead wild animals in the same general location. Examples of diseases recently tested for and diagnosed in wildlife include avian cholera, schistosomiasis, trematodiasis and botulism type C. Most events relate to wild birds, though recent events have also covered bats, frogs, turtles, salamanders, rabbits, muskrats and moles. [2] The USGS also collaborates with the Centers for Disease Control and Prevention (CDC) to maintain dynamic vector-borne disease maps online, integrating vector (mosquito, tick), animal, and human vector-borne disease surveillance data. [1, 3] The CDC's National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) sometimes assists other countries with wildlife disease monitoring. For instance, in January 2019 NCEZID reported its involvement in a project to track bats to understand their role in spreading Marburg disease to humans in Uganda. There is no evidence on NCEZID's website of current work to monitor wildlife zoonoses in the US. [4] The CDC has a passive surveillance programme for rabies in wildlife, while the US Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) conducts active rabies surveillance in wildlife in selected geographical regions. [5, 6]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 22 December 2020.
[2] US Geological Service (USGS), National Wildlife Health Center (NWHC). 2020. "Wildlife Health Information Sharing Partnership - event reporting system." [https://www.usgs.gov/centers/nwhc/science/whispers?qt-science_center_objects=0#qt-science_center_objects]. Accessed 22 December 2020.
[3] Centers for Disease Control and Prevention (CDC). "ArboNET." 2020. [https://wwwn.cdc.gov/arbonet/maps/ADB_Diseases_Map/index.html]. Accessed 22 December 2020.
[4] National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). 2020 "Recent work." [https://www.cdc.gov/ncezid/what-we-do/recent-work.html]. Accessed 22 December 2020.
[5] Xiaoyue Ma et al. 15 Dec 2018. "Rabies surveillance in the United States during 2017," in Journal of the American Veterinary Medical Association, 253

[12]. [https://avmajournals.avma.org/doi/full/10.2460/javma.253.12.1555]. Accessed 22 December 2020.
[6] Centers for Disease Control and Prevention (CDC). 6 April 2020. “Is rabies in your state?” [https://www.cdc.gov/rabies/location/usa/surveillance/index.html]. Accessed 22 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: 36.76

2019

OIE WAHIS database

1.2.4b

Number of veterinary para-professionals per 100,000 people

Input number

Current Year Score: 20.37

2019

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: 1

There is evidence that the national plans on zoonotic disease in the United States include mechanisms for working with the private sector in controlling and responding to zoonoses. The US briefly addresses zoonotic diseases under its National Health Security Strategy 2019-2022 (NHSS). The NHSS, developed by the Department for Health and Human Services (DHHS), has "Leverage the capabilities of the private sector" as one of its main objectives. In its section on protecting the nation from emerging and pandemic infectious diseases (not specifically, but including, zoonoses), it calls for "Greater coordination with non-government entities, including private sector hospitals and the full array of health care providers, the R&D community, NGOs, and academia". [1, 2] The National Center for Emerging and Infectious Zoonotic Diseases (NCEZID), under the Centers for Disease Control and Prevention (CDC), also has a 2018-2023 national strategy addressing zoonoses. It states that NCEZID's partnerships include businesses, and calls for private-sector experts to be engaged in identifying broad-based solutions to public health problems. [3] A 2011 CDC framework for infectious diseases called for "electronic mechanisms for exchange of public health information—including laboratory orders and test results—between diagnostic laboratories (both public and private)." [4] NCEZID's 2017 brochure mentions some specific current public-private initiatives. These include partnering with the Mayo Clinic (a non-profit organisation) to obtain clinical specimens from patients with tick-borne diseases; and NCEZID's online tool, MicrobeNet, which gives public and private laboratories free access to a library of information about bacteria and fungi. [5] The US also has mechanisms for engaging with the private sector in its international work to implement the Global Health Security Agenda (GHSA) more broadly, building capacity overseas. These include the GHSA Consortium (GHSAC), GHSA Private-Sector Roundtable (PSRT), and the Next Generation for Global Health Security Network (NextGen). [6] As evidence of mechinisms the US has established for working with the private sector in controlling or responding to zoonoses, the U.S. Department of State's Office of Global Partnerships has established a COVID-19 Private Sector Engagement & Partnership Fund, and public-private partnerships have been established to increase national testing capacities and develop vaccines for COVID-19, including Operation Warp Speed. [7, 8, 9]

[1] Department of Health and Human Services. 2019. "National Health Security Strategy 2019-2022." [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/NHSS-Strategy-508.pdf]. Accessed 22 December 2020.
[2] Department of Health and Human Services. 2019. "National Health Security Strategy: Implementation plan 2019-2022." [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/2019-2022-nhss-ip-v508.pdf]. Accessed 22 December 2020.
[3] National Center for Emerging and Zoonotic Infectious Diseases. 2012. "National Center for Emerging and Zoonotic Infectious Diseases Strategic Plan 2018-2023." [https://www.cdc.gov/ncezid/pdf/ncezid-strategic-plan-2018-2023-508.pdf]. Accessed 22 December 2020.
[4] Centers for Disease Control (CDC). 2011. "A CDC framework for preventing infectious diseases: Sustaining the essentials and innovating for the future." [https://www.cdc.gov/ddid/docs/ID-Framework.pdf]. Accessed 22 December 2020.
[5] National Center for Emerging and Zoonotic Infectious Diseases. 2017. "Emerging and zoonotic infectious diseases (2017 brochure)." [https://www.cdc.gov/ncezid/pdf/infectious-diseases-brochure-2017.pdf]. Accessed 22 December 2020.
[6] Global Health Security Agenda. 2018. "Implementing the Global Health Security Agenda: Progress and impact from US government investments." Feb 2018. [https://www.cdc.gov/globalhealth/healthprotection/resources/pdf/GHSA-Report-_Feb-2018.pdf]. Accessed 22 December 2020.
[7] U.S. Department of State, Office of Global Partnerships. ND. "Office of Global Partnerships: COVID-19 Private Sector Engagement & Partnership Fund." [https://www.state.gov/office-of-global-partnerships-covid-19-private-sector-engagement-partnership-fund/]. Accessed 21 April 2021.
[8] Financialnewsmedia.com. 16 March 2020. "U.S. Government, Public and Private Sectors Collaborate to Quickly Minimize Coronavirus Outbreak." [https://www.prnewswire.com/news-releases/us-government-public-and-private-sectors-collaborate-to-quickly-minimize-coronavirus-outbreak-301024780.html]. Accessed 21 April 2021.
[9] U.S. Department of State. ND. "Coronavirus: Operation Warp Speed." [https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/]. Accessed 21 April 2021.

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: 1

The United States has 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. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires the Secretary of Health and Human Services to maintain a list of biological agents and toxins with the potential to pose a severe threat to public health and safety, and a national database of the names and locations of registered persons, the listed agents and toxins such persons are possessing, using, or transferring, and information regarding the characterization of such agents and toxins. [1] The Federal Select Agent Program (FSAP), jointly run by the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS), maintains the list of biological select agents and toxins (BSAT). The BSAT list includes dangerous pathogens of pandemic potential, for example Ebola virus, Variola major virus, Nipah virus and Avian influenza virus (the full current list is available online). [2, 3] FSAP also maintains the National Select Agent Registry (NSAR) of individuals/entities handling BSAT materials. Registration must be amended any time registration information changes, and annual reports on the database are published. [2, 4, 5] FSAP enforces the Select Agent Regulations. [4] These require registering entities/individuals to provide a security plan, which describes procedures for physical security, including inventory control. [6, 7, 8] The US' 2017, 2018, 2019 and 2020 Confidence Building Measure Returns submitted to the United Nations under the Biological Weapons Convention mention the NSAR and also include overview information on facilities in which especially dangerous pathogens and toxins are permitted to be stored or processed. [9, 10, 11, 12]

[1] Government of the United States. 12 June 2002. "Public Health Security and Bioterrorism Preparedness and Response Act of 2002." Public Law 107-188. [https://www.gpo.gov/fdsys/pkg/PLAW-107publ188/pdf/PLAW-107publ188.pdf]. Accessed 17 December 2020.
[2] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 17 December 2020.
[3] Federal Select Agent Program. 2018. "Select agents and toxins list." [https://www.selectagents.gov/SelectAgentsandToxinsList.html]. Accessed 17 December 2020.
[4] Federal Select Agent Program. 2018. Official website. [https://www.selectagents.gov/]. Accessed 17 December 2020.
[5] Federal Select Agent Program. 2020. "2019 Annual Report of the Federal Select Agent Program." [https://www.selectagents.gov/resources/publications/annualreport/2019.htm]. Accessed 17 December 2020.
[6] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 42: Public health, Part 73: Select agents and toxins." [https://ecfr.federalregister.gov/current/title-42/chapter-I/subchapter-F/part-73]. Accessed 17 December 2020.
[7] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 9: Animals and Animal Products Part 121: Possession, use and transfer of select agents and toxins." [https://ecfr.federalregister.gov/current/title-9/chapter-I/subchapter-E/part-121]. Accessed 17 December 2020.
[8] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 7: Agriculture, Part 331: Possession, use and transfer of select agents and toxins." Electronic Code of Federal Regulations, 7 CFR Part 331.

[https://ecfr.federalregister.gov/current/title-7/subtitle-B/chapter-III/part-331?toc=1]. Accessed 17 December 2020.
[9] Government of the United States. 15 Apr 2020. "United States of America: Confidence Building Measure Return covering 2019." [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_us.pdf]. Accessed 17 December 2020.
[10] Government of the United States. 15 Apr 2019. "United States of America: Confidence Building Measure Return covering 2018." [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2019_usa.pdf]. Accessed 17 December 2020.
[11] Government of the United States. 15 Apr 2018. "United States of America: Confidence Building Measure Return covering 2017." [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2018_usa.pdf]. Accessed 17 December 2020.
[12] Government of the United States. 15 Apr 2017. "United States of America: Confidence Building Measure Return covering 2016." [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2017_usa.pdf]. Accessed 17 December 2020.

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

The US has in place legislation and regulations related to biosecurity which address requirements including physical containment, operation practices, failure reporting systems and cybersecurity of facilities in which especially dangerous pathogens and toxins are stored or processed. The Federal Select Agent Program (FSAP), jointly run by the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS), is responsible for developing, implementing, and enforcing regulations on "biological select agents and toxins" (BSAT, or select agents) with the potential to pose a severe threat to public health and safety with regard to agriculture, animals and animal products, and public health. [1, 2, 3] Legislation and regulations address requirements including a biocontainment plan, and a security plan covering (but not limited to) procedures for physical security, inventory control, and information systems control; provisions for routine maintenance and cleaning; procedures for addressing and reporting loss, theft or access by unauthorised persons; and specified provisions for information security. [4, 5, 6, 7, 8] FSAP also publishes guidance on security, containment and operation practices in general and specific to particular materials. [9] The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires the Secretary of Health and Human Services to maintain a list of BSAT and a national database of people/entities registered to handle them. [1] The BSAT list includes dangerous pathogens of pandemic potential, for example Ebola virus, Variola major virus, Nipah virus and Avian influenza virus (the full current list is available online). [2] The US' 2017, 2018, 2019 and 2020 Confidence Building Measure Returns submitted to the United Nations under the Biological Weapons Convention document incremental changes to the biosecurity framework aimed at strengthening the system and keeping the BSAT list up to date with current threats. [10, 11, 12, 13]

[1] Government of the US. 2002. "Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' Public Law 107-188, 12 Jun 2002. [https://www.gpo.gov/fdsys/pkg/PLAW-107publ188/pdf/PLAW-107publ188.pdf]. Accessed 17 December 2020.
[2] Federal Select Agent Program. 2020. "Select agents and toxins list." [https://www.selectagents.gov/SelectAgentsandToxinsList.html]. Accessed 17 December 2020.
[3] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 17 December 2020.
[4] Federal Select Agent Program. 2020. "Legislation." [https://www.selectagents.gov/resources/legislation.htm]. Accessed 17 December 2020.
[5] Federal Select Agent Program. 2018. "Select agents regulations." [https://www.selectagents.gov/regulations/index.htm].

Accessed 17 December 2020.
[6] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 42: Public health, Part 73: Select agents and toxins." [https://ecfr.federalregister.gov/current/title-42/chapter-I/subchapter-F/part-73]. Accessed 17 December 2020.
[7] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 9: Animals and Animal Products Part 121: Possession, use and transfer of select agents and toxins." [https://ecfr.federalregister.gov/current/title-9/chapter-I/subchapter-E/part-121]. Accessed 17 December 2020.
[8] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 7: Agriculture, Part 331: Possession, use and transfer of select agents and toxins." Electronic Code of Federal Regulations, 7 CFR Part 331. [https://ecfr.federalregister.gov/current/title-7/subtitle-B/chapter-III/part-331?toc=1]. Accessed 17 December 2020.
[9] Federal Select Agent Program. 2020. "Guidance documents." [https://www.selectagents.gov/compliance/guidance/index.htm]. Accessed 17 December 2020.
[10] Government of the United States. 15 Apr 2020. "United States of America: Confidence Building Measure Return covering 2019." [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_us.pdf]. Accessed 17 December 2020.
[11] Government of the United States. 15 Apr 2019. "United States of America: Confidence Building Measure Return covering 2018." [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2019_usa.pdf]. Accessed 17 December 2020.
[12] Government of the United States. 15 Apr 2018. "United States of America: Confidence Building Measure Return covering 2017." [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2018_usa.pdf]. Accessed 17 December 2020.
[13] Government of the United States. 15 Apr 2017. "United States of America: Confidence Building Measure Return covering 2016." [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2017_usa.pdf]. Accessed 17 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 United States has an established agency responsible for the enforement of biosecurity legislation and regulations. The Federal Select Agent Program (FSAP), jointly run by the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS), is responsible for enforcing biosecurity legislation and regulations. FSAP is responsible for enforcing biosecurity regulations with regard to agriculture, animals and animal products, and public health. It maintains a list of restricted biological select agents and toxins (BSAT), a database of individuals/entities registered to store, process or transport them, and enforces biosecurity regulations through a system of regular inspections. [1, 2, 3]. The BSAT list includes dangerous pathogens of pandemic potential, for example Ebola virus, Variola major virus, Nipah virus and Avian influenza virus (the full current list is available online). [4] The role of FSAP as the main agency responsible for the enforcement of biosecurity legislation and regulations is reflected in the US' 2017, 2018, 2019 and 2020 Confidence Building Measure Returns submitted to the United Nations under the Biological Weapons Convention, which document incremental improvements to the biosecurity regulatory and policy framework. [5, 6, 7, 8]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 17 December 2020.
[2] Federal Select Agent Program. 2018. Official website. [https://www.selectagents.gov/]. Accessed 17 December 2020.
[3] Federal Select Agent Program. 2018. "Select agents regulations." [https://www.selectagents.gov/regulations/index.htm]. Accessed 17 December 2020.
[2] Federal Select Agent Program. 2020. "Select agents and toxins list." [https://www.selectagents.gov/SelectAgentsandToxinsList.html]. Accessed 17 December 2020.
[5] Government of the United States. 15 Apr 2020. "United States of America: Confidence Building Measure Return covering

2019." [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_us.pdf]. Accessed 17 December 2020.
[6] Government of the United States. 15 Apr 2019. "United States of America: Confidence Building Measure Return covering 2018." [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2019_usa.pdf]. Accessed 17 December 2020.
[7] Government of the United States. 15 Apr 2018. "United States of America: Confidence Building Measure Return covering 2017." [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2018_usa.pdf]. Accessed 17 December 2020.
[8] Government of the United States. 15 Apr 2017. "United States of America: Confidence Building Measure Return covering 2016." [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2017_usa.pdf]. Accessed 17 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 insufficient evidence that the US government has taken action to consolidate its inventories of especially dangerous pathogens and toxins into a minimum number of facilities, though it has issued non-mandatory guidance aimed at avoiding unnecessary duplication of facilities in the future. According to the 2016 Joint external evaluation of the United States of America: Self-assessment report, the Federal Experts Security Advisory Panel (FESAP) published an internal review of government biosafety and biosecurity practices in 2014, proposing a three-phase approach to identifying the "appropriate number" of federally-funded high containment laboratories (HCL) required to possess, use, or transfer items on the government's list of dangerous biological select agents and toxins (BSAT). This did not lead to consolidation of facilities (no "appropriate number" of facilities has been agreed), but did lead to the introduction of a "best practices checklist" for departments and agencies to follow when considering the construction or modification of HCL. The checklist is advisory and only applies to facilities receiving federal funding. A principle of the checklist is that: "Departments and agencies should be able to show a demonstrated need for HCL space, and should have a process that carefully considers alternatives before constructing new HCL space." [1, 2] The Centers for Disease Control and Prevention (CDC) maintains a web page with updates on changes as a result of the FESAP and other reviews of BSAT work. It does not mention consolidation of inventories. [3] There is no evidence of action to consolidate inventories from the Federal Select Agent Program (which oversees BSAT)—including in its 2019 annual report, the Department of Health and Human Services, the Department of Agriculture or the Department of Defense. [4, 5, 6, 7, 8] There is no evidence of such action in the US' 2017, 2018, 2019, or 2020 Confidence Building Measure Returns submitted to the United Nations under the Biological Weapons Convention. [9] There is no relevant legislation listed for the US in the VERTIC Biological Weapons Convention (BWC) Legislation Database. [10]

[1] Department of Health and Human Services. 20 September 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 23 December 2020.
[2] Department of Health and Human Services. 25 September 2019. "The Federal Security Advisory Panel (FESAP) best practices checklist for assessment of current and projected needs for high or maximum containment laboratory space." Public Health Emergency website. [https://www.phe.gov/s3/BioriskManagement/biocontainment/Pages/FESAP-checklist-containment-lab.aspx]. Accessed 23 December 2020.
[3] Centers for Disease Control and Prevention (CDC). 29 September 2020. "Division of Select Agents and Toxins: Progress towards change." [https://www.cdc.gov/phpr/dsat/review_initiatives.htm]. Accessed 23 December 2020.
[4] Federal Select Agent Program. 9 September 2020. Official website. [https://www.selectagents.gov/]. Accessed 23 December 2020.
[5] Federal Select Agent Program. 2020. "2019 Annual Report of the Federal Select Agent Program."

[https://www.selectagents.gov/resources/publications/annualreport/2019.htm]. Accessed 23 December 2020.
[6] Department of Health and Human Services. 2020. Official website. [https://www.hhs.gov/]. Accessed 23 December 2020.
[7] Department of Agriculture. 2020. Official website. [https://www.usda.gov/]. Accessed 23 December 2020.
[8] Department of Defense. 2020. Official website. [https://www.defense.gov/]. Accessed 23 December 2020.
[9] The United Nations Office at Geneva (UNOG). 2020. "BWC Electronic Confidence Building Measures Portal: United States of America." [https://bwc-ecbm.unog.ch/state/united-states-america]. Accessed 23 December 2020.
[10] Verification Research, Training and Information Centre (VERTIC). "Biological Weapons Convention (BWC) Legislation Database". [http://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/u/]. Accessed 26 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

According to the 2017 Joint External Evaluation of the IHR core capacities of the United States and the 2016 self-assessment report, the US' national laboratory system has the ability to conduct PCR testing for Ebola virus and anthrax, among other non-culture-based tests to screen for dangerous pathogens and toxins. [1, 2]

[1] World Health Organisation (WHO). 2017. "Joint external evaluation of IHR core capacities of the United States of America – Mission report: June 2016." Geneva: World Health Organisation. [http://apps.who.int/iris/bitstream/10665/254701/1/WHO-WHE-CPI-2017.13-eng.pdf?ua=1&ua=1]. Accessed 16 December 2020.
[2] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 16 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 trainthe-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: 1

The United States 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 Federal Select Agent Program (FSAP) has standardized curriculum guidance and enforces the Select Agent Regulations (SAR), which apply to people/entities handling, storing or transporting items on a list of biological materials considered to pose a serious public health risk ("select agents"). [1] The list includes dangerous pathogens of pandemic potential, for example Ebola virus, Variola major virus, Nipah virus and Avian influenza virus. [2] Section 15 of the SAR (7 CFR 331.15, 9 CFR 121.15, and 42 CFR 73.15) requires that individuals who access select agents and toxins must receive information and training concerning security. Entities with Tier 1 (highest risk) BSAT must also provide insider threat awareness training. Training should be site-

specific and based on the hazards of the materials in question. It can take a number of different forms. FSAP maintains training guidance as a living document online. The guidance on security training states that it "should consist of information on how to protect the select agents and toxins from theft and be based on the individual's job duties." A list of suggested topics is provided. There are additional regulatory requirements for entities possessing Tier 1 agents (the most dangerous category). These entities must provide annual insider threat awareness briefings on how to identify and report suspicious behaviours. The responsible officer (registered with FSAP for the facility) must maintain training records. Refresher training must be provided annually. [3, 4, 5, 6, 7] No additional information on training requirements is available from the US' 2017, 2018, 2019 or 2020 Confidence Building Measure Returns submitted to the United Nations under the Biological Weapons Convention. [8]

[1] Federal Select Agent Program. 2018. Official website. [https://www.selectagents.gov/]. Accessed 17 December 2020.
[2] Federal Select Agent Program. 2018. "Select agents and toxins list." [https://www.selectagents.gov/SelectAgentsandToxinsList.html]. Accessed 17 December 2020.
[3] Federal Select Agent Program. 2020. "Guidance for select agent regulation training requirements." [https://www.selectagents.gov/rtr-changes.html]. Accessed 27 January 2021.
[4] National Archives and Records Administration, Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 42: Public health, Part 73: Select agents and toxins." [https://ecfr.federalregister.gov/current/title-42/chapter-I/subchapter-F/part-73]. Accessed 17 December 2020.
[5] National Archives and Records Administration, Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 9: Animals and Animal Products Part 121: Possession, use and transfer of select agents and toxins." [https://ecfr.federalregister.gov/current/title-9/chapter-I/subchapter-E/part-121]. Accessed 17 December 2020.
[6] National Archives and Records Administration, Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 7: Agriculture, Part 331: Possession, use and transfer of select agents and toxins." Electronic Code of Federal Regulations, 7 CFR Part 331. [https://ecfr.federalregister.gov/current/title-7/subtitle-B/chapter-III/part-331?toc=1]. Accessed 17 December 2020.
[7] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 27 January 2021.
[8] The United Nations Office at Geneva (UNOG). 2021. "BWC Electronic Confidence Building Measures Portal: United States of America." [https://bwc-ecbm.unog.ch/state/united-states-america]. Accessed 27 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: 2

In the United States, regulations specify that security and other personnel with access to especially dangerous pathogens, toxins, or biological materials with pandemic potential are subject to background and mental health checks, but not drug testing, though questions are asked about unlawful drug use. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires that individuals or entities that possess, use, or transfer restricted biological "select agents" undergo background checks by the Attorney General. These checks are based on criminal, immigration, national security, and

other electronic databases are available to the federal government. [1, 2] The requirement for security risk assessments by the Attorney General is also stated in the Select Agent Regulations enforced by the Federal Select Agent Program (FSAP). [3, 4, 5] The security risk assessment form linked to by FSAP is published by the Federal Bureau of Investigation (FBI). It includes questions on criminal background; connection to terrorists; connection to foreign governments; unlawful drug use; and mental health history. Applicants are checked using their social security numbers and fingerprints, and recent drug tests may referred to; however the FBI does not state that a drug test is required as part of the process. [6] According to the US' 2018, 2019, and 2020 Confidence Building Measure Returns submitted to the United Nations under the Biological Weapons Convention, the FBI conducts around 3,600-3,800 security risk assessments per year, covering all entities and personnel requesting possession, use, or transfer of BSAT. Using biographical and biometric databases, the FBI determines if a candidate meets the criteria of a "restricted person" based upon a list of prohibitors found under 18 US Code 175b (derived from the USA PATRIOT Act and the Public Health Security and Bioterrorism Preparedness and Response Act). [7, 8, 9] Under US Code 175b, the definition of restricted persons includes people under indictment for or convicted of a crime, fugitives from justice, illegal/unlawful aliens in the US, unlawful users of any controlled substance, and those adjudicated as mental defectives or who have been admitted to any mental institution (among others); but there is no mention of how drug use is to be proven. [10]

[1] Government of the United States. 2002. "Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' Public Law 107-188, 12 Jun 2002. [https://www.gpo.gov/fdsys/pkg/PLAW-107publ188/pdf/PLAW-107publ188.pdf]. Accessed 26 December 2020.
[2] Department of Health and Human Services. 2016. "International health regulations - Joint external evaluation of the United States of America." Self-assessment report, 5 May 2016. [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 26 December 2020.
[3] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 42: Public health, Part 73: Select agents and toxins." [https://ecfr.federalregister.gov/current/title-42/chapter-I/subchapter-F/part-73?toc=1]. Accessed 26 December 2020.
[4] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 9: Animals and Animal Products Part 121: Possession, use and transfer of select agents and toxins." [https://ecfr.federalregister.gov/current/title-9/chapter-I/subchapter-E/part-121?toc=1]. Accessed 26 December 2020.
[5] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 7: Agriculture, Part 331: Possession, use and transfer of select agents and toxins." Electronic Code of Federal Regulations, 7 CFR Part 331. [https://ecfr.federalregister.gov/current/title-7/subtitle-B/chapter-III/part-331?toc=1]. Accessed 26 December 2020.
[6] Federal Bureau of Investigation (FBI). 2018. "Bioterrorism security risk assessment form." [https://www.fbi.gov/file-repository/fd-961-for-internet.pdf/view]. Accessed 26 December 2020.
[7] Government of the United States. 15 Apr 2020. "United States of America: Confidence Building Measure Return covering 2019." [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_us.pdf]. Accessed 26 December 2020.
[8] Government of the United States. 15 Apr 2019. "United States of America: Confidence Building Measure Return covering 2018." [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2019_usa.pdf]. Accessed 26 December 2020.
[9] Government of the United States. 15 Apr 2018. "United States of America: Confidence Building Measure Return covering 2017." [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2018_usa.pdf]. Accessed 26 December 2020.
[10] Federal Government. 25 December 2020. "18 USC 175b: Possession by restricted persons." [http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title18-section175b&num=0&edition=prelim]. Accessed 26 December 2020.

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: 1

The United States has publicly available information on national regulations on the safe and secure transport of infectious substances. The US Department of Transport (DOT) maintains and enforces up-to-date national regulations for the safe and secure transport of infectious substances (Categories A and B). The Hazardous Materials Regulations (49 CFR Parts 171-180) provide national, up-to-date regulations on the transport of infectious substances (Categories A and B). According to the 2016 Joint external evaluation of the United States of America: Self-assessment report, these regulations are maintained and enforced by the DOT, and cover packaging, marking, labelling, shipping paper documentation, training, security, and incident reporting. [1, 2] The Federal Select Agent Program, which regulates the use and storage of restricted biological materials ("select agents"), provides guidance on transportation of select agents as a living document, last updated in June 2020. This includes specific guidance for transportation of Category A infectious substances, referencing the DOT regulations mentioned above. [3] No additional information on regulations on the safe and secure transport of infectious substances is available from the US' 2017, 2018, 2019, or 2020 Confidence Building Measure Returns submitted to the United Nations under the Biological Weapons Convention. [4]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 26 December 2020.
[2] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 49, Subtitle B, Chapter I, Subchapter C: Hazardous materials regulations." [https://ecfr.federalregister.gov/current/title-49/subtitle-B/chapter-I/subchapter-C]. Accessed 26 December 2020.
[3] US Centers for Disease Control and Prevention (CDC) and US Department of Agriculture. June 2020. "Guidance on the transfer of select agents and toxins." [https://www.selectagents.gov/compliance/guidance/transfer/docs/Transfer_Guidance.pdf]. Accessed 26 December 2020.
[4] The United Nations Office at Geneva (UNOG). 2020. "BWC Electronic Confidence Building Measures Portal: United States of America." [https://bwc-ecbm.unog.ch/state/united-states-america]. Accessed 26 December 2020.

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: 1

There are national laws and regulations in the United States that oversee the cross-border transfer and end-user screening of especially dangerous pathogens and toxins. The Federal Select Agent Program (FSAP) enforces regulations on the transfer of items on a list of especially dangerous biological "select agents". [1] Select agents are those biological agents and toxins determined to have "the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products," for example Ebola virus, Variola major virus, Nipah virus and Avian influenza virus. [2] Only entities

registered with FSAP are allowed to receive select agents, including when imported from outside the US. [1] The Centers for Disease Control and Prevention (CDC) also has more generally-applicable regulations on the import of infectious biological agents, infectious substances, and vectors of human disease under its Import Permit Program (IPP). The IPP screens applications to ensure that recipients have measures in place for working safely with these imported materials. [3] As for exports, the export of select agents requires an export licence issued by the Bureau of Industry and Security (BIS) at the Department of Commerce. [1, 4, 5] BIS implements the Export Administration Regulations (under the Export Administration Act 1979), which address the export of dual-use items. [6] Licensing is based on consideration of the item category, end user and end use. [7] The CDC notes that other infectious items may also require an export licence from the Department of Commerce Bureau of Export Administration, and advises exporters to phone the Bureau for further information. [3] No additional relevant information is available from the US' 2017, 2018, 2019 or 2020 Confidence Building Measure Returns submitted to the United Nations under the Biological Weapons Convention. [8]

[1] US Centers for Disease Control and Prevention (CDC) and US Department of Agriculture. June 2020. "Guidance on the transfer of select agents and toxins." [https://www.selectagents.gov/compliance/guidance/transfer/docs/Transfer_Guidance.pdf]. Accessed 26 December 2020.
[2] Federal Select Agent Program. 2020. "Select agents and toxins list." [https://www.selectagents.gov/selectagentsandtoxinslist.html]. Accessed 26 December 2020.
[3] Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HSS). 2020. "Import Permit Program." [https://www.cdc.gov/phpr/ipp/index.htm]. Accessed 26 December 2020.
[4] Bureau of Industry and Security (BIS), Department of Commerce. 4 December 2020. "The Commerce Control List Part 774." [https://www.bis.doc.gov/index.php/documents/regulations-docs/2345-774-2/file]. Accessed 26 December 2020.
[5] Bureau of Industry and Security (BIS), Department of Commerce. 6 October 2020. "Commerce Control List - Index: Supplement No. 1 to part 774 - Index 1." [https://www.bis.doc.gov/index.php/documents/regulations-docs/2329-commerce-control-list-index-3/file]. Accessed 26 December 2020.
[6] Bureau of Industry and Security (BIS), Department of Commerce. 15 May 2020. "Part 730 - General information." [https://www.bis.doc.gov/index.php/documents/regulation-docs/410-part-730-general-information/file]. Accessed 26 December 2020.
[7] Bureau of Industry and Security (BIS), Department of Commerce. 29 June 2020. "Part 732 - Steps for using the EAR." [https://www.bis.doc.gov/index.php/documents/regulation-docs/411-part-732-steps-for-using-the-ear/file]. Accessed 26 December 2020.
[8] The United Nations Office at Geneva (UNOG). 2020. "BWC Electronic Confidence Building Measures Portal: United States of America." [https://bwc-ecbm.unog.ch/state/united-states-america]. Accessed 26 December 2020.

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

The United States has in place national legislation and regulations addressing biosafety. According to the 2016 Joint external evaluation of the United States of America: Self-assessment report (JEE self-assessment), the regulations which most directly address especially dangerous pathogens are the Select Agent Regulations (SAR), implemented jointly by the Departments of Health and Human Services (HHS) and Agriculture (USDA) through the Federal Select Agent Program (FSAP) (in the Code of

Federal Regulations (CFR): 42 CFR Part 73, 7 CFR Part 331 and 9 CFR Part 12). [1] These address biosafety plans, biocontainment, personal protective equipment, operating procedures, incident response, training, drills and transfers, with reference to biosafety guidance from the National Institutes of Health (NIH) and HHS mentioned later in the justification. [2, 3, 4] Select agents are biological agents and toxins determined to have "the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products," for example Ebola virus, Variola major virus, Nipah virus and Avian influenza virus. [5] In addition, the National Institutes of Health (NIH) has issued guidelines for research involving recombinant or synthetic nucleic acid molecules, which address biosafety. However, they only apply to research which is conducted by the NIH; at institutions which receive funding from the NIH for research involving recombinant or synthetic nucleic acid molecules; or which involves human testing of materials containing recombinant or synthetic nucleic acid molecules developed by institutions run or funded by the NIH. [6, 7] According to the 2016 JEE self-assessment, other biosafety regulations which cover hazardous biological materials more broadly include the Occupational Safety and Health Administration (OSHA) regulations which implement the Occupational Health and Safety Act 1970 (General Duty Clause, Personal Protective Equipment Standards, and Bloodborne Pathogens Standard); the Animal and Plant Health Inspection Service (APHIS, under USDA) permitting regulations; and the Centers for Disease Control and Prevention (CDC, under HHS) regulations which require a permit for the importation of infectious biological agents, infectious substances, and vectors of human disease. The Department of Transport also has regulations relating to the safe transportation of hazardous materials. With regard to safeguarding human health in laboratories, federal guidance is also available in the HHS publication, Biosafety in microbiological and biomedical laboratories (BMBL), sixth edition. [1, 8] The US' 2017, 2018, 2019, and 2020 Confidence Building Measure Returns submitted to the United Nations under the Biological Weapons Convention document incremental changes to FSAP's biosafety framework, including minor regulatory amendments and the release of new guidelines on meeting regulatory requirements. [9, 10, 11, 12]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 26 December 2020.
[2] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 42: Public health, Part 73: Select agents and toxins." [https://ecfr.federalregister.gov/current/title-42/chapter-I/subchapter-F/part-73?toc=1]. Accessed 26 December 2020.
[3] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 9: Animals and Animal Products Part 121: Possession, use and transfer of select agents and toxins." [https://ecfr.federalregister.gov/current/title-9/chapter-I/subchapter-E/part-121?toc=1]. Accessed 26 December 2020.
[4] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 7: Agriculture, Part 331: Possession, use and transfer of select agents and toxins." Electronic Code of Federal Regulations, 7 CFR Part 331. [https://ecfr.federalregister.gov/current/title-7/subtitle-B/chapter-III/part-331?toc=1]. Accessed 26 December 2020.
[5] Federal Select Agent Program. 2020. "Select agents and toxins list." [https://www.selectagents.gov/selectagentsandtoxinslist.html]. Accessed 26 December 2020.
[6] Office of Science Policy (OSP), National Institutes of Health (NIH). 2020. "NIH guidelines." [https://osp.od.nih.gov/biotechnology/nih-guidelines/]. Accessed 26 December 2020.
[7] National Institutes of Health (NIH), Department of Health and Human Services. April 2019. "NIH Guidelines for research involving recombinant or synthetic nucleic acid molecules (NIH Guidelines)." [https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf]. Accessed 26 December 2020.
[8] US Centers for Disease Control and Prevention and National Institutes of Health. June 2020. "Biosafety in microbiological and biomedical laboratories (BMBL)." 6th edition. [https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2020-P.pdf]. Accessed 26 December 2020.
[9] Government of the United States. 15 Apr 2020. "United States of America: Confidence Building Measure Return covering 2019." [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2020_us.pdf]. Accessed 26 December 2020.
[10] Government of the United States. 15 Apr 2019. "United States of America: Confidence Building Measure Return covering

2018." [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2019_usa.pdf]. Accessed 26 December 2020.
[11] Government of the United States. 15 Apr 2018. "United States of America: Confidence Building Measure Return covering 2017." [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2018_usa.pdf]. Accessed 26 December 2020.
[12] Government of the United States. 15 Apr 2017. "United States of America: Confidence Building Measure Return covering 2016." [https://bwc-ecbm.unog.ch/system/files/form-pdf/bwc_cbm_2017_usa.pdf]. Accessed 26 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

The United States has several established agencies responsible for the enforcement of biosafety legislation and regulations. According to the 2016 Joint external evaluation of the United States of America: Self-assessment report (JEE self-assessment), the agency responsible for enforcing biosafety regulations on especially dangerous pathogens is the Federal Select Agent Program (FSAP). Jointly run by the Departments of Health and Human Services (HHS) and Agriculture (USDA), it enforces the Select Agent Regulations (SAR) which address biosafety regarding "select agents": those biological agents and toxins determined to have "the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products," for example Ebola virus, Variola major virus, Nipah virus and Avian influenza virus. [1, 2, 3] The regulations address biosafety plans, biocontainment, personal protective equipment, operating procedures, incident response, training, drills and transfers. [4, 5, 6] In addition, the Office of Science Policy (OSP) in the National Institutes of Health (NIH) enforces NIH guidelines for research involving recombinant or synthetic nucleic acid molecules (NIH Guidelines), which address biosafety. However, they only apply to research which is conducted by the NIH; at institutions which receive funding from the NIH for research involving recombinant or synthetic nucleic acid molecules; or which involves human testing of materials containing recombinant or synthetic nucleic acid molecules developed by institutions run or funded by the NIH. [7, 8] More broadly, according to the JEE self-assessment, the Occupational Safety and Health Administration (Department of Labor) enforces regulations and standards under the Occupational Health and Safety Act 1970, including mandatory standards on biosafety in laboratories handling biological agents. [1, 9, 10] The Animal and Plant Health Inspection Service (APHIS) enforces a system of permits for the import, transit and release of regulated animals, animal products, veterinary biologics, plants, plant products, pests, organisms, soil, and genetically engineered organisms. [1, 10] The Centers for Disease Control and Prevention (CDC, under HHS) enforces a system of permits for the import of infectious biological agents, infectious substances, and vectors of human disease. [1, 11] The HHS publication "Biosafety in microbiological and biomedical laboratories (BMBL)" is advisory and so not legally enforceable in itself. However, it is referred to in some of the other biosafety regulations – including the SAR – and where that is the case, compliance is enforced by the enforcement agency in question. [4, 5, 12] No additional information with regard to the agency responsible for the enforcement of biosafety legislation and regulations is available from the US' 2017, 2018 and 2019 Confidence Building Measure Returns submitted to the United Nations under the Biological Weapons Convention. [13]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 26 December 2020.
[2] Federal Select Agent Program. 2020. Official website. [https://www.selectagents.gov/]. Accessed 26 December 2020.
[3] Federal Select Agent Program. 2020. "Select agents and toxins list." [https://www.selectagents.gov/selectagentsandtoxinslist.html]. Accessed 26 December 2020.
[4] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 42: Public health, Part 73: Select agents and toxins." [https://ecfr.federalregister.gov/current/title-42/chapter-I/subchapter-F/part-73?toc=1]. Accessed 26 December 2020.

[5] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 9: Animals and Animal Products Part 121: Possession, use and transfer of select agents and toxins." [https://ecfr.federalregister.gov/current/title-9/chapter-I/subchapter-E/part-121?toc=1]. Accessed 26 December 2020.
[6] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 7: Agriculture, Part 331: Possession, use and transfer of select agents and toxins." Electronic Code of Federal Regulations, 7 CFR Part 331. [https://ecfr.federalregister.gov/current/title-7/subtitle-B/chapter-III/part-331?toc=1]. Accessed 26 December 2020.
[7] Office of Science Policy (OSP), National Institutes of Health (NIH). 2020. "NIH guidelines." [https://osp.od.nih.gov/biotechnology/nih-guidelines/]. Accessed 26 December 2020.
[8] National Institutes of Health (NIH), Department of Health and Human Services. April 2019. "NIH Guidelines for research involving recombinant or synthetic nucleic acid molecules (NIH Guidelines)." [https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf]. Accessed 26 December 2020.
[9] Occupational Safety and Health Administration, Department of Labor. 2020. "Laboratories." [https://www.osha.gov/SLTC/laboratories/index.html]. Accessed 26 December 2020.
[10] Occupational Safety and Health Administration, Department of Labor. 2020. "OSHA standards." [https://www.osha.gov/SLTC/laboratories/standards.html]. Accessed 26 December 2020.
[11] Animal and Plant Health Inspection Service (APHIS), Department of Agriculture. 2020. "Permits and certifications." [https://www.aphis.usda.gov/aphis/resources/permits]. Accessed 26 December 2020.
[12] US Centers for Disease Control and Prevention and National Institutes of Health. June 2020. "Biosafety in microbiological and biomedical laboratories (BMBL)." 6th edition. [https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2020-P.pdf]. Accessed 26 December 2020.
[13] The United Nations Office at Geneva (UNOG). 2020. "BWC Electronic Confidence Building Measures Portal: United States of America." [https://bwc-ecbm.unog.ch/state/united-states-america]. Accessed 26 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 trainthe-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: 1

The United States requires biosafety training, using a standardized, required approach, such as through a common curriculum or a trainthe-trainer program, for personnel working in facilities housing or working with especially dangerous pathogens, toxins, or biological materials with pandemic potential. The Federal Select Agent Program (FSAP) enforces the Select Agent Regulations (SAR), which apply to people/entities handling, storing or transporting biological materials considered to pose a serious public health risk ("select agents"). [1] Select agents include dangerous pathogens of pandemic potential, for example Ebola virus, Variola major virus, Nipah virus and Avian influenza virus (the full current list is available online). [2] Section 15 of the SAR (7 CFR 331.15, 9 CFR 121.15, and 42 CFR 73.15) stipulates that individuals who access select agents and toxins must receive information and training concerning biosafety and biocontainment. Training should be site-specific and based on the hazards of the materials in question; repeated annually or whenever there is a change to materials or processes; and training records kept. Regulatory requirements for training are performance-based, and training can take a number of different forms. FSAP maintains training guidance as a living document online, and the SAR also refer to guidelines in the document "Biosafety in microbiological and biomedical laboratories", published by the Department of Health and Human Services (HSS), which in effect provides a curriculum and set of standards to follow. [3, 4, 5, 6, 7] Biosafety training more broadly is also required by the Occupational Safety and Health Administration (OSHA). Its mandatory standards for

workplaces where hazardous materials, including bloodborne pathogens, are handled include lists of minimum training elements which are detailed enough to constitute a curriculum. [8] No additional information on training requirements is available from the US' 2017, 2018 or 2019 Confidence Building Measure Returns submitted to the United Nations under the Biological Weapons Convention. [9]

[1] Federal Select Agent Program. 2020. Official website. [https://www.selectagents.gov/]. Accessed 26 December 2020.
[2] Federal Select Agent Program. 2020. "Select agents and toxins list." [https://www.selectagents.gov/selectagentsandtoxinslist.html]. Accessed 26 December 2020.
[3] Federal Select Agent Program. 2017. "Guidance for select agent regulation training requirements." [https://www.selectagents.gov/rtr-changes.html]. Accessed 26 December 2020.
[4] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 42: Public health, Part 73: Select agents and toxins." [https://ecfr.federalregister.gov/current/title-42/chapter-I/subchapter-F/part-73?toc=1]. Accessed 26 December 2020.
[5] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 9: Animals and Animal Products Part 121: Possession, use and transfer of select agents and toxins." [https://ecfr.federalregister.gov/current/title-9/chapter-I/subchapter-E/part-121?toc=1]. Accessed 26 December 2020.
[6] Code of Federal Regulations. 2020. "Electronic Code of Federal Regulations, Title 7: Agriculture, Part 331: Possession, use and transfer of select agents and toxins." Electronic Code of Federal Regulations, 7 CFR Part 331. [https://ecfr.federalregister.gov/current/title-7/subtitle-B/chapter-III/part-331?toc=1]. Accessed 26 December 2020.
[7] US Centers for Disease Control and Prevention and National Institutes of Health. June 2020. "Biosafety in microbiological and biomedical laboratories (BMBL)." 6th edition. [https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2020-P.pdf]. Accessed 26 December 2020.
[8] Occupational Safety and Health Administration, Department of Labor. 2015. "Training requirements in OSHA standards." [https://www.osha.gov/Publications/osha2254.pdf]. Accessed 26 December 2020.
[9] The United Nations Office at Geneva (UNOG). 2020. "BWC Electronic Confidence Building Measures Portal: United States of America." [https://bwc-ecbm.unog.ch/state/united-states-america]. Accessed 26 December 2020.

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: 1

There is publicly available evidence that the United States 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 government introduced a policy on oversight of life sciences dual-use research of concern (DURC) in 2012, and a policy for institutional oversight of life sciences DURC was released in 2014, effective as of September 2015. These established a process for institutional reporting on, and regular federal review of, government-funded or -conducted life-sciences DURC. When the 2012 policy was introduced, institutions had 60 days to report all current and planned research projects covered by the policy. However, these policies only apply to research conducted in institutions which receive federal funding for life sciences research, and which involve a specific list of 15 agents and toxins. [1, 2, 3, 4] In addition, the Public

Health Security and Bioterrorism Preparedness and Response Act of 2002 requires the Secretary of Health and Human Services to maintain a list of biological agents and toxins with the potential to pose a severe threat to public health and safety, and a national database of persons registered to handle them. [5] The Federal Select Agent Program (FSAP), jointly run by the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS), maintains the list of biological select agents and toxins (BSAT) and the National Select Agent Registry (NSAR) of individuals/entities handling BSAT materials. Registration must be amended any time registration information changes. [1, 6, 7] The BSAT list includes dangerous pathogens of pandemic potential, for example Ebola virus, Variola major virus, Nipah virus and Avian influenza virus. [6] No additional relevant evidence is available from the US' 2017, 2018, 2019, or 2020 Confidence Building Measure Returns submitted to the United Nations under the Biological Weapons Convention. [8]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 27 December 2020.
[2] Government of the US. 2012. "United States government policy for oversight of life sciences dual use research of concern." [http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf]. Accessed 27 December 2020.
[3] Government of the US. 24 September 2014. "United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern". [https://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf]. Accessed 27 December 2020.
[4] National Institutes of Health (NIH), Department of Health and Human Services. 2014. "Implementation of the U.S. government policy for institutional oversight of life sciences DURC: FAQs."
[http://www.phe.gov/s3/dualuse/Documents/durc-faqs.pdf]. Accessed 27 December 2020.
[5] Government of the US. 2002. "Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' Public Law 107-188, 12 Jun 2002. [https://www.gpo.gov/fdsys/pkg/PLAW-107publ188/pdf/PLAW-107publ188.pdf]. Accessed 27 December 2020.
[6] Federal Select Agent Program. 2020. "Select agents and toxins list."
[https://www.selectagents.gov/SelectAgentsandToxinsList.html]. Accessed 27 December 2020.
[7] Federal Select Agent Program. 2020. Official website. [https://www.selectagents.gov/]. Accessed 27 December 2020.
[8] The United Nations Office at Geneva (UNOG). 2020. "BWC Electronic Confidence Building Measures Portal: United States of America." [https://bwc-ecbm.unog.ch/state/united-states-america]. Accessed 27 December 2020.

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: 1

The United States has a policy requiring oversight of research with especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research. The government introduced a policy on oversight of life sciences dual-use research of concern (DURC) in 2012, and a policy for institutional oversight of life sciences DURC was released in 2014, effective as of 2015. These established a process for institutional reporting on, and regular federal review of, government-funded or -conducted life-sciences DURC. However, these policies only apply to research conducted in institutions which receive federal funding for life sciences research, and which involve a specific list of 15 agents and toxins. [1, 2, 3, 4] In addition, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires the Secretary of Health and Human Services to maintain a list of biological agents and toxins with the potential to pose a severe threat to public health and safety, and a national database of persons registered to handle them. [5] The Federal Select Agent Program (FSAP), jointly run by the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection

Service (APHIS), maintains the list of biological select agents and toxins (BSAT) and the National Select Agent Registry (NSAR) of individuals/entities handling BSAT materials. The BSAT list includes dangerous pathogens of pandemic potential, for example Ebola virus, Variola major virus, Nipah virus and Avian influenza virus (the full current list is available online). FSAP has published a number of policies related to oversight of BSAT research. [6, 7, 8] No additional relevant evidence is available from the US' 2017, 2018, 2019, and 2020 Confidence Building Measure Returns submitted to the United Nations under the Biological Weapons Convention. [9]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 27 December 2020.
[2] Government of the US. 2012. "United States government policy for oversight of life sciences dual use research of concern." [http://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf]. Accessed 27 December 2020.
[3] Government of the US. 24 September 2014. "United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern". [https://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf]. Accessed 27 December 2020.
[4] National Institutes of Health (NIH), Department of Health and Human Services. 2014. "Implementation of the U.S. government policy for institutional oversight of life sciences DURC: FAQs."
[http://www.phe.gov/s3/dualuse/Documents/durc-faqs.pdf]. Accessed 27 December 2020.
[5] Government of the US. 2002. "Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' Public Law 107-188, 12 Jun 2002. [https://www.gpo.gov/fdsys/pkg/PLAW-107publ188/pdf/PLAW-107publ188.pdf]. Accessed 27 December 2020.
[6] Federal Select Agent Program. 2020. "Select agents and toxins list."
[https://www.selectagents.gov/SelectAgentsandToxinsList.html]. Accessed 27 December 2020.
[7] Federal Select Agent Program. 2020. Official website. [https://www.selectagents.gov/]. Accessed 27 December 2020.
[8] Federal Select Agent Program. 2020. "Policy statements." [https://www.selectagents.gov/regulations-policy.html]. Accessed 27 December 2020.
[9] The United Nations Office at Geneva (UNOG). 2020. "BWC Electronic Confidence Building Measures Portal: United States of America." [https://bwc-ecbm.unog.ch/state/united-states-america]. Accessed 27 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: 1

The United States has agencies responsible for oversight of all research involving especially dangerous pathogens and toxins, and of federally-funded institutions conducting dual-use research of concern (DURC). The government introduced a policy on oversight of life sciences DURC in 2012, and a policy for institutional oversight of life sciences DURC was released in 2014, effective as of 2015. These established a process for institutional reporting on, and regular federal review of, government-funded or -conducted life-sciences DURC. The National Institutes for Health (NIH) under the Department of Health and Human Services (HHS) implements these policies, with an important role also played by the agencies which grant federal funding to research institutions. [1, 2, 3] However, these policies only apply to research conducted in institutions which receive federal funding for life sciences research, and which involve a specific list of 15 agents and toxins. [4] In addition, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires the Secretary of Health and Human Services to maintain a list of biological agents and toxins with the potential to pose a severe threat to public health and safety, and a national database of persons registered to handle them. [5] The Federal Select Agent Program (FSAP), jointly

run by the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS), maintains the list of biological select agents and toxins (BSAT) and the National Select Agent Registry (NSAR) of individuals/entities handling BSAT materials. The BSAT list includes dangerous pathogens of pandemic potential, for example Ebola virus, Variola major virus, Nipah virus and Avian influenza virus. FSAP implements regulations related to oversight of BSAT research. [1, 6, 7, 8] No additional relevant evidence is available from the US' 2017, 2018, 2019 or 2020 Confidence Building Measure Returns submitted to the United Nations under the Biological Weapons Convention. [9]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 27 December 2020.
[2] Science Safety Security. N.d. "Training on the US government policy for institutional oversight of life sciences dual use research." [http://www.phe.gov/s3/dualuse/Documents/durc-us-policy-trng.pdf]. Accessed 27 December 2020.
[3] Department of Health and Human Services (HHS), Public Health Emergency website. 2015. "Implementation of the Institutional DURC Policy." [http://www.phe.gov/s3/dualuse/Pages/implementation.aspx]. Accessed 27 December 2020.
[4] National Institutes of Health (NIH), Department of Health and Human Services. 2014. "Implementation of the U.S. government policy for institutional oversight of life sciences DURC: FAQs." [http://www.phe.gov/s3/dualuse/Documents/durc-faqs.pdf]. Accessed 27 December 2020.
[5] Government of the US. 2002. "Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' Public Law 107-188, 12 Jun 2002. [https://www.gpo.gov/fdsys/pkg/PLAW-107publ188/pdf/PLAW-107publ188.pdf]. Accessed 27 December 2020.
[6] Federal Select Agent Program. 2020. "Select agents and toxins list." [https://www.selectagents.gov/SelectAgentsandToxinsList.html]. Accessed 27 December 2020.
[7] Federal Select Agent Program. 2020. Official website. [https://www.selectagents.gov/]. Accessed 27 December 2020.
[8] Federal Select Agent Program. 2020. "Policy statements." [https://www.selectagents.gov/regulations-policy.html]. Accessed 27 December 2020.
[9] The United Nations Office at Geneva (UNOG). 2020. "BWC Electronic Confidence Building Measures Portal: United States of America." [https://bwc-ecbm.unog.ch/state/united-states-america]. Accessed 27 December 2020.

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

The United States does not have legislation and/or regulation requiring the screening of synthesized DNA (deoxyribonucleic acid) against lists of known pathogens and toxins before it is sold. The US has national guidance recommending standards for the screening of synthesized DNA before it is sold, but no mandatory requirement to do so. The Department of Health and Human Services (HHS) document 'Screening framework guidance for providers of synthetic double-stranded DNA' recommends standards for use by companies to screen orders for synthetic DNA products. These include screening customers (individuals and entities) and DNA sequences, as well as follow-up screening and consulting with government contacts as necessary. The primary goal of the guidance is to minimize the risk that unauthorized individuals or those with malicious intent will obtain "toxins and agents of concern" through the use of nucleic acid synthesis technologies, and to simultaneously minimize any negative impacts on the conduct of research and business operations. Following the guidance is voluntary. [1, 2] In August 2020, HHS released a notice of request for information (RFI) inviting public comment on whether,

and how, the Guidance should be modified. Responses to the RFI were due in October 2020, and there is no additional information available. [3] No additional relevant evidence is available from the US' 2017, 2018 or 2019 Confidence Building Measure Returns submitted to the United Nations under the Biological Weapons Convention. [4] There is no evidence of legislation and/or regulations requiring requiring the screening of synthesized DNA against lists of known pathogens and toxins before it is sold available through the US Departments of Transportation, Defense, or Agriculture. [5, 6, 7] There is no relevant legislation listed for the US in the VERTIC Biological Weapons Convention (BWC) Legislation Database. [8]

[1] Department of Health and Human Services. 2010. "Screening framework guidance for providers of synthetic double-stranded DNA". [https://www.phe.gov/Preparedness/legal/guidance/syndna/Documents/syndna-guidance.pdf]. Accessed 3 December 2018.
[2] Department of Health and Human Services. 13 October 2010. "Federal guidance helps protect against misuse of synthetic DNA." [https://www.phe.gov/Preparedness/news/Pages/syndna.aspx]. Accessed 27 December 2020.
[3] US Federal Register. "Review and Revision of the Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA - A Notice by the Health and Human Services Department on 08/26/2020." [https://www.federalregister.gov/documents/2020/08/26/2020-18444/review-and-revision-of-the-screening-framework-guidance-for-providers-of-synthetic-double-stranded]. Accessed 27 December 2020.
[4] The United Nations Office at Geneva (UNOG). 2020. "BWC Electronic Confidence Building Measures Portal: United States of America." [https://bwc-ecbm.unog.ch/state/united-states-america]. Accessed 27 December 2020.
[5] US Department of Transportation. 2021. [https://www.transportation.gov/]. Keyword search. Accessed 26 January 2021.
[6] US Department of Defense. 2021. [https://www.defense.gov/]. Keyword search. Accessed 26 January 2021.
[7] US Department of Agriculture. 2021. [https://www.usda.gov/]. Keyword search. Accessed 26 January 2021.
[8] Verification Research, Training and Information Centre (VERTIC). "Biological Weapons Convention (BWC) Legislation Database". [http://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/u/]. Accessed 26 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: 2

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 United States' national laboratory system has the capacity to conduct diagnostic tests for 6 of the 10 WHO-defined core tests. The 2016 Joint External Evaluation (JEE) self-assessment report states that reference laboratories in the national laboratory system have the capacity to conduct polymerase chain reaction (PCR) testing for Influenza virus, virus culture for poliovirus, serology for HIV, microscopy for mycobacterium tuberculosis; rapid diagnostic testing for plasmodium spp., and bacterial culture for Salmonella enteritidis serotype Typhi. It notes that there has not been an official prioritisation of additional disease tests, but selected sites in the USA's laboratory system can also test for MERS-CoV, measles, carbapenam-resistant Enterobacteriaceae, and Ebola virus (by PCR). Most locations have the capability to conduct a wide range of screening and diagnostic tests, and all locations have access to a regional reference laboratory for both human and animal health. [1] There is no evidence from media reporting that the US has identified a set of country-specific core tests since 2016.

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 20 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: 0

There is insufficient evidence that there is 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. The 2016 Joint External Evaluation of IHR Core Capacities of the US, under Detect: National Laboratory System, recommends the country "[d]evelop an inventory of vulnerabilities in capacity and capability for all health sectors at the state level to improve testing service with surge requirements for a concerted whole-of government plan" as a priority action and notes that "[l]aboratory systems are vulnerable to fluctuations due to federal and/or local funding. An analysis of vulnerabilities in capacity and capability to provide testing services (especially with surge requirements) would help support whole-of-government resilience planning." [1] Under Capability 12: Public Health Laboratory Testing of the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention's (CDC) Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health—published in October 2018 and updated in January 2019—there are three functions described: conduct laboratory testing and report results, enhance laboratory communications and coordination, and support training and outreach. This document is an update to the 2011 capability standards, and encompasses activities during a public health emergency, however, these are standards for preparedness and response capablities and do not constitute a comprehensive plan or strategy. [2] The HHS National Health Security Strategy (NHSS) 2019-2022 lists laboratory testing among the key areas the country "must modernize," but there is no specific strategy or plan for testing during a public health emergency, including in the NHSS Implementation Plan. [3, 4] While the Federal Emergency Management Agency's (FEMA) National Response Framework encompasses public health emergencies, it does not mention plans for testing. [5] In May 2020, HHS Food and Drug Administration (FDA) issued a Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency, however, this document contains nonbinding recommendations as guidance for clinical laboratories, commercial manufacturers, and FDA staff and does not constitute a national plan or strategy for COVID-19 or any other public health emergency. [6] Since 1995, the CDC has run the Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) program, which includes a Cooperative Agreement and funding to 64 jurisdictions to "detect, prevent, and respond to the growing threats posed by infectious diseases." [7] Individual states' ELC Enhancing Detection Testing Plans for SARS-COV-2—Iowa, for example—are available on the HHS website. [8] A July 2020 article in The New York Times describes a nationally fragmented testing sytem, with plans for coronavirus testing left largely up to state and local municipalities, and a December 2020 Associated Press article in The Philadelphia Inquirer indicates there is no comprehensive national testing strategy for COVID-19. [9, 10]

[1] World Health Organisation (WHO). 2017. "Joint external evaluation of IHR core capacities of the United States of America - Mission report: June 2016." Geneva: World Health Organisation. [http://apps.who.int/iris/bitstream/10665/254701/1/WHO-WHE-CPI-2017.13-eng.pdf?ua=1&ua=1]. Accessed 3 January 2021.
[2] US Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC). October 2018, Updated Janaury 2019. "Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health." [https://www.cdc.gov/cpr/readiness/00_docs/CDC_PreparednesResponseCapabilities_October2018_Final_508.pdf]. Accessed 3 January 2021.
[3] US Department of Health and Human Services (HHS). 2019. "National Health Security Strategy 2019-2022." [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/NHSS-Strategy-508.pdf]. Accessed 3 January 2021.
[4] Department of Health and Human Services (HHS). 2019. "National Health Security Strategy: Implementation plan 2019-2022." [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/2019-2022-nhss-ip-v508.pdf]. Accessed 3 January 2021.
[5] Federal Emergency Management Agency (FEMA), Department of Homeland Security (DHS). 2020. "National Response Framework." [https://www.fema.gov/emergency-managers/national-preparedness/frameworks/response]. Accessed 3 January 2021.
[6] US Department of Health and Human Services (HHS), Food and Drug Administration (FDA), Center for Devices and Radiological Health. 11 May 2020. "Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) - Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration

Staff." [https://www.fda.gov/media/135659/download]. Accessed 3 January 2021.
[7] Centers for Disease Control and Prevention (CDC) Advanced Search Division of Preparedness and Emerging Infections (DPEI). 2020. "Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC)." [https://www.cdc.gov/ncezid/dpei/epidemiology-laboratory-capacity.html]. Accessed 3 January 2021.
[8] US Department of Health and Human Services (HHS). 2020. "ELC Enhancing Detection: Iowa Testing Plan: 2020 Overarching Jurisdictional SARS-COV-2 Testing Strategy." [https://www.hhs.gov/sites/default/files/iowa-testing-plans.pdf]. Accessed 3 January 2021.
[9] Mervosh, S. and Fernandez, S. 6 July 2020. "Months Into Virus Crisis, U.S. Cities Still Lack Testing Capacity." The New York Times. [https://www.nytimes.com/2020/07/06/us/coronavirus-test-shortage.html]. Accessed 3 January 2021.
[10] Stobbe, M. and Perrone, M. 6 December 2020. "Will the U.S. ever have a national COVID-19 testing strategy?" The Philadelphia Inquirer. [https://www.inquirer.com/health/coronavirus/national-covid-19-coronavirus-testing-strategy-20201206.html]. Accessed 3 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: 1

All the national and subnational reference laboratories which form the United States' Laboratory Response Network (LRN) are Clinical Laboratory Improvement Amendments (CLIA) accredited. The Association of Public Health Laboratories (APHL) supports public health laboratories to implement quality systems, including CLIA and a Laboratory System Improvement Program (L-SIP). [1] Public health laboratories form the backbone of the CDC's LRN of reference laboratories. [2] Public health laboratories which perform tests on human samples, regulated under the CLIA, "must obtain a CLIA certificate corresponding to the complexity of the tests performed." [3] The APHL's guidance on regulations and standards applicable to public health laboratories includes ISO 17025:2005(E) and ISO 15189:2012. [4] The LRN is coordinated by the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), part of the Centers for Disease Control and Prevention (CDC). NCEZID's own laboratories serve as national reference laboratories for certain diseases, including by providing reference materials, though there is insufficient evidence on NCEZID's website to suggest that it provides a reference testing service for the WHO-defined core tests. NCEZID's laboratories are CLIA accredited. [5, 6]

[1] Association of Public Health Laboratories. 2021. "About Quality Systems and Analytics." [https://www.aphl.org/programs/QSA/Pages/About-QSA.aspx]. Accessed 26 January 2021.
[2] Association of Public Health Laboratories. 2021. "About Public Health Laboratories." [https://www.aphl.org/aboutAPHL/Pages/aboutphls.aspx]. Accessed 26 January 2021.
[3] Association of Public Health Laboratories. 2021. "CLIA resources." [https://www.aphl.org/programs/QSA/Pages/CLIA-Resources.aspx]. Accessed 26 January 2021.
[4] Association of Public Health Laboratories. May 2017. "Crosswalk of regulations and guidance affecting laboratories—sorted by QSE." [https://www.aphl.org/aboutAPHL/publications/Documents/QS-2017Jun-Crosswalk-of-Regulations.pdf]. Accessed 18 December 2020.
[5] Centers for Disease Control and Prevention (CDC). 2019. "NCEZID: Laboratory expertise." [https://www.cdc.gov/ncezid/what-we-do/our-topics/lab-expertise.html]. Accessed 18 December 2020.
[6] Centers for Disease Control and Prevention (CDC). 2021. "CLIA certificates." [https://www.cdc.gov/ncezid/who-we-

are/clia/certificates.html]. Accessed 26 January 2021.

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: 1

All the national and subnational public health laboratories which serve as reference facilities in the United States' laboratory network are subject to external quality assurance review. Public health laboratories which perform tests on human specimens, regulated under the Clinical Laboratory Improvement Amendments (CLIA), "must obtain a CLIA certificate corresponding to the complexity of the tests performed."[1,2] CLIA regulations include external quality assurance, referred to in the US as proficiency testing (PT). [3] A laboratory can receive a certificate of CLIA compliance once the state department of health has conducted an inspection, and can receive a certificate of accreditation once an approved accreditation organization has conducted its own review. Certificates of compliance and accreditation last two years, so external inspections are carried out every two years. [4] The Centers for Medicare and Medicaid Services (CMS) maintains a list of approved accreditation organizations. [5] There are around 130 reference laboratories under the US' Laboratory Response Network (LRN), serving human, animal and food health sectors, among others. [6, 7] The LRN is coordinated by the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), part of the Centers for Disease Control and Prevention (CDC). NCEZID's own laboratories serve as national reference laboratories. [8] NCEZID's laboratories are CLIA accredited and therefore subject to external quality assurance. [9]

[1] Association of Public Health Laboratories. 2020. "CLIA resources." [https://www.aphl.org/programs/QSA/Pages/CLIA-Resources.aspx]. Accessed 18 December 2020.
[2] Centres for Disease Control and Prevention (CDC). 2020. "CLIA." [https://wwwn.cdc.gov/CLIA/]. Accessed 18 December 2020.
[3] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 18 December 2020.
[4] Centers for Medicare and Medicaid Services (CMS). 2006. "How to obtain a CLIA certificate." [https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCLIACertificate.pdf]. Accessed 18 December 2020.
[5] Centers for Medicare and Medicaid Services (CMS). 2020. "List of approved accreditation organizations under the Clinical Laboratory Improvement Amendments (CLIA). [https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/AOList.pdf]. Accessed 18 December 2020.
[6] Centers for Disease Control and Prevention (CDC). 2019. "The Laboratory Response Network partners in protection." [https://emergency.cdc.gov/lrn/]. Accessed 18 December 2020.
[7] Centers for Disease Control and Prevention (CDC). 2019. "Laboratory Response Network for Biological Threats (LRN-B)." [https://emergency.cdc.gov/lrn/biological.asp]. Accessed 18 December 2020.
[8] Centers for Disease Control and Prevention (CDC). 2019. "NCEZID: Laboratory expertise." [https://www.cdc.gov/ncezid/what-we-do/our-topics/lab-expertise.html]. Accessed 18 December 2020.
[9] Centers for Disease Control and Prevention (CDC). 2021. "CLIA certificates." [https://www.cdc.gov/ncezid/who-we-are/clia/certificates.html]. Accessed 26 January 2021.

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

The US has a nationwide specimen transport system. The 2016 Joint external evaluation (JEE) of IHR core capacities of the United States that "there is a system in place to transport specimens to national laboratories for both animal and human sectors under the federal regulations of the Department of Transportation (DOT), which includes a classification scheme and corresponding packaging, labelling and shipping requirements for substances that are known to contain infectious/hazardous materials as well as those that are for diagnostic or investigational purposes". [1] The 2016 JEE self-assessment notes that the DOT regulations are aligned with International Civil Aviation Organisation (ICAO) standards, the ICAO 'Technical instructions on dangerous goods', and World Health Organisation (WHO) guidelines. Certain surveillance programmes, such as the National Animal Health Laboratories Network (NAHLN) and the Integrated Consortium of Laboratory Networks (ICLN), have additional requirements. Transport systems involve both public and commercial carriers, and there is a national system for all clinical laboratories to work with their state public health laboratory for direct shipment of specimens to the Centers for Disease Control and Prevention (CDC) for selected suspect (potentially dangerous) agents and circumstances. [2]

[1] World Health Organisation (WHO). 2017. "Joint external evaluation of IHR core capacities of the United States of America – Mission report: June 2016." Geneva: World Health Organisation. [http://apps.who.int/iris/bitstream/10665/254701/1/WHO-WHE-CPI-2017.13-eng.pdf?ua=1&ua=1]. Accessed 20 December 2020.
[2] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 20 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: 0

There is insufficient evidence that there is a plan in place in the United States to rapidly authorize or license laboratories to supplement the capacity of the national public health laboratory system to scale-up testing during an outbreak. There is no mention of such a plan in place in the 2016 Joint External Evaluation of IHR Core Capacities of the US, or the country's self-assessment. [1, 2] The US' Laboratory Response Network (LRN) was established by the Centers for Disease Control and Prevention in 1999, and there are around 130 reference laboratories under the LRN serving human, animal and food health sectors, among others. [3, 4] There is no evidence through the CDC of a plan to rapidly authorize or license laboratories for the LRN. [5] The Department of Health and Human Services (HHS), Centers for Disease Control and Prevention's (CDC) Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health—published in October 2018 and updated in January 2019—includes a section on Public Health Laboratory Testing

(Capability 12), but there is not mention of a plan to rapidly authorize or license laboratories during a public health emergency. [6] There is no mention of such a plan in the HHS National Health Security Strategy (NHSS) 2019-2022 or NHSS Implementation Plan, or National Response Framework. [7, 8, 9] There is also no evidence of a plan in place available through the Integrated Consortium of Laboratory Networks (ICLN), a consortium of federal departments and agencies that coordinates federally sponsored analytical laboratory services. [10] There is no additional evidence on a plan to rapidly authorize or license laboratories during an outbreak available through the US Department of Agriculture. [11]

[1] World Health Organisation (WHO). 2017. "Joint external evaluation of IHR core capacities of the United States of America – Mission report: June 2016." Geneva: World Health Organisation. [http://apps.who.int/iris/bitstream/10665/254701/1/WHO-WHE-CPI-2017.13-eng.pdf?ua=1&ua=1]. Accessed 6 January 2021.
[2] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 6 January 2021.
[3] Centers for Disease Control and Prevention (CDC). 2019. "The Laboratory Response Network partners in protection." [https://emergency.cdc.gov/lrn/]. Accessed 6 January 2021.
[4] Centers for Disease Control and Prevention (CDC). 2019. "Laboratory Response Network for Biological Threats (LRN-B)." [https://emergency.cdc.gov/lrn/biological.asp]. Accessed 6 January 2021.
[5] Centers for Disease Control and Prevention (CDC). 2020. CDC Website [https://www.cdc.gov/]. Accessed 6 January 2021.
[6] US Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC). October 2018, Updated Janaury 2019. "Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health." [https://www.cdc.gov/cpr/readiness/00_docs/CDC_PreparednesResponseCapabilities_October2018_Final_508.pdf]. Accessed 6 January 2021.
[7] US Department of Health and Human Services (HHS). 2019. "National Health Security Strategy 2019-2022." [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/NHSS-Strategy-508.pdf]. Accessed 6 January 2021.
[8] Department of Health and Human Services (HHS). 2019. "National Health Security Strategy: Implementation plan 2019-2022." [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/2019-2022-nhss-ip-v508.pdf]. Accessed 6 January 2021.
[9] Federal Emergency Management Agency (FEMA), Department of Homeland Security (DHS). 2020. "National Response Framework." [https://www.fema.gov/emergency-managers/national-preparedness/frameworks/response]. Accessed 6 January 2021.
[10] The Integrated Consortium of Laboratory Networks (ICLN). 2020. ICLN Website. [https://www.icln.org/]. Accessed 6 January 2021.
[11] US Department of Agriculture. 2021. [https://www.usda.gov/]. Keyword search. Accessed 27 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

There is evidence that the United States is conducting ongoing event-based surveillance and analysis for infectious disease, and evidence that the data is being analysed on a daily basis. The Emergency Operation Center (EOC) of the Centers for Disease Control and Prevention (CDC) has an event-based surveillance unit, the Situation Awareness Branch. The Situation Awareness Branch gathers, organises and analyses event-based surveillance information (domestic and global) using tools such as the Red Sky database. Red Sky is a "dynamic, real-time dashboard", which replaced previous daily reports by the EOC. It includes not only epidemiological data, but contextual information about how the CDC is responding to events. [1, 2, 3] The CDC's EOC also operates the Global Disease Detection Operations Center (GDDOC), an epidemic intelligence and response unit that provides early warning and rapid response to international disease threats. It uses text-mining software to scan reports online in multiple languages for relevant events. The GDDOC monitors around 30-40 reported public health events each day. [3, 4]

[1] Centers for Disease Control and Prevention (CDC). 2019. "Situation awareness." [https://www.cdc.gov/phpr/sa-branch.htm]. Accessed 28 December 2020.
[2] Sowers, L. 2014. Centers for Disease Control and Prevention (CDC). "Red Sky: New tool for health threats." Centers for Disease Control and Prevention (CDC) Intranet: CDC Connects/Inside Story. 8 May 2014. [https://www.cdc.gov/phpr/science/documents/Red-Sky-New-Tool-for-Health-Threats-6272014.pdf]. Accessed 28 December 2020.
[3] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 28 December 2020.
[4] Centers for Disease Control and Prevention (CDC). 2017. "Global Disease Detection Operations Center: About us." [https://www.cdc.gov/globalhealth/healthprotection/gddopscenter/what.html]. Accessed 28 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 evidence that the United States has reported a potential public health emergency of international concern (PHEIC) to the World Health Organization (WHO) within the last two years.

The US reported COVID-19 cases to the WHO before January 30th 2020 when it was declared a PHEIC by the WHO. [1] However, there is no evidence that the US reported any other potential PHEIC through the WHO's Disease Outbreak News. [2, 3]

[1] World Health Organization. "Novel Coronavirus (2019-nCoV) Situation Report - 10" 30 January 2020. [https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200130-sitrep-10-ncov.pdf?sfvrsn=d0b2e480_2]
[2] World Health Organization (WHO). "Emergencies preparedness, response - Disease Outbreak News (DONs)". [http://www.who.int/csr/don/en/]. Accessed 28 December 2020.
[3] World Health Organization (WHO). "United States of America". [https://www.who.int/countries/usa/]. Accessed 28 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 United States government operates electronic reporting surveillance systems at national and sub-national levels. The Centers for Disease Control and Prevention (CDC) operates the National Notifiable Diseases Surveillance System (NNDSS). This enables all levels of public health (local, state, territorial, federal and international) to share notifiable disease-related health information, which is processed by the CDC Division of Health Informatics and Surveillance (DHIS) and passed to disease-specific CDC programmes. [1] Some local jurisdictions still use non-electronic reporting methods for disease surveillance, but all 50 states and Washington DC report electronically to the NNDSS using a single data standard, the National Electronic Disease Surveillance System (NEDSS). [2, 3] The CDC's National Syndromic Surveillance Program (NSSP) also operates the BioSense Platform. This cloud-based platform hosts tools for sharing and analysing information, including ESSENCE, which allows syndromic data-sharing across geopolitical boundaries and nearly real-time situational analysis. [3, 4, 5, 6]

[1] Centers for Disease Control and Prevention (CDC). 2019. "National Notifiable Diseases Surveillance System (NNDSS)." [https://wwwn.cdc.gov/nndss/]. Accessed 28 December 2020.
[2] Centers for Disease Control and Prevention (CDC). 2017. "National Notifiable Diseases Surveillance System (NNDSS) – Integrated Surveillance Information Systems/NEDSS." [https://wwwn.cdc.gov/nndss/nedss.html]. Accessed 28 December 2020.
[3] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 28 December 2020.
[4] Centers for Disease Control and Prevention (CDC). 2020. "National Syndromic Surveillance Program (NSSP) - Onboarding." [https://www.cdc.gov/nssp/biosense/onboarding.html]. Accessed 28 December 2020.
[5] Centers for Disease Control and Prevention (CDC), National Syndromic Surveillance Program (NSSP). September 2020. "New Facility Onboarding: Guide for the BioSense Platform." [https://www.cdc.gov/nssp/biosense/onboarding-guide/pdf/New-Facility-OG-508.pdf]. Accessed 28 December 2020.
[6] Centers for Disease Control and Prevention (CDC). 2020. "National Syndromic Surveillance Program (NSSP) - What is Syndromic Surveillance?" [https://www.cdc.gov/nssp/overview.html]. Accessed 28 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 United States' electronic reporting surveillance system, the National Notifiable Diseases Surveillance System (NNDSS), collects ongoing/real-time laboratory data. Electronic laboratory reporting (ELR) under the NNDSS involves the automated transmission of reportable laboratory findings (cases of reportable diseases) from commercial, public health, hospital, and other labs to state and local public health departments, from a laboratory information management system or an electronic health records system. ELR supports national public health surveillance by improving the timeliness and accuracy of notifiable disease data voluntarily shared by states with CDC. [1] The 2016 Joint External Evaluation (JEE) self-assessment notes that work is ongoing to improve the ELR system. [2] The National Syndromic Surveillance Program (NSSP) BioSense platform is a

cloud-based electronic health information system with standardized tools and processes that serves as an integrated public health surveillance system and includes users from federal and nonfederal hospitals and state and local health departments. [3, 4] The BioSense platform has data available for analysis within 24 hours of patient visits, from more than 5,000 health care facilities in over 47 states and the District of Columbia. [5] The US CDC also notes that teh NSSP system connects real time data: "Emergency departments and other sources send this information [syndromic surveillance data] as electronic data to public health agencies. These data are monitored daily to understand usual levels of illness and to detect changes that require a response". [6]

[1] Centers for Disease Control and Prevention (CDC). 2017. "National Notifiable Diseases Surveillance System (NNDSS) - Electronic Laboratory Reporting". [https://wwwn.cdc.gov/nndss/meaningful-use-electronic-lab-reporting.html]. Accessed 28 December 2020.
[2] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 28 December 2020.
[3] Centers for Disease Control and Prevention (CDC). 2020. "National Syndromic Surveillance Program (NSSP) - What is Syndromic Surveillance?" [https://www.cdc.gov/nssp/overview.html]. Accessed 27 January 2021.
[4] Gould, Deborah W., David Walker, and Paula W. Yoon. 2017. "The evolution of BioSense: lessons learned and future directions." Public Health Reports 132.1_suppl : 7S-11S [https://journals.sagepub.com/doi/pdf/10.1177/0033354917706954]. Accessed 28 December 2020.
[5] Centers for Disease Control and Prevention (CDC). August 2020. "The National Syndromic Surveillance Program." [https://www.cdc.gov/nssp/images/nsspinfo/Final_NSSP-Infographic.pdf]. Accessed 28 December 2020.
[6] US Center for Disease Control and Prevention. "Project — Connecting Real Time Data". [https://www.cdc.gov/surveillance/projects/Connecting-Real-Time-Data.html] Accessed June 23, 2021.

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: 2

Electronic health records (EHR) are commonly in use in the United States. The Centers for Disease Control and Prevention (CDC), under the Department of Health and Human Services (HHS), last surveyed nationwide use of electronic medical/health records (EMR/EHR) in 2017. The 2017 survey data was published in January 2019, and the CDC's EMR webpage was last reviewed in March 2020. The survey found that 85.9% of office-based physicians use some form of EMR/EHR system, and 79.7% of office-based physicians have a certified EMR/EHR system. [1] The Centers for Medicare and Medicaid Services (CMS) established the Promoting Interoperability Programs (PIP; formerly known as the Medicare and Medicaid Electronic Health Records (EHR) Incentive Program) in 2011, to promote meaningful use of certified electronic health record technology (CEHRT). In 2015, CMS released a final rule that established Stage 3 of PIP, focusing on using CEHRT to improve health outcomes. [2]

[1] Centers for Disease Control and Prevention (CDC), National Center for Health Statistics. 3 March 2020. “Electronic medical records/ Electronic health records (EMRs/EHRs).” [https://www.cdc.gov/nchs/fastats/electronic-medical-records.htm].

Accessed 28 December 2020.
[2] Centers for Medicare and Medicaid Services. 3 December 2020. “Promoting interoperability Programs.” [https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/ehrincentiveprograms]. Accessed 28 December 2020.

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: 0

The national public health system in the United States does not have access to electronic health records of individuals in their country. However, there is evidence that the national Centers Disease Control and Prevention (CDC), has piloted and expanded EHR access for disease surveillance purposes. The CDC’s surveillance strategy aims to increase the use of EHR and to use them to link private health care with public health authorities, primarily through case reporting. The CDC participates in Digital Bridge, a collaborative partnership that was formed in 2016 and engages representatives from health care, public health, and health information technology. [1, 2] The first initiative of Digital Bridge, electronic case reporting (eCR)—a collaborative initiative of CDC, the Association of Public Health Laboratories (APHL), and the Council of State and Territorial Epidemiologists (CSTE)—was developed to leverage "existing EHRs to automatically flag potentially reportable disease cases and create a case report." [3] The CDC website states that the initiative was tested at seven sites in California, Houston, Kansas, Massachusetts, Michigan, New York City, and Utah, and the Digital Bridge website names eight sites, adding New York State to the list. [1, 3] In fall 2019, "onboarding to eCR" transitioned to CDC, APHL, and CSTE. [3] The CDC's website provides details on how the current eCR system functions, which has been updated as recently as November 2020. [4] CDC has been rapidly onboarding healthcare facilities to eCR during the COVID-19 pandemic, with over 6,600 facilities sending COVID-19 electronic initial case reports to public health using eCR as of January 22, 2021. [5] Some other limited linkages of the public health system to EHR records of individuals exist. The public health system has access to electronic data from emergency departments nationwide through the CDC’s National Syndromic Surveillance Program, which receives data from over 4000 hospitals in 45 states and Washington, DC. [6] Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and associated health information privacy standards, it is legal for health care providers to share data from electronic health records to public health authorities for the purpose of disease surveillance. [7] However, the CDC does not have the ability to access these records directly. There is no additional evidence from the CDC or the US Department of Heatlh and Human Services. [8, 9]

[1] Centers for Disease Control and Prevention (CDC). 2018. “Surveillance strategy report — How sharing data digitally benefits health.” [https://www.cdc.gov/surveillance/innovation/sharing-data-digitally.html]. Accessed 3 January 2021.
[2] Digital Bridge. 2021. [https://digitalbridge.us/about/]. Accessed 27 January 2021.
[3] Digital Bridge. 2021. "Past Projects - Electronic Case Reporting (eCR)." [https://digitalbridge.us/past-projects/]. Accessed 27 January 2021.
[4] Centers for Disease Control and Prevention (CDC). 2020. “Electronic Case Reporting (eCR).” [https://www.cdc.gov/ecr/]. Accessed 27 January 2021.
[5] Centers for Disease Control and Prevention (CDC). 2021. “Electronic Case Reporting (eCR) - Facilities Map.” [https://www.cdc.gov/coronavirus/2019-ncov/hcp/electronic-case-reporting/hcfacilities-map.html]. Accessed 27 January 2021.
[6] Centers for Disease Control and Prevention (CDC). 2018. “Surveillance Strategy Report — Syndromic Reporting.” [https://www.cdc.gov/surveillance/Connecting-Real-Time-Data.html]. Accessed 3 January 2021.
[7] Centers for Disease Control and Prevention (CDC). 2003. “HIPAA Privacy Rule and public health.” [https://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm]. Accessed 3 January 2021.

[8] US Department of Health and Human Services. 2021. [https://www.hhs.gov/]. Keyword search. Accessed 26 January 2021.
[9] US Centers for Disease Control and Prevention. 2021. [https://www.cdc.gov/]. Keyword search. Accessed 27 January 2021.

2.4.1c

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

Yes = 1 , No = 0

Current Year Score: 1

There are data standards in the United States to ensure electronic health records' (EHR) data is comparable. In March 2020, the Department of Health and Human Services (HHS) announced two final rules—issued by the Office of the National Coordinator for Health Information Technology (ONC) and Centers for Medicare and Medicaid Services (CMS)—focused on data interoperability, preventing information blocking, and facilitating patient access to electronic health records (EHRs), and effective 60 days after publication in the Federal Register. "The ONC rule changes the minimum commonly available baseline data requirements for interoperable exchange required for EHR certification," now requiring EHRs to meet United States Core Data for Interoperability (USCDI) standards." [1, 2, 3, 4] Prior to the 2020 final rules, in 2010, the US Department of Health and Human Services (HHS) issued a first set of standards to incentivize health practicioners who treat Medicare and Medicaid patients to make "meaningful use" of EHRs. However, the federal regulations did not require EHR systems to follow the standards. [5] A 2017 article in Pharmacy and Therapeutics on interoperability of EHRs in the US describes significant barriers in interoperability of EHR systems in the US, and as of 2015 "only 6% of health care providers could share patient data with other clinicians who use an EHR system different from their own." The article also notes that meaningful use incentives are focused on EHR adoption and not health information exchange. [6] The electronic case reporting (eCR) initiative, which was developed to leverage "existing EHRs to automatically flag potentially reportable disease cases and create a case report" for the purposed of disease surveillance, specifies that the standard for eCR is Health Level 7 (HL7), and a set of industry standard codes (e.g. ICD-10, LOINC, SNOMED) are used for Reportable Conditions Trigger Codes. [7, 8]

[1] US Department of Health and Human Services (HHS). 9 March 2020. "HHS Finalizes Historic Rules to Provide Patients More Control of Their Health Data." [https://www.hhs.gov/about/news/2020/03/09/hhs-finalizes-historic-rules-to-provide-patients-more-control-of-their-health-data.html]. Accessed 29 January 2021.
[2] The National Law Review. "HHS Finalizes Joint Rules on Electronic Health Record Interoperability and Access." [https://www.natlawreview.com/article/hhs-finalizes-joint-rules-electronic-health-record-interoperability-and-access]. Accessed 29 January 2021.
[3] US Department of Health and Human Services (HHS). 9 March 2020. "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program." [https://www.healthit.gov/sites/default/files/cures/2020-03/ONC_Cures_Act_Final_Rule_03092020.pdf]. Accessed 29 January 2021.
[4] US Department of Health and Human Services (HHS). 9 March 2020. "Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges, and Health Care Providers." [https://www.cms.gov/files/document/cms-9115-f.pdf]. Accessed 29 January 2021.
[5] Halamka, John. 28 September 2010. "Electronic Health Record Standards." [https://www.healthaffairs.org/do/10.1377/hpb20100928.658660/full/]. Accessed 29 January 2021.
[6] Reisman, Miriam. 2017. "EHRs: the challenge of making electronic data usable and interoperable." Pharmacy and Therapeutics 42.9: 572. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5565131/]. Accessed 27 January 2021.
[7] Digital Bridge. 2021. "Past Projects - Electronic Case Reporting (eCR)." [https://digitalbridge.us/past-projects/]. Accessed 27 January 2021.

[8] Digital Bridge. 29 Aug 2018. "Digital Bridge electronic case reporting (eCR) technical specifications." [https://digitalbridge.us/wp-content/uploads/2018/09/Digital-Bridge-eCR-Technical-Specifications-v1.0.pdf]. Accessed 3 January 2021.

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 the United States has established mechanisms at the relevant agencies responsible for animal, human, and wildlife surveillance to share data. The 2016 Joint External Evaluation (JEE) of the IHR Core Capacities of the United States states that human and animal health programmes within the Animal and Plant Health Inspection Services (APHIS, under the Department of Agriculture, USDA), Centers for Disease Control and Prevention (CDC, under the Department of Health and Human Services), Department of Homeland Security (DHS), Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS) "maintain liaisons embedded in each other's organisations to ensure ongoing and daily collaborations in surveillance, detection and response." Human and animal health agencies also share surveillance information through their emergency operations centres (EOCs). [1] Furthermore, the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), under the CDC, is home to the One Health Office, which facilitates collaboration and information-sharing across human, animal and environmental health sectors. [2] The 2016 JEE self-assessment notes that interoperability among information systems used for animal and human health surveillance is minimal, but the CDC and USDA collaborate directly on a number of zoonotic disease surveillance programs including rabies, bovine spongiform encephalopathy, swine influenza and avian influenza. [3]

[1] World Health Organisation (WHO). 2017. "Joint external evaluation of IHR core capacities of the United States of America – Mission report: June 2016." Geneva: World Health Organisation. [http://apps.who.int/iris/bitstream/10665/254701/1/WHO-WHE-CPI-2017.13-eng.pdf?ua=1&ua=1]. Accessed 28 December 2020.
[2] National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). 2016. "One Health Office." [https://www.cdc.gov/ncezid/who-we-are/ncezid-divisions/oho.html]. Accessed 28 December 2020.
[3] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 28 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

The United States makes de-identified health surveillance data on infectious diseases publicly available on government websites. The US' Centers for Disease Control and Prevention (CDC) makes de-identified data from the National Notifiable Diseases Surveillance System (NNDSS)—a nationwide collaboration to share notifiable disease-related health information—publicly available. Weekly and annual statistics are available from the CDC, published with a lag time of no more than one month. [1, 2, 3] In addition, selected data is published with analysis focusing on specific diseases in the CDC's Morbidity and Mortality Weekly Report (MMWR). [4]

[1] Centers for Disease Control and Prevention (CDC). 2020. "National Notifiable Infectious Diseases and Conditions: United States Data Tables." [https://stacks.cdc.gov/cbrowse?parentId=cdc:49375&pid=cdc:49375]. Accessed 28 December 2020.
[2] Centers for Disease Control and Prevention (CDC). 2020. "Nationally Notifiable Infectious Diseases and Conditions, United States: Weekly Tables." [https://wonder.cdc.gov/nndss/nndss_weekly_tables_menu.asp]. Accessed 28 December 2020.
[3] Centers for Disease Control and Prevention (CDC). 2020. "Nationally Notifiable Infectious Diseases and Conditions, United States: Annual Tables." [https://wonder.cdc.gov/nndss/nndss_annual_tables_menu.asp]. Accessed 28 December 2020.
[4] Centers for Disease Control and Prevention (CDC). 2020. "Morbidity and Mortality Weekly Report (MMWR)." [https://www.cdc.gov/mmwr/index2018.html]. Accessed 28 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

The United States makes de-identified COVID-19 surveillance data (including details such as daily case count, mortality rate, etc) available via a data tracker on government websites. The Centers for Disease Control and Prevention's (CDC) COVID Data Tracker has maps, charts, and data provided by the CDC—including case counts, mortality, and vaccinations distributed and initiated. The data is updated daily, though the website's disclaimer notes, "National total test counts reflect data from the previous day and may not match the sum of the data presented for all jurisdictions. Data reported for each state and territory may be delayed several days in order to mitigate discrepancies in daily test counts due to variation in jurisdiction reporting. " [1]

[1] Centers for Disease Control and Prevention's (CDC) COVID Data Tracker. 2020. [https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days]. Accessed 3 January 2021.

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

The United States has regulations and guidelines safeguarding the confidentiality of identifiable health information for individuals, including that generated through health surveillance activities. Under the National Notifiable Diseases Surveillance System (NNDSS), mandatory reporting of notifiable diseases at the state level, which is governed by state law, includes personal identifiers, whereas voluntary reporting by states to the Centers for Disease Control and Prevention (CDC)

for national disease monitoring does not. [1] The Department of Health and Human Services (HHS) introduced national health information privacy standards in 2003, pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The HIPAA Privacy Rule (in the Code of Federal Regulations: 45 CFR 164.512(b)) protects the privacy of certain individually identifiable health data, referred to as protected health information (PHI). There are exceptions which allow disclosure of PHI "without individual authorization to public health authorities authorized by law to collect or receive the information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to public health surveillance, investigation, and intervention." Disclosure should consist of the minimum information necessary to achieve the specified goal. The public health authorities receiving identifiable data must be prepared to verify their identity, and must protect the data in line with state and federal laws. [2, 3, 4] According to the CDC, "the majority of states as well as the federal government have laws that govern the use of, and serve to protect, identifiable information collected by public health authorities." [4] At the federal level, the Privacy Act 1974 protects personal identifiable information held by federal agencies. [5]

[1] Centers for Disease Control and Prevention (CDC). 2018. "National Notifiable Diseases Surveillance System (NNDSS): Data collection and reporting." [https://wwwn.cdc.gov/nndss/data-collection.html]. Accessed 28 December 2020.
[2] Department of Health and Human Services. N.d. "Health information privacy: Public health." [https://www.hhs.gov/hipaa/for-professionals/special-topics/public-health/index.html]. Accessed 28 December 2020.
[3] Code of Federal Regulations. 2020. "Title 45 (Public Welfare)164.512(b))."[https://ecfr.federalregister.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-E/section-164.512]. Accessed 28 December 2020.
[4] Centers for Disease Control and Prevention (CDC). 2003. "HIPAA Privacy Rule and public health." [https://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm]. Accessed 28 December 2020.
[5] Department of Justice. 2020. "Privacy Act of 1974." [https://www.justice.gov/opcl/privacy-act-1974]. Accessed 28 December 2020.

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 the United States has 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.

There are some laws, regulations, or guidelines safeguarding the confidentiality of identifiable health information for individuals. However, these vary by state across the US, and not all have statutory rules on cybersecurity. This means that protection is not legally guaranteed nationwide. However, a Security Rule was introduced under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), established national standards to protect individuals' electronic personal health information that is created, received, used, or maintained by a covered entity. [1] The definition of "covered entities" includes health service providers which may provide surveillance information, but does not include state health authorities receiving and analysing surveillance data. [2] These are subject to state-level data security laws. [3]

Nonetheless, the US Department of Health and Human Services (DHHS)' HIPAA security compliance has several comprehensive safeguards in place for the protection of electronic personal health information (e-PHI). [4] According to the DHHS website, "the Security Standards for the Protection of Electronic Protected Health Information (the Security Rule)

establish a national set of security standards for protecting certain health information that is held or transferred in electronic form. The Security Rule operationalizes the protections contained in the Privacy Rule by addressing the technical and non-technical safeguards that organizations called “covered entities” must put in place to secure individuals’ “electronic protected health information” (e-PHI)". [4] This Security Rule is applicable to all "health plans, health care clearinghouses, and to any health care provider who transmits health information in electronic form in connection with a transaction for which the Secretary of HHS has adopted standards under HIPAA (the “covered entities”) and to their business associates". [4] Technical safeguards under the HIPAA Security Rule include access control, audit controls, integrity controls, and transmission security. [4]

On the other hand, in January 2017, the National Conference of State Legislatures reported that just 19 states had statutory requirements for specific policies or measures on data security. [5] Since then, new/expanded legislation containing cybersecurity requirements applicable to state public health authorities has been introduced in two more states, bringing coverage to 21 out of 50 states. [6, 7, 8] At the federal level, the Privacy Act 1974 (in the US Code as amended at 5 U.S.C. 552a) protects personal identifiable information held by federal agencies, so this does not apply to those holding personal health information at the state level. [9] The Privacy Act mentions protection against cyber attacks: Under section (e) ‘Agency requirements’, part 10 requires each [federal] agency that maintains a system of records to “establish appropriate administrative, technical, and physical safeguards to insure the security and confidentiality of records and to protect against any anticipated threats or hazards to their security or integrity”. [10] Under the Privacy Act, the Health and Human Services (HHS) Privacy Act Regulations are in the Code of Federal Regulations (CFR) at 45 CFR Part 5b. [9] The HHS Privacy Act Regulations do not mention cybersecurity. [11]

[1] US Department of Health and Human Services. 2020. “HIPAA Security Rule”. [https://www.hhs.gov/hipaa/for-professionals/security/index.html]. Accessed 29 December 2020.
[2] Centers for Disease Control and Prevention (CDC). 2003. “HIPAA Privacy Rule and Public Health: Guidance from CDC and the U.S. Department of Health and Human Services.” [https://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm]. Accessed 29 December 2020.
[3] Association of State and Territorial Health Officials. 2012. “Public health collection, use, sharing, and protection of information: Issue brief.” [http://www.astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Public-Health-and-Information-Sharing-Toolkit/Collection-Use-Sharing-and-Protection-Issue-Brief/]. Accessed 29 December 2020.
[4] US Department of Health and Human Services. July 26, 2013. “Summary of the HIPAA Security Rule”. [https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html]. Accessed June 4, 2021.
[5] National Conference of State Legislatures. 14 February 2020. “Data security laws: state government.” [http://www.ncsl.org/research/telecommunications-and-information-technology/data-security-laws-state-government.aspx]. Accessed 29 December 2020.
[6] Kim Serrrato, J, Cwalina, C, Rudawski, A, Coughlin, T and Fardelmann, K. 9 Jul 2018. “US states pass data protection laws on the heels of the GDPR.” [https://www.dataprotectionreport.com/2018/07/u-s-states-pass-data-protection-laws-on-the-heels-of-the-gdpr/]. Accessed 29 December 2020.
[7] Alabama State Legislature. 27 Mar 2018. “Alabama Senate Bill 318.” [https://legiscan.com/AL/text/SB318/2018]. Accessed 29 December 2020.
[8] Louisiana State Legislature. 1 Aug 2018. “Act No. 382.” [https://www.legis.la.gov/legis/ViewDocument.aspx?d=1101149]. Accessed 29 December 2020.
[9] Department of Health and Human Services. 8 September 2020. “The Privacy Act.” [https://www.hhs.gov/foia/privacy/index.html]. Accessed 29 December 2020.
[10] Federal Government. 2012. “United States Code 552a. Records maintained on individuals.” [https://www.govinfo.gov/content/pkg/USCODE-2012-title5/pdf/USCODE-2012-title5-partI-chap5-subchapII-sec552a.pdf]. Accessed 29 December 2020.
[11] Code of Federal Regulations. 2020. "Title 45 (Public Welfare), Part 5b."[https://ecfr.federalregister.gov/current/title-

45/subtitle-A/subchapter-A/part-5b]. Accessed 29 December 2020.

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: 2

The United States has committed to sharing surveillance data for more than one disease with neighbouring countries during a public health emergency at national and sub-national levels. In 2003, the Department of Health and Human Services (HHS) introduced the US Border State Early Warning Infectious Disease Surveillance (EWIDS) Project. This established cross-border early warning systems, run by state-level health authorities. [1] Federal funding for EWIDS was withdrawn in 2012, but some border states continue to operate cross-border surveillance systems. [2] For instance, the ongoing Great Lakes Border Health Initiative is based on a 2009 data-sharing agreement signed by sub-national authorities on both sides of the US-Canada border. [3] In another example, in 2012, the governments of Canada, Mexico and the US issued the "North American plan for animal and pandemic influenza", committing the three countries to immediately share notifications regarding animal and/or new subtype human influenza directly with each other as well as to the World Health Organization (WHO). [4] Separately, Mexico and Canada both have laboratories which are members of the US' Laboratory Response Network (LRN), which enables cooperation over responses to public health emergencies. [5] In addition, the US's Association of Public Health Laboratories (APHL) has signed a memorandum of understanding (MOU) with the Canadian Public Health Laboratory Network, under which the two networks have committed to exchange information regarding disease outbreaks. [6]

[1] Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR). 2017. "ASPR International Capacity Building Programs." Public Health Emergency website. [https://www.phe.gov/about/OPP/dihs/Pages/capacity.aspx]. Accessed 29 December 2020.
[2] Michigan Department of Health and Human Services. 2020. "An updated overview of the Great Lakes Border Health Initiative." [http://www.michigan.gov/mdhhs/0,5885,7-339-71548_54783_54875-170665--,00.html]. Accessed 29 December 2020.
[3] Great Lakes Border Health Initiative. February 2009. "Public health data sharing agreement." [https://www.michigan.gov/documents/mdch/2007-06-21_-_DATA_SHARING_AGREEMENT_202933_7.pdf]. Accessed 29 December 2020.
[4] Governments of Canada, Mexico and the US. 2 April 2012. "North American plan for animal and pandemic influenza." [http://www.phe.gov/Preparedness/international/Documents/napapi.pdf]. Accessed 29 December 2020.
[5] Centers for Disease Control and Prevention (CDC). March 2018. "Laboratory response: On the front lines of America's health." [https://stacks.cdc.gov/view/cdc/57341]. Accessed 29 December 2020.
[6] Association of Public Health Laboratories (APHL). 18 September 2018. "APHL and Canadian Public Health Laboratory Network reaffirm cross-border partnership with MOU." [http://www.aphlblog.org/aphl-canadian-public-health-laboratory-network-reaffirm-cross-border-partnership-mou/]. Accessed 29 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 evidence that the United States provides support to sub-national systems to conduct contact tracing in the event of a public health emergency, but only in response to active public health emergencies. During the COVID-19 pandemic, the Centers for Disease Control and Prevention (CDC) provides contact tracing resources for health departments—such as guidance documents, communication resources, and digital tools—through its website. [1] The CDC also provides Interim Guidance on Developing a COVID-19 Case Investigation & Contact Tracing Plan accompanied by a checklist to assist health departments in developing a comprehensive plan. [2] The CDC's "COVIDTracer and COVIDTracer Advanced are spreadsheet-based tools that allow state- and local-level public health officials and policy makers to compare the effectiveness, and the resources needed, of three user defined contact tracing and monitoring strategies." [3] These contact tracing supports for COVID-19 do not indicate that they are intended for other public health emergencies. Included under Function 2—conduct public health and epidemiological investigations—of the CDC's 2018 Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health is a priorty item that calls for "Procedures in place to support jurisdictional methods for conducting investigations of public health, environmental, and occupational threats, incidents, and hazards", including "Identification of exposed persons and contact tracing." [4] However, there is no further detail available on a national system of procedures and supports in place at the sub-national level. There is no mention of contact tracing in the Department of Health and Human Services (HHS) National Health Security Strategy 2019-2022, its implementation plan, or the Federal Emergency Management Agency's National Response Framework. [5, 6, 7] There is also no further detail from the CDC, beyond resources and supports for COVD-19 contact tracing, on a national system to support contact tracing. [8]

[1] Centers for Disease Control and Prevention (CDC). 2021. “Contact Tracing Resources for Health Departments.” [https://www.cdc.gov/coronavirus/2019-ncov/php/open-america/contact-tracing-resources.html]. Accessed 6 January 2021.
[2] Centers for Disease Control and Prevention (CDC). 2021. “Interim Guidance on Developing a COVID-19 Case Investigation & Contact Tracing Plan: Overview.” [https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/overview.html]. Accessed 6 January 2021.
[3] Centers for Disease Control and Prevention (CDC). 2020. “COVIDTracer and COVIDTracer Advanced.” [https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/COVIDTracerTools.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fphp%2Fcontact-tracing%2FCOVIDTracer.html]. Accessed 6 January 2021.
[4] US Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC). October 2018, Updated Janaury 2019. "Public Health Emergency Preparedness and Response Capabilities: National Standards for State, Local, Tribal, and Territorial Public Health." [https://www.cdc.gov/cpr/readiness/00_docs/CDC_PreparednesResponseCapabilities_October2018_Final_508.pdf]. Accessed 31 January 2021.
[5] US Department of Health and Human Services (HHS). 2019. “National Health Security Strategy 2019-2022.”

[https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/NHSS-Strategy-508.pdf]. Accessed 31 January 2021.
[6] Department of Health and Human Services (HHS). 2019. "National Health Security Strategy: Implementation plan 2019-2022." [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/2019-2022-nhss-ip-v508.pdf]. Accessed 31 January 2021.
[7] Federal Emergency Management Agency (FEMA), Department of Homeland Security (DHS). 2020. "National Response Framework." [https://www.fema.gov/emergency-managers/national-preparedness/frameworks/response]. Accessed 31 January 2021.
[8] US Centers for Disease Control and Prevention. 2021. [https://www.cdc.gov/]. Keyword search. Accessed 31 January 2021.

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: 0

There is insufficient evidence that the United States provides wraparound services to enable infected people and their contacts to self-isolate or quarantine as recommended, particularly economic support and medical attention. Through the Centers for Disease Control and Prevention's (CDC) Interim Guidance on Developing a COVID-19 Case Investigation & Contact Tracing Plan, the agency provides guidance to jurisdictions on social support services to include for cases to self-isolate, and recommend that jurisdictions "take inventory of the existing resources available to assist clients and contacts who are self-isolating/self-quarantining, as well as their families, and find ways to fill any critical service gaps," with health insurance navigation and economic support among the social support services listed. [1, 2] The CDC also provides a checklist for case investigators and contact tracers to assess an indvidiual's ability to safely isolate or quarantine at home—which includes assessing financial impact and access to a primary care provicer—but there is no mention of services available if an individual does not have access. [3] Some local jurisdictions in the US, such as the City of San Francisco in California, offer economic support to indivduals who anticipate experiencing financial hardship during quarantine or isolation due to COVID-19. [4] There is no additional information available through the Department of Health and Human Services or its Centers for Disease Control and Prevention. [5, 6]

[1] Centers for Disease Control and Prevention (CDC). 2021. "Interim Guidance on Developing a COVID-19 Case Investigation & Contact Tracing Plan: Overview." [https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/overview.html]. Accessed 6 January 2021.
[2] Centers for Disease Control and Prevention (CDC). 2021. "Support Services." [https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/support-services.html]. Accessed 6 January 2021.
[3] Centers for Disease Control and Prevention (CDC). 2021. "Self-Isolation and Self-Quarantine Home Assessment Checklist for Coronavirus Disease 2019 (COVID-19)." [https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/self-quarantine_form.pdf]. Accessed 6 January 2021.
[4] City and County of San Francisco, Office of Economic and Workforce Development. "For Employees Impacted by COVID-19 - Right to Recover Program (City)." [https://oewd.org/employees-impacted-covid-19]. Accessed 6 January 2021.
[5] US Department of Health and Human Services. 2021. [https://www.hhs.gov/]. Keyword search. Accessed 27 January 2021.
[6] US Centers for Disease Control and Prevention. 2021. [https://www.cdc.gov/]. Keyword search. Accessed 27 January 2021.

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

There is no evidence that the United States makes de-identified data on contact tracing efforts for COVID-19 available via daily reports on government websites. The Centers for Disease Control and Prevention's (CDC) COVID Data Tracker has maps, charts, and data provided by the CDC—including case counts, mortality, and vaccinations distributed and initiated. The data is updated daily, though the website's disclaimer notes, "National total test counts reflect data from the previous day and may not match the sum of the data presented for all jurisdictions. Data reported for each state and territory may be delayed several days in order to mitigate discrepancies in daily test counts due to variation in jurisdiction reporting. " [1] However, there is no mention of data related to contact tracing efforts through the COVID Data Tracker or weekly summaries released by CDC. [1, 2] There is no evidence of de-identified data on contract tracing efforts for COVID-19 available through the US Dpartment of Health and Human Services or the CDC. [3, 4]

[1] Centers for Disease Control and Prevention's (CDC) COVID Data Tracker. 2020. [https://covid.cdc.gov/covid-data-tracker/#vaccinations]. Accessed 3 January 2021.
[2] Centers for Disease Control and Prevention's (CDC). "COVIDView: A Weekly Surveillance Summary of U.S. COVID-19 Activity - Key Updates for Week 52, ending December 26, 2020." 2020. [https://www.cdc.gov/coronavirus/2019-ncov/covid-data/pdf/covidview-01-04-2021.pdf]. Accessed 3 January 2021.
[3] US Department of Health and Human Services. 2021. [https://www.hhs.gov/]. Keyword search. Accessed 26 January 2021.
[4] US Centers for Disease Control and Prevention. 2021. [https://www.cdc.gov/]. Keyword search. Accessed 26 January 2021.

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: 2

There is a joint plan or cooperative agreement in the United States 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 place to prepare for future public health emergencies. The 2016 Joint External Evaluation of IHR Core Capacities of the US and self-assessment states that a 2005 Memorandum of Understanding (MOU) exists "with relevant stakeholders regarding the method to share information of travellers' health and medical services, and disease reporting with a good coordination mechanism in place." [1, 2] This MOU between the Departments of Homeland Security (DHS) and Health and Human Services (HHS), available through the American Civil Liberties Union website, formalizes existing practices of sharing DHS' customs declarations and allows the HHS' Centers for Disease Control and Prevention (CDC) to carry out contact investigation, quarantine, and isolation. [3, 4] According to the December 2020 Privacy Impact Assessment for the U.S. Customs and Border Protection (CBP) Support of the Centers for Disease Control and Prevention (CDC) for Public Health Contact Tracing, under

the 2005 MOU, the US Customs and Border Patrol has been routinely providing information to the CDC. "Upon receipt from CBP, CDC shares the information with state and local public health departments so they can contact travelers who may have been exposed to a communicable disease during travel and identify appropriate public health interventions. In rare cases, CDC may use the data to perform the contact investigation directly." [5]

[1] World Health Organisation (WHO). 2017. "Joint external evaluation of IHR core capacities of the United States of America - Mission report: June 2016." Geneva: World Health Organisation. [http://apps.who.int/iris/bitstream/10665/254701/1/WHO-WHE-CPI-2017.13-eng.pdf?ua=1&ua=1]. Accessed 8 January 2021.
[2] Department of Health and Human Services. 20 September 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 8 January 2021.
[3] American Civil Liberties Union. 19 October 2005. "Memorandum of Understanding between the Department of Homeland Security and Department of Health and Human Services." [https://www.aclu.org/sites/default/files/pdfs/privacy/hhs_dhs_mou.pdf]. Accessed 8 January 2021.
[4] Becker, A.L., and Roos, R. 27 April 2006. University of Minnesota. Center for Infectious Disease Research and Policy. "DHS-CDC deal to share travelers' data draws fire." [https://www.cidrap.umn.edu/news-perspective/2006/04/dhs-cdc-deal-share-travelers-data-draws-fire]. Accessed 8 January 2021.
[5] US Department of Homeland Security. 15 December 2020. "Privacy Impact Assessment for the [U.S. Customs and Border Protection] CBP Support of [Centers for Disease Control and Prevention] CDC for Public Health Contact Tracing." [https://www.dhs.gov/sites/default/files/publications/privacy-pia-cbp056-cdccontactracing-december2020.pdf]. Accessed 8 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

The United States has applied epidemiology training programmes available in the country, and publicly-funded fellowships are available from the Centers for Disease Control and Prevention (CDC) to send citizens to participate in fellowships in CDC offices overseas, which include an applied epidemiology element. There are two main epidemiology training programmes. The first is the Epidemic Intelligence Service (EIS), which is an advanced, two-year, on the job training and service fellowship conducted by the CDC. EIS trains physicians, veterinarians, scientists and other public health professionals from a variety of settings to apply epidemiology to solve public health problems. [1, 2] The second is the Applied Epidemiology Fellowship (AEF), which is similar in design to EIS but is conducted by the Council of State and Territorial Epidemiologists (CSTE). [1, 3] Besides these two main programmes, CDC offers the Epidemiology Elective Program, an internship programme in

epidemiology and public health for veterinary and medical students during their last two years of their training. [4, 5] Under the Department of Agriculture, the Animal and Plant Health Inspection Service (APHIS) Veterinary Services offers a veterinary field epidemiology training programme for current veterinary epidemiologists, which trains about 25 epidemiologists annually in animal disease surveillance and eradication. [4, 6] The US Geological Survey (USGS) National Wildlife Health Center veterinary externship programme trains approximately six veterinary students per year in wildlife disease investigation techniques, including epidemiology. [4, 7] There is no evidence of resources to send US citizens to attend an applied epidemiology training programme run by another country or international organisation, from the CDC, the Department of Health and Human Services, the Department of Agriculture or from a wider search. [8, 9, 10] However, the CDC runs a funded programme, along with the Public Health Institute, for public health graduates to participate in yearlong fellowships, working alongside CDC experts in Atlanta and in CDC offices abroad. This is not explicitly described as an applied/field epidemiology programme, but does include an applied epidemiology element: it covers epidemiology, HIV prevention, monitoring and evaluation (M&E), strategic information, program management, and surveillance. [11, 12]

[1] World Health Organisation (WHO). 2017. "Joint external evaluation of IHR core capacities of the United States of America – Mission report: June 2016." Geneva: World Health Organisation. [http://apps.who.int/iris/bitstream/10665/254701/1/WHO-WHE-CPI-2017.13-eng.pdf?ua=1&ua=1]. Accessed 29 December 2020.
[2] Centers for Disease Control and Prevention (CDC). 2020. "Epidemic Intelligence Service: 2020 annual update." [https://www.cdc.gov/eis/downloads/eis-annual-update-2020-508.pdf]. Accessed 29 December 2020.
[3] Council of State and Territorial Epidemiologists (CSTE). 2020. "Applied Epidemiology Fellowship." [https://cstefellows.org/]. Accessed 29 December 2020.
[4] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 29 December 2020.
[5] Centers for Disease Control and Prevention (CDC). 2020. "Epidemiology Elective Program (EEP)." [https://www.cdc.gov/epielective/]. Accessed 29 December 2020.
[6] US Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) Veterinary Services. 2020. "Learning and Development - Fiscal Year 2021." [https://www.aphis.usda.gov/animal_health/prof_development/downloads/pds_catalog.pdf]. Accessed 29 December 2020.
[7] US Geological Survey (USGS) National Wildlife Health Center. 2020. "Employment opportunities." [https://www.usgs.gov/centers/nwhc/about/employment-opportunities]. Accessed 29 December 2020.
[8] Centers for Disease Control and Prevention (CDC). 2020. Official website. [https://www.cdc.gov/]. Accessed 29 December 2020.
[9] Department of Health and Human Services. 2020. Official website. [https://www.hhs.gov/]. Accessed 29 December 2020.
[10] Department of Agriculture. 2020. Official website. [https://www.usda.gov/]. Accessed 29 December 2020.
[11] Public Health Institute (PHI) and Centers for Disease Control and Prevention (CDC). 2020. "What is a PHI/CDC global health fellow?" [https://phi-cdcfellows.org/]. Accessed 29 December 2020.
[12] Public Health Institute (PHI) and Centers for Disease Control and Prevention (CDC). 2020. "About the program." [https://phi-cdcfellows.org/about-us/phi-cdc-global-health-fellowship-program/]. Accessed 29 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

Some field epidemiology training programmes in the United States are explicitly inclusive of animal health professionals and some specifically target them. There are two main epidemiology training programmes. The first is the Epidemic Intelligence Service (EIS) run by the Centers for Disease Control and Prevention (CDC). EIS accepts physicians, veterinarians, scientists and other public health professionals from a variety of settings. [1, 2] The second is the Applied Epidemiology Fellowship (AEF), run by the Council of State and Territorial Epidemiologists (CSTE). The AEF is open to anyone with masters-level education in epidemiology or a similar field, including those with Doctor of Veterinary Medicine (DVM) degrees. [1, 3] The CDC also offers the Epidemiology Elective Program, an internship programme in epidemiology and public health for veterinary and medical students during their last two years of their training. [4, 5] Under the US Department of Agriculture (USDA), the Animal and Plant Health Inspection Service (APHIS) Veterinary Services offers a veterinary field epidemiology training programme for current veterinary epidemiologists, which trains about 25 epidemiologists annually in animal disease surveillance and eradication. [4, 6] The US Geological Survey (USGS) National Wildlife Health Center veterinary externship programme trains approximately six veterinary students per year in wildlife disease investigation techniques, including epidemiology. [4, 7] The CDC also funds a Public Health Institute and CDC (PHI/CDC) Global Health Fellowship program for rececent graduates to work "on the front lines of global health. [8] The PHI/CDC fellowship is not explicitly inclusive of animal health professionals, only public health graduates; and there is no evidence of a comparable programme for animal health professionals from the CDC, Department of Health and Human Services, or USDA. [8, 9, 10, 11, 12]

[1] World Health Organisation (WHO). 2017. “Joint external evaluation of IHR core capacities of the United States of America – Mission report: June 2016.” Geneva: World Health Organisation. [http://apps.who.int/iris/bitstream/10665/254701/1/WHO-WHE-CPI-2017.13-eng.pdf?ua=1&ua=1]. Accessed 29 December 2020.
[2] Centers for Disease Control and Prevention (CDC). 2020. “Epidemic Intelligence Service: 2020 annual update.” [https://www.cdc.gov/eis/downloads/eis-annual-update-2020-508.pdf]. Accessed 29 December 2020.
[3] Council of State and Territorial Epidemiologists (CSTE). 2020. “Applied Epidemiology Fellowship.” [https://cstefellows.org/]. Accessed 29 December 2020.
[4] Department of Health and Human Services. 20 Sep 2016. “International health regulations - Joint external evaluation of the United States of America: Self-assessment report.” [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 29 December 2020.
[5] Centers for Disease Control and Prevention (CDC). 2020. “Epidemiology Elective Program (EEP).” [https://www.cdc.gov/epielective/]. Accessed 29 December 2020.
[6] US Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) Veterinary Services. 2020. “Learning and Development - Fiscal Year 2021.” [https://www.aphis.usda.gov/animal_health/prof_development/downloads/pds_catalog.pdf]. Accessed 29 December 2020.
[7] US Geological Survey (USGS) National Wildlife Health Center. 2020. “Employment opportunities.” [https://www.usgs.gov/centers/nwhc/about/employment-opportunities]. Accessed 29 December 2020.
[8] Public Health Institute (PHI) and Centers for Disease Control and Prevention (CDC). 2020. “What is a PHI/CDC global health fellow?” [https://phi-cdcfellows.org/]. Accessed 29 December 2020.
[9] Public Health Institute (PHI) and Centers for Disease Control and Prevention (CDC). 2020. “About the program.” [https://phi-cdcfellows.org/about-us/phi-cdc-global-health-fellowship-program/]. Accessed 29 December 2020.
[10] Centers for Disease Control and Prevention (CDC). 2020. Official website. [https://www.cdc.gov/]. Accessed 29 December 2020.
[11] Department of Health and Human Services. 2020. Official website. [https://www.hhs.gov/]. Accessed 29 December 2020.
[12] Department of Agriculture. 2020. Official website. [https://www.usda.gov/]. Accessed 29 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: 1

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

The United States has an overarching national public health emergency response plan in place which addresses planning for multiple communicable diseases with epidemic or pandemic potential and is publicly available. Public health emergency planning exists in the context of overall disaster planning, set out in the National Preparedness System (NPS). The publicly available National Response Framework (NRF), last updated 2019, defines US doctrine for managing any type of disaster or emergency. The NRF consists of a base document and Emergency Support Function (ESF) Annexes. The Department of Health and Human Services (HHS) leads on ESF #8 - Public Health and Medical Services, with responsibility delegated to the Assistant Secretary for Preparedness and Response (ASPR). [1, 2] The ASPR was created under the Pandemic and All-Hazards Preparedness Act (PAHPA) 2006. The Act called for the establishment of a quadrennial National Health Security Strategy (NHSS). [3] The ASPR has published an NHSS for 2019-2022 and associated implementation plan, both of which are publicly available. These plan to improve interoperability among stakeholders (public and private, federal and state, and public health, disaster response and military) and raise capacity to quickly and effectively detect disease outbreaks and biological threats. They address newly emerging and re-emerging diseases such as pandemic influenza, Ebola virus, and Zika virus, the potential for these diseases to be animal-related, and related threats such as antimicrobial resistance and biological attacks. They call to modernize key areas such as cybersecurity, agile logistics, command and control, surveillance, laboratory testing and diagnostics, and decontamination capabilities; and address availability and dissemination of medical countermeasures. The NHSS and implementation plan are broad, and guide the development of more specific plans related to particular

diseases by federal agencies and state, local, tribal, and territorial (SLTT) partners. [4, 5] According to the 2016 Joint External Evaluation (JEE) of the IHR Core Capacities of the United States, the US' preparedness and response system was "outstanding". [6]

[1] Department of Health and Human Services (HHS). 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 29 December 2020.
[2] Federal Emergency Management Agency (FEMA), Department of Homeland Security (DHS). 2020. "National Response Framework." [https://www.fema.gov/emergency-managers/national-preparedness/frameworks/response]. Accessed 29 December 2020.
[3] Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services. 2019. "Pandemic and All Hazards Preparedness Act." [http://www.phe.gov/Preparedness/legal/pahpa/Pages/default.aspx]. Accessed 29 December 2020.
[4] Department of Health and Human Services (HHS). 2019. "National Health Security Strategy 2019-2022." [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/NHSS-Strategy-508.pdf]. Accessed 29 December 2020.
[5] Department of Health and Human Services (HHS). 2019. "National Health Security Strategy: Implementation plan 2019-2022." [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/2019-2022-nhss-ip-v508.pdf]. Accessed 29 December 2020.
[6] World Health Organisation (WHO). 2017. "Joint external evaluation of IHR core capacities of the United States of America - Mission report: June 2016." Geneva: World Health Organisation. [http://apps.who.int/iris/bitstream/10665/254701/1/WHO-WHE-CPI-2017.13-eng.pdf?ua=1&ua=1]. Accessed 29 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: 1

The United States' overarching national public health emergency response plan, which addresses planning for multiple communicable diseases with epidemic or pandemic potential, has been updated in the last 3 years. The US' national public health emergency response plan—the National Health Security Strategy (NHSS) and its implementation plan—was updated in 2019. The guiding framework for the NHSS—Emergency Support Function (ESF) #8 of the National Preparedness System (NPS)'s National Response Framework (NRF)—was also updated in 2019. The NRF defines US doctrine for managing any type of disaster or emergency, including epidemics and pandemics. The NRF consists of a base document and ESF Annexes. The Department of Health and Human Services (HHS) leads on ESF #8 - Public Health and Medical Services, with responsibility delegated to the Assistant Secretary for Preparedness and Response (ASPR). [1, 2] The ESF #8 Annex was last updated in June 2016. [3] The ASPR was created under the Pandemic and All-Hazards Preparedness Act (PAHPA) 2006. The Act called for the establishment of a quadrennial NHSS. [4] This addresses planning for countermeasures and non-pharmaceutical interventions for infectious diseases, including pandemic influenza, emerging and re-emerging pathogens, antimicrobial-resistant pathogens and CBRN threats; surveillance and situational awareness to prepare for outbreaks; and coordination among stakeholders for preparedness and response. The NHSS and associated implementation plan guide the development of more specific plans related to particular diseases by federal and local government agencies. The ASPR published the current NHSS and implementation plan in early 2019. [5, 6]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 26 January 2021.
[2] Federal Emergency Management Agency (FEMA), Department of Homeland Security (DHS). 30 Jan 2019. "National Planning Frameworks." [https://www.fema.gov/national-planning-frameworks]. Accessed 26 January 2021.
[3] Federal Emergency Management Agency (FEMA), Department of Homeland Security (DHS). 2016. "Emergency Support Function #8 – Public Health and Medical Services Annex." [https://www.fema.gov/sites/default/files/2020-07/fema_ESF_8_Public-Health-Medical.pdf]. Accessed 26 January 2021.
[4] Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services. 2019. "Pandemic and All Hazards Preparedness Act." [http://www.phe.gov/Preparedness/legal/pahpa/Pages/default.aspx]. Accessed 26 January 2021.
[5] Department of Health and Human Services. 2019. "National Health Security Strategy 2019-2022." [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/NHSS-Strategy-508.pdf]. Accessed 26 January 2021.
[6] Department of Health and Human Services. 2019. "National Health Security Strategy: Implementation plan 2019-2022." [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/2019-2022-nhss-ip-v508.pdf]. Accessed 26 January 2021.

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 United States' overarching national public health emergency response plan, which addresses planning for multiple communicable diseases with epidemic or pandemic potential, includes considerations for paediatric and other vulnerable populations. The National Response Framework (NRF), which plans for disasters and emergencies of all types, including epidemics and pandemics, states: "[T]his Framework is intended to enable the whole community to contribute to and benefit from national preparedness. This includes children; older adults; individuals with disabilities and others with access and functional needs; those from religious, racial, and ethnically diverse backgrounds; people with limited English proficiency; and owners of animals, including household pets and service and assistance animals. Their contributions must be integrated into the Nation's efforts, and their needs must be incorporated as the whole community plans and executes the core capabilities"; and "Children require a unique set of considerations across the core capabilities contained within this document. Their needs must be taken into consideration as part of any integrated planning effort." [1] Under the NRF, Emergency Support Function (ESF) Annex #8 - Public Health and Medical Services also includes consideration of children and adults with additional needs. [2] The National Health Security Strategy (NHSS) and associated implementation plan address planning for countermeasures and non-pharmaceutical interventions for infectious diseases, including pandemic influenza, emerging and re-emerging pathogens, antimicrobial-resistant pathogens and CBRN threats; surveillance and situational awareness to prepare for outbreaks; and coordination among stakeholders for preparedness and response. The NHSS states that "during response and recovery individuals with access and functional needs may have greater challenges accessing services or may be displaced for longer periods of time. Effective national health security requires planners, emergency responders, health professionals, public health specialists, educators, community organizations, families, and individuals to work together to address the needs of at-risk individuals (such as older adults, individuals with disabilities, individuals with limited English proficiency, people relying on home-health care, and children)." There is a statutory requirement for the NHSS to address the needs of at-risk individuals in health emergency planning. [3, 4]

[1] Federal Emergency Management Agency (FEMA), Department of Homeland Security (DHS). 2020. "National Response Framework." [https://www.fema.gov/emergency-managers/national-preparedness/frameworks/response]. Accessed 29 December 2020.
[2] Federal Emergency Management Agency (FEMA), Department of Homeland Security (DHS). 2016. "Emergency Support Function #8 – Public Health and Medical Services Annex." [https://www.fema.gov/media-library-data/1470149644671-642ccad05d19449d2d13b1b0952328ed/ESF_8_Public_Health_Medical_20160705_508.pdf]. Accessed 29 December 2020.
[3] Department of Health and Human Services (HHS). 2019. "National Health Security Strategy 2019-2022." [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/NHSS-Strategy-508.pdf]. Accessed 29 December 2020.
[4] Department of Health and Human Services (HHS). 2019. "National Health Security Strategy: Implementation plan 2019-2022." [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/2019-2022-nhss-ip-v508.pdf]. Accessed 29 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: 1

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: 1

The United States has specific mechanisms for engaging with the private sector to assist with outbreak emergency preparedness and response. The 2016 Joint External Evaluation (JEE) of the IHR Core Capacities of the United States notes the existence of strong public-private partnerships nationwide that help with preparedness and response to public health emergencies though multiple mechanisms (e.g. risk communication; medical countermeasures; immunization). [1] The Federal Emergency Management Agency (FEMA)'s National Business Emergency Operations Center (NBEOC) facilitates engagement between public and private sector stakeholders in support of Emergency Support Function #15 of the National Response Framework (NRF), regarding information sharing to prepare for, respond to and recover from disasters, including public health emergencies. [2, 3] The NBEOC supports "the ability of state, local tribal and territorial governments to respond to and recover from disasters, by connecting them with FEMA's regional private sector liaisons and the NBEOC's national network of private sector partners"; and to "assist FEMA's regional and joint field offices by identifying potential sources of operational support and providing situational awareness during response and recovery phases of a disaster". [3] The Centers for Disease Control and Prevention (CDC) provides guidelines for setting up collaboration with the private sector in order to achieve public health objectives, though these do not specifically mention outbreak preparedness and response. [4] The US also has mechanisms for engaging with the private sector in its international work to implement the Global Health Security

Agenda (GHSA) more broadly, building outbreak preparedness and response capacity overseas. These include the GHSA Consortium (GHSAC), GHSA Private-Sector Roundtable (PSRT), and the Next Generation for Global Health Security Network (NextGen). [5]

[1] World Health Organisation (WHO). 2017. "Joint external evaluation of IHR core capacities of the United States of America – Mission report: June 2016." Geneva: World Health Organisation. [http://apps.who.int/iris/bitstream/10665/254701/1/WHO-WHE-CPI-2017.13-eng.pdf?ua=1&ua=1]. Accessed 29 December 2020.
[2] Federal Emergency Management Agency (FEMA), Department of Homeland Security (DHS). 2020. "National Response Framework." [https://www.fema.gov/emergency-managers/national-preparedness/frameworks/response]. Accessed 29 December 2020.
[3] Federal Emergency Management Agency (FEMA). 2019. "National Business Emergency Operations Center (NBEOC) Fact Sheet". [https://www.fema.gov/sites/default/files/2020-03/nbeoc-fact-sheet_2019.pdf]. Accessed 29 December 2020.
[4] Centers for Disease Control and Prevention (CDC) Foundation. 2020. "Public and private partnerships and conflict of interest guidelines". [https://www.cdcfoundation.org/public-private-partnership-guidelines#]. Accessed 29 December 2020.
[5] Global Health Security Agenda. February 2018. "Implementing the Global Health Security Agenda: Progress and impact from US government investments." [https://www.cdc.gov/globalhealth/healthprotection/resources/pdf/GHSA-Report-_Feb-2018.pdf]. Accessed 29 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: 1

There is evidence that the United States has a policy, plan and/or guidelines in place to implement non-pharmaceutical interventions (NPIs) during an epidemic or pandemic for one disease, such as for respiratory illness like pandemic flu. The Centers for Disease Control and Prevention (CDC) provides educational materials, planning guidance and checklists, and research references for NPIs related to flu prevention for various settings, including home, schools, and work. [1] These materials are related to the guidance the CDC released in 2017 as "pre-pandemic planning guidelines for community mitigation strategies, including NPIs, that can be used to plan and prepare for a flu pandemic," along with a series of user-friendly guides to put the Guidelines into action in different settings. [2] However, these guidelines do not include language that says the plan can be used for other diseases. [2, 3] There is no mention of a policy, plan and/or guidelines in the National Health Security Strategy (NHSS) 2019-2022 or NHSS Implementation Plan, nor in the National Reponse Framework. [4, 5, 6]

[1] Centers for Disease Control and Prevention (CDC). 2020. "Nonpharmaceutical Interventions (NPIs)." [https://www.cdc.gov/phpr/pubs-links/2018/documents/2018_Preparedness_Report.pdf]. Accessed 6 January 2021.
[2] Centers for Disease Control and Prevention (CDC). 2020. "Nonpharmaceutical Interventions (NPIs): Planning Guidance and Checklists." [https://www.cdc.gov/nonpharmaceutical-interventions/tools-resources/planning-guidance-checklists.html]. Accessed 6 January 2021.
[3] Centers for Disease Control and Prevention (CDC). 21 April 2017. "Community mitigation guidelines to prevent pandemic influenza — United States, 2017 : Technical report 1: Chapters 1-4." [https://stacks.cdc.gov/view/cdc/44313]. Accessed 6 January 2021.

[4] Department of Health and Human Services. 2019. “National Health Security Strategy 2019-2022.” [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/NHSS-Strategy-508.pdf]. Accessed 6 January 2021.
[5] Department of Health and Human Services. 2019. “National Health Security Strategy: Implementation plan 2019-2022.” [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/2019-2022-nhss-ip-v508.pdf]. Accessed 6 January 2021.
[6] Federal Emergency Management Agency (FEMA), Department of Homeland Security (DHS). 2020. “National Response Framework.” [https://www.fema.gov/emergency-managers/national-preparedness/frameworks/response]. Accessed 6 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 the United States has activated their national emergency response plan for an infectious disease outbreak in the past year, and there is no evidence that the country has completed a national-level biological threat-focused exercise in the past year. Public health emergency planning exists in the context of overall disaster planning, set out in the National Preparedness System (NPS). The publicly available National Response Framework (NRF), last updated 2019, defines US doctrine for managing any type of disaster or emergency. The NRF consists of a base document and Emergency Support Function (ESF) Annexes. The Department of Health and Human Services (HHS) leads on ESF #8 - Public Health and Medical Services, with responsibility delegated to the Assistant Secretary for Preparedness and Response (ASPR). [1, 2] On March 13, 2020 the president declared an emergency for COVID-19 under Section 501(b) of the Stafford Act, which activates the National Response Framework (NRF). [3] There is no evidence with the WHO that the US has completed a national-level biological threat-focused exercise in the past year. [4] There is no evidence of an exercise completed in the past year from the Centers for Disease Control and Prevention or Federal Emergency Management Agency. [5, 6]

[1] Department of Health and Human Services (HHS). 20 Sep 2016. “International health regulations - Joint external evaluation of the United States of America: Self-assessment report.” [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 8 January 2021.
[2] Federal Emergency Management Agency (FEMA), Department of Homeland Security (DHS). 2020. “National Response Framework.” [https://www.fema.gov/emergency-managers/national-preparedness/frameworks/response]. Accessed 8 January 2021.
[3] National Conference of State Legislatures. 25 March 2020. “President Trump Declares State of Emergency for COVID-19.” [https://www.ncsl.org/ncsl-in-dc/publications-and-resources/president-trump-declares-state-of-emergency-for-covid-19.aspx]. Accessed 8 January 2021.
[4] World Health Organization. 2021. "Simulation Exercise." [https://extranet.who.int/sph/simulation-exercise]. Accessed 8 January 2021.

[5] Centers for Disease Control and Prevention. 2021. [https://www.cdc.gov/]. Keyword search. Accessed 8 January 2021.
[6] Federal Emergency Management Agency. 2021. [https://www.fema.gov/]. Keyword search. Accessed 8 January 2021.

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 the United States in the past year has identified a list of gaps and best practices in response and developed a plan to improve response capabilities. The Centers for Disease Control and Prevention (CDC) supports local health departments to prepare for and respond to public health emergencies, and the Federal Emergency Management Agency (FEMA) provides guidance and templates for after-action reviews of public health responses to emergencies of all kinds. [1, 2] Over a year ago, a CDC review of nationwide preparedness work, published in April 2018, noted that public health incidents in the past year had included Zika, Salmonella and Seoul Virus outbreaks (no biological attacks were noted). [1] There is no evidence of after-action review reports based on these or other disease outbreak incidents in the past year, either from the CDC, FEMA, the WHO or media reporting. [3, 4, 5] There is no evidence that the US has carried out a biological threat-focused IHR exercise with the WHO in recent years, or undergone an exercise to identify a list of gaps and best practices from such an exercise in the past year. [6] In December 2020, FEMA published National Incident Management System Basic Guidance for Public Information Officers, which provides Public Information Officers (PIOs) with operational practices to help PIOs perform their duties within the National Incident Management System (NIMS) Command and Coordination structures. Completing an After-Action Review (AAR) and participating in evaluation discussions is listed among the actions the PIO should take to deactivate a Joint Information Center when operational activities decline. [7] Among FEMA's preparedness webinars—which "focus on topics impacting individual and community preparedness"—a webinar on how organizations can document lessons learned from COVD-19 covers "how to prepare for and facilitate an After-Action Review" for Continuous Improvement. [8] The CDC's May 2020 Guidance for U.S. Centers for Disease Control and Prevention Staff for the Establishment and Management of Public Health Rapid Response Teams for Disease Outbreaks lists an After Action Review by the Rapid Response Team (RRT) as part of the suggested standard operating procedures during the post-deployment phase. [9] AARs are also mentioned in the Homeland Security Exercise and Evaluation Program (HSEEP) principles and approach document from January 2020. [10]

[1] Centers for Disease Control and Prevention (CDC). 2018. “Public health preparedness and response: 2018 national snapshot.” Apr 2018. [https://www.cdc.gov/phpr/pubs-links/2018/documents/2018_Preparedness_Report.pdf]. Accessed 8 January 2021.
[2] US Department of Homeland Security. January 2020. "Homeland Security Exercise and Evaluation Program (HSEEP)." [https://preptoolkit.fema.gov/documents/1269813/1269861/HSEEP_Revision_Jan20_Final.pdf/65bc7843-1d10-47b7-bc0d-45118a4d21da?t=1580851559070]. Accessed 8 January 2021.
[3] Centers for Disease Control and Prevention (CDC). “Center for Preparedness and Response.” [https://www.cdc.gov/cpr/index.htm]; and key word search of CDC website. Accessed 8 January 2021.
[4] Federal Emergency Management Agency (FEMA). 2021. [https://www.fema.gov/]. Key word search. Accessed 8 January 2021.[https://extranet.who.int/sph/after-action-review]. Accessed 8 January 2021.
[5] World Health Organisation (WHO). 2021. “After action review.” [https://extranet.who.int/sph/after-action-review]. Accessed 8 January 2021.
[6] World Health Organisation (WHO), Strategic Partnership for International Health Regulations (2005) and Health Security

(SPH). 2018. “Health security calendar.” [https://extranet.who.int/sph/calendar]. Accessed 8 January 2021.
[7] Federal Emergency Management Agency (FEMA). December 2020. "National Incident Management System Basic Guidance for Public Information Officers." [https://www.fema.gov/sites/default/files/documents/fema_nims-basic-guidance-public-information-officers_12-2020.pdf]. Accessed 8 January 2021.
[8] Federal Emergency Management Agency (FEMA). 2020. "Preparedness Webinars." [https://www.fema.gov/emergency-managers/individuals-communities/preparedness-webinars?fbclid=IwAR2Nw2qQKGh5ytoPVfB7C1mEGs9HUb5cP4v-74btPu4uGnAknYQK0xEmBMI]. Accessed 8 January 2021.
[9] Centers for Disease Control and Prevention (CDC). May 2020. “Guidance for U.S. Centers for Disease Control and Prevention Staff for the Establishment and Management of Public Health Rapid Response Teams for Disease Outbreaks.” [https://www.cdc.gov/coronavirus/2019-ncov/downloads/global-covid-19/RRTManagementGuidance-508.pdf]. Accessed 8 January 2021.

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 no evidence that the United States in the past year has undergone a national-level biological threat-focused exercise that has included private sector representatives. The Centers for Disease Control and Prevention (CDC) supports local health departments to prepare for and respond to public health emergencies, and the Federal Emergency Management Agency (FEMA) Homeland Security Exercise and Evaluation Program (HSEEP) provides a set guidance and templates for public health responses to emergencies of all kinds. [1, 2] There is no evidence of a national-level biological threat-focused exercise within the past year from the CDC, FEMA, the World Health Organization, or media reporting. [3, 4, 5, 6] There is no evidence that the US has carried out a biological threat-focused IHR exercise with the WHO in recent years, or undergone an exercise to identify a list of gaps and best practices from such an exercise in the past year. [7]

[1] Centers for Disease Control and Prevention (CDC). 2018. “Public health preparedness and response: 2018 national snapshot.” Apr 2018. [https://www.cdc.gov/phpr/pubs-links/2018/documents/2018_Preparedness_Report.pdf]. Accessed 8 January 2021.
[2] US Department of Homeland Security. January 2020. "Homeland Security Exercise and Evaluation Program (HSEEP)." [https://preptoolkit.fema.gov/documents/1269813/1269861/HSEEP_Revision_Jan20_Final.pdf/65bc7843-1d10-47b7-bc0d-45118a4d21da?t=1580851559070]. Accessed 8 January 2021.
[3] Centers for Disease Control and Prevention (CDC). “Center for Preparedness and Response.” [https://www.cdc.gov/cpr/index.htm]. Accessed 30 January 2021.
[4] Centers for Disease Control and Prevention (CDC). 2021. [https://www.fema.gov/]. Keyword search. Accessed 30 January 2021.
[5] Federal Emergency Management Agency (FEMA). 2021. [https://www.fema.gov/]. Keyword search. Accessed 30 January 2021.
[6] World Health Organization. 2021. "Simulation Exercise." [https://extranet.who.int/sph/simulation-exercise]. Accessed 30 January 2021.
[7] World Health Organisation (WHO), Strategic Partnership for International Health Regulations (2005) and Health Security (SPH). 2018. “Health security calendar.” [https://extranet.who.int/sph/calendar]. Accessed 8 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: 1

The United States has in place an emergency operations centre (EOC) for health-related emergencies, which is part of a wider network of EOCs. According to the 2016 Joint External Evaluation (JEE) self-assessment, the United States has "an extensive multiagency, multisectoral EOC network for coordinating information and resources to support public health incident management at all levels of government." [1] The national EOC for public health emergencies is that under the Centers for Disease Control and Prevention (CDC), operated by the Office of Public Health Preparedness and Response (OPHPR), Division of Emergency Operations (DEO). It is staffed 24 hours a day, 7 days a week, 365 days a year. [2]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 26 January 2021.
[2] Centers for Disease Control and Prevention (CDC). 2020. "CDC Emergency Operations Center (EOC)." [https://www.cdc.gov/cpr/eoc.htm]. Accessed 26 January 2021.

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 national emergency operations centre (EOC) for public health emergencies at the Centers for Disease Control and Prevention (CDC) is required to conduct a drill at least once a year. The CDC EOC's website states that it conducts exercises, but does not state the frequency. [1, 2] The 2016 Joint External Evaluation (JEE) self-assessment notes that as a federal agency involved in disaster response, the CDC must participate in routine training and exercising through the Department for Homeland Security National Exercise Program: an ongoing programme of exercises on a two-year cycle, culminating in a national exercise. This implies that the CDC's EOC must participate in multiple sub-national drills each year, and a national drill every two years. [3] The CDC also provides financial support to sub-national public health EOCs through the Public Health Emergency Preparedness (PHEP) programme. The PHEP cooperative agreement requires local health authorities receiving PHEP funding to conduct annual drills or real incident responses, as well as three annual medical countermeasure drills and a hospital surge test. [4, 5]

[1] Centers for Disease Control and Prevention (CDC). 2016. "CDC Emergency Operations Center: How an EOC works." [https://www.cdc.gov/cpr/eoc/how-eoc-works.htm]. Accessed 29 December 2020.
[2] Centers for Disease Control and Prevention (CDC). "The public health preparedness and response 2018 national snapshot." [https://www.cdc.gov/cpr/pubs-links/2018/index.htm]. Accessed 29 December 2020.
[3] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-

assessment.pdf]. Accessed 29 December 2020.
[4] Centers for Disease Control and Prevention (CDC). 2019. "Public Health Emergency Preparedness (PHEP) Cooperative Agreement." [https://www.cdc.gov/cpr/readiness/00_docs/PHEP_Cooperative_Agreement_TP19-1901_RevisedMay3_508Compliant.pdf]. Accessed 29 December 2020.
[5] Centers for Disease Control and Prevention (CDC). 2017. "2017-2022 Hospital Preparedness Program (HPP) – Public Health Emergency Preparedness (PHEP) Cooperative Agreement CDC-RFA-TP17-1701." [https://www.cdc.gov/cpr/readiness/00_docs/PHEP-Funding-CDC-RFA-TP17-1701.pdf]. Accessed 29 December 2020.

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 insufficient evidence that the national public health emergency operations centre (EOC) at the Centers for Disease Control and Prevention (CDC) can conduct a coordinated emergency response within 120 minutes of the identification of the public health emergency, and that regular drills are conducted, though details of a specific drill proving this in the past year are not available. The 2016 Joint External Evaluation of the IHR Core Capabilities of the United States confirms the US' capability to activate any of the EOCs in its public and animal health sectors within the required timeframe of two hours. EOC activation is guided by the National Incident Management System (NIMS), which does not specify response times. [1, 2] The CDC's EOC has constant staffing (24 hours a day, 7 days a week), indicating that immediate activation is always possible. [3] The CDC provides funding for emergency preparedness to sub-national public health authorities under cooperative agreements. States are required to participate in drills that show response times of 45 minutes for exchanging emergency notifications between the CDC and on-call epidemiologists and laboratorians. [4] The CDC EOC conducts regular exercises under its own system and as part of the National Exercise Program run by the Department for Homeland Security (DHS). [5, 6] The guidance from DHS does not specify response times. [7] No reports or press releases are available with details of CDC EOC activation times in real responses or drills in the past year. [8, 9] There is no additional evidence available from the Department of Health and Human Services or its CDC. [10, 11]

[1] World Health Organisation (WHO). 2017. "Joint external evaluation of IHR core capacities of the United States of America – Mission report: June 2016." Geneva: World Health Organisation. [http://apps.who.int/iris/bitstream/10665/254701/1/WHO-WHE-CPI-2017.13-eng.pdf?ua=1&ua=1]. Accessed 9 January 2021.
[7] Federal Emergency Management Agency (FEMA). December 2020. "National Incident Management System Basic Guidance for Public Information Officers." [https://www.fema.gov/sites/default/files/documents/fema_nims-basic-guidance-public-information-officers_12-2020.pdf]. Accessed 8 January 2021.
[3] Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention (CDC). 2020. "Emergency Operations Centers: CDC Emergency Operations Center (EOC)." [https://www.cdc.gov/phpr/eoc.htm]. Accessed 9 January 2021.
[4] Centers for Disease Control and Prevention (CDC). "2017-2022 Hospital Preparedness Program (HPP) - Public health Emergency Preparedness (PHEP) Cooperative Agreement." [https://www.cdc.gov/phpr/readiness/00_docs/PHEP-Funding-CDC-RFA-TP17-1701.pdf]. Accessed 9 January 2021.
[5] Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention (CDC). 2020. "CDC Emergency Operations Center: How an EOC works." [https://www.cdc.gov/phpr/eoc/how-eoc-works.htm]. Accessed 9 January 2021.

[6] Department of Health and Human Services. 20 Sep 2016. “International health regulations - Joint external evaluation of the United States of America: Self-assessment report.” [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 9 January 2021.
[7] US Department of Homeland Security. January 2020. "Homeland Security Exercise and Evaluation Program (HSEEP)." [https://preptoolkit.fema.gov/documents/1269813/1269861/HSEEP_Revision_Jan20_Final.pdf/65bc7843-1d10-47b7-bc0d-45118a4d21da?t=1580851559070]. Accessed 9 January 2021.
[8] Centers for Disease Control and Prevention (CDC). 2018. “The public health preparedness and response 2018 national snapshot.” [https://www.cdc.gov/cpr/pubs-links/2018/index.htm]. Accessed 9 January 2021.
[9] Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR). 2020. Public Health Emergency official website. [http://www.phe.gov/emergency/pages/default.aspx]. Accessed 9 January 2021.
[10] US Department of Health and Human Services. 2021. [https://www.hhs.gov/]. Keyword search. Accessed 27 January 2021.
[11] US Centers for Disease Control and Prevention. 2021. [https://www.cdc.gov/]. Keyword search. Accessed 27 January 2021.

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 public evidence that the public health and national security authorities have carried out exercises to respond to a potential deliberate biological event, and there are procedures for public health and security authorities to jointly respond to such an event. In 2018, the Federal Bureau of Investigation (FBI) Weapons of Mass Destruction (WMD) Directorate and Centers for Disease Control and Prevention (CDC) ran several Joint Criminal-Epidemiological (Crim-Epi) Investigations Workshops in locations across the US. These included tabletop exercises to promote the Crim-Epi Model for conducting joint investigations during a suspicious biological incident. Learning objectives included “Understand[ing] roles, responsibilities, and authorities of law enforcement and public health during a suspicious biological incident”. [1] The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) collaborates with the Federal Bureau of Investigation (FBI) to prepare for biological events, with 2019 highlights of this coordination describing "a Joint Criminal-Epidemiological Investigations Workshop developed with the FBI, NCEZID trained select global public health and law enforcement professionals to work together to identify, assess, and investigate suspicious biological threats." [2] More detail on health security coordination during a bioterrorism incident is provided in CDC and Criminal and FBI's Epidemiological Investigation Handbook, last updated in 2018. [3] The 2016 Joint External Evaluation (JEE) self-assessment notes that several states have also developed MOUs between their health departments and the FBI. [4]

[1] National Association of County and City Health Officials. 3 Jan 2018. “FBI and CDC Announces 2018 Schedule for Joint Criminal-Epidemiological Investigations Workshops.” [http://nacchopreparedness.org/fbi-and-cdc-announces-2018-schedule-for-joint-criminal-epidemiological-investigations-workshops/]. Accessed 9 January 2021.
[2] Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). 2020. “Collaborating to make a difference.” [https://www.cdc.gov/ncezid/what-we-do/2019-highlights/collaborating-to-make-a-difference.html]. Accessed 9 January 2021.
[3] Centers for Disease Control and Prevention (CDC) and Federal Bureau of Investigation (FBI). 2018. “Criminal and Epidemiological Investigation Handbook - 2018 Domestic Edition.” [https://www.fbi.gov/file-repository/criminal-and-epidemiological-investigation-handbook.pdf/view]. Accessed 9 January 2021.
[4] Department of Health and Human Services. 20 Sep 2016. “International health regulations - Joint external evaluation of the United States of America: Self-assessment report.” [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 9 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: 1

The United States risk communication plan outlines how messages will reach populations and sectors with different communications needs. The 2016 Joint External Evaluation of the IHR Core Capacities of the United States and 2016 self-assessment confirm that guidance documents on public risk communication consider community-specific needs, including social, religious, cultural, political and economic aspects; and that information is provided in different languages where appropriate. The main risk communication documents referenced are CDC's Crisis and Emergency Risk Communication (CERC) programme and the National Response Framework Incident Communications Emergency Policy and Procedures (ICEPP). [1, 2] The CDC's "Emergency preparedness and response" website provides information related to public health emergency preparedness and response for specific groups of people, including older people, parents, people with chronic illnesses or disabilities, evacuees, the homeless, and tribal communities. [3] It also provides public health officials with advice on identifying special, vulnerable and at-risk groups and reaching them in an emergency, including through the creation of community leader networks. [4] The CERC manual includes sections on "Other communication channels", which describes the need to use multiple communication methods to reach all target audiences; and on "Messages and audiences", which describes the need to consider the needs, cultural background, community history, location, and values of the audience. [5]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 9 January 2021.
[2] World Health Organisation (WHO). 2017. "Joint external evaluation of IHR core capacities of the United States of America - Mission report: June 2016." Geneva: World Health Organisation. [http://apps.who.int/iris/bitstream/10665/254701/1/WHO-WHE-CPI-2017.13-eng.pdf?ua=1&ua=1]. Accessed 9 January 2021.
[3] Centers for Disease Control and Prevention (CDC). 2018. "Information for specific groups."

[https://www.emergency.cdc.gov/groups.asp]. Accessed 9 January 2021.
[4] Centers for Disease Control and Prevention (CDC). 2018. "Reaching At-Risk Populations in an Emergency." [https://www.emergency.cdc.gov/workbook/index.asp]. Accessed 9 January 2021.
[5] Centers for Disease Control and Prevention (CDC). 2018. "CERC manual." [https://emergency.cdc.gov/cerc/manual/index.asp]. Accessed 9 January 2021.

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

The United States has in place, as part of the national public health emergency response plan, a section detailing a risk communication plan that is specifically intended for use during a public health emergency. The US government provides guidance on risk communication as part of its general disaster management system and in information relating specifically to public health emergencies. The Incident Communications Emergency Policy and Procedures (ICEPP), part of the National Response Framework (NRF) for disasters and emergencies of all kinds, provide guidance for risk communicators during a coordinated federal response. [1] The ICEPP is comprised of two annexes from the NRF: the Public Affairs Support Annex, which describes interagency policies and procedures for communications with the public, and the Emergency Support Function #15 - External Affairs Annex, which outlines the functions, resources, and capabilities for external affairs. [2, 3] The ESF #15 Standard Operating Procedures (SOP) establish specific procedures and protocols for ESF #15 support during an incident. [4] The Centers for Disease Control and Prevention (CDC) under the Department of Health and Human Services is responsible for leading public health emergency preparedness and response. CDC's Crisis and Emergency Risk Communication (CERC) programme "provides trainings, tools, and resources to help health communicators, emergency responders, and leaders of organizations communicate effectively during emergencies." Details of the programme and a CERC manual are available from the CDC's website. [1, 5, 6]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 29 December 2020.
[2] Federal Emergency Management Agency (FEMA). January 2008. "Public Affairs Support Annex." [https://www.fema.gov/pdf/emergency/nrf/nrf-support-pa.pdf]. Accessed 27 January 2021.
[3] Federal Emergency Management Agency (FEMA). June 2016. "ESF #15 – External Affairs Annex." [https://www.fema.gov/sites/default/files/2020-07/fema_ESF_15_External-Affairs.pdf]. Accessed 27 January 2021.
[4] US Department of Homeland Security. July 2019. "Emergency Support Function 15 - Standard Operating Procedures" [https://www.fema.gov/sites/default/files/2020-10/fema_esf-15_sop_2019.pdf]. Accessed 27 January 2021.
[5] Centers for Disease Control and Prevention (CDC). 2018. "Crisis & Emergency Risk Communication (CERC)." [https://emergency.cdc.gov/cerc/index.asp]. Accessed 29 December 2020.
[6] Centers for Disease Control and Prevention (CDC). 2018. "CERC manual". [https://emergency.cdc.gov/cerc/manual/index.asp]. Accessed 29 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

There is evidence that the risk communication plan for the United States designates a specific position within the government to serve as the primary spokesperson to the public during a public health emergency. The US government provides guidance on risk communication as part of its general disaster management system and in information relating specifically to public health emergencies. According to the 2016 Joint External Evaluation of IHR Core Capacities of the US and self-assessment report, the country's departments and agencies have trained spokespersons within communication offices or divisions,. [1, 2] The Incident Communications Emergency Policy and Procedures (ICEPP), part of the National Response Framework (NRF) for disasters and emergencies of all kinds, provide guidance for risk communicators during a coordinated federal response. [2] However, the NRF annexes and standard operating procedures that comprise the ICEPP do not designate a specific position to serve as the primary spokesperson during a public health emergency. [3, 4, 5] The Centers for Disease Control and Prevention (CDC) under the Department of Health and Human Services is responsible for leading public health emergency preparedness and response. CDC's Crisis and Emergency Risk Communication (CERC) programme "provides trainings, tools, and resources to help health communicators, emergency responders, and leaders of organizations communicate effectively during emergencies." Details of the programme and a CERC manual are available from the CDC's website. [2, 6, 7] The CERC manual includes a chapter titled Spokesperson, last updated in 2014, which provides guidance on the role, responsibilities, and effective communication of a spokesperson. However, the CERC manual is not intended for a specific position within the government to serve as the primary spokesperson, but rather serve as guidelines for "organizations." [8]

[1] World Health Organisation (WHO). 2017. "Joint external evaluation of IHR core capacities of the United States of America – Mission report: June 2016." Geneva: World Health Organisation. [http://apps.who.int/iris/bitstream/10665/254701/1/WHO-WHE-CPI-2017.13-eng.pdf?ua=1&ua=1]. Accessed 3 January 2021.
[2] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 3 January 2021.
[3] Federal Emergency Management Agency (FEMA). January 2008. "Public Affairs Support Annex." [https://www.fema.gov/pdf/emergency/nrf/nrf-support-pa.pdf]. Accessed 27 January 2021.
[4] Federal Emergency Management Agency (FEMA). June 2016. "ESF #15 – External Affairs Annex." [https://www.fema.gov/sites/default/files/2020-07/fema_ESF_15_External-Affairs.pdf]. Accessed 27 January 2021.
[5] US Department of Homeland Security. July 2019. "Emergency Support Function 15 - Standard Operating Procedures." [https://www.fema.gov/sites/default/files/2020-10/fema_esf-15_sop_2019.pdf]. Accessed 27 January 2021.
[6] Centers for Disease Control and Prevention (CDC). 2018. "Crisis & Emergency Risk Communication (CERC)." [https://emergency.cdc.gov/cerc/index.asp]. Accessed 3 January 2021.
[7] Centers for Disease Control and Prevention (CDC). 2018. "CERC manual". [https://emergency.cdc.gov/cerc/manual/index.asp]. Accessed 29 December 2020.
[8] Centers for Disease Control and Prevention (CDC). 2014. "Crisis & Emergency Risk Communication (CERC): Spokesperson." [https://emergency.cdc.gov/cerc/ppt/CERC_Spokesperson.pdf]. Accessed 3 January 2021.

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 that the public health system in the United States has actively shared messages via online media platforms to inform the public about ongoing public health concerns and/or dispel rumors, misinformation or disinformation in the past year. In the US, the Centers for Disease Control and Prevention (CDC), under the Department for Health and Human Services, utilises website updates and social media platforms to inform the public about public health emergencies. The CDC updates pages on its own website with alerts on local and global disease outbreaks and related travel advice. [1, 2] The CDC's Office of Public Health Preparedness and Response (OPHPR) has Twitter and Facebook accounts which provide public alerts about disease outbreaks and public health emergencies. [3, 4] Posts on these platforms from January 2021 include a description of the importance of social distancing in helping protect against COVID-19—with a image overlayed by the word "FACT"—and a link to the CDC's COVID Data Tracker describing the data available therein. [5, 6] Beyond public health emergencies, the public health system regularly shares information on health concerns. For instance, the CDC's Public Health Matters blog post from January 2020 shared information about preparation and protection from flu. [7] The CDC's general Twitter and Facebook accounts provide similar information and updates, such as a February 2020 Twitter post linking to information on vaccinating against measles. [8]

[1] Centers for Disease Control and Prevention (CDC). 2021. "CDC current outbreak list". [https://www.cdc.gov/outbreaks/index.html]. Accessed 5 January 2021.
[2] Centers for Disease Control and Prevention (CDC). 2021. "Travel health notices." [https://wwwnc.cdc.gov/travel/notices]. Accessed 5 January 2021.
[3] Twitter. 2021. Account: "CDC Emergency (@CDCemergency)." [https://twitter.com/cdcemergency?lang=en]. Accessed 5 January 2021.
[4] Facebook. 2021. Account: "CDC Emergency Preparedness and Response." [https://www.facebook.com/pg/cdcemergency/about/?ref=page_internal]. Accessed 5 January 2021.
[6] Facebook. 4 January 2021. Post: "COVID Data Tracker." [https://www.facebook.com/CDC/photos/a.184668026025/10158761289326026/]. Accessed 5 January 2021.
[7] Centers for Disease Control and Prevention (CDC). 22 January 2020. "Five Things You Need to Know About Flu Season." [https://blogs.cdc.gov/publichealthmatters/2020/01/fivethingsflu/]. Accessed 30 January 2021.
[8] Twitter. 25 February 2020. Post: "Measles - Maintaining Disease Elimination and Enhancing Vaccine Confidence." [https://twitter.com/CDCgov/status/1232360618990108673]. Accessed 5 January 2021.

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: 0

There is evidence that senior leaders in the United States have shared misinformation or disinformation on infectious diseases in the past two years. Researchers out of Cornell University identified over 1.1 million media articles mentioning COVID-19 misinformation, with 38 percent of these mentioning President Trump within the misinformation conversation, as reported on by The New York Times in October 2020. [1, 2] Examples of misinformation include President Trump suggesting publicly that injecting patients with disinfectants or exposing patients to "ultraviolet or just very powerful light" might help treat coronavirus. [3] The Cornell study found that after these statements were made, "there were more than 30,000 articles in the 'miracle cures' category, up from fewer than 10,000 only days earlier." [2]

[1] Evanega, S., Lynas, M., Adams, J., Smolenyak, K. 2020. "Coronavirus misinformation: quantifying sources and themes in the COVID-19 'infodemic'." JMIR Preprints. [https://int.nyt.com/data/documenttools/evanega-et-al-coronavirus-misinformation-submitted-07-23-20-1/080839ac0c22bca8/full.pdf]. Accessed 9 January 2021.
[2] Stolberg, S.G. and Weiland, N. "Study Finds 'Single Largest Driver' of Coronavirus Misinformation: Trump." The New York Times. [https://www.nytimes.com/2020/09/30/us/politics/trump-coronavirus-misinformation.html]. Accessed 9 January 2021.
[3] Reality Check team, BBC News. 24 April 2020. "Coronavirus: Trump's disinfectant and sunlight claims fact-checked." [https://www.bbc.com/news/world-us-canada-52399464]. Accessed 9 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: 87.27

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: 123.69

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: 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: 0

In the past year, the United States has issued a restriction, without international/bilateral support, on the export of medical goods due to an infectious disease outbreak. On April 10, 2020, the Federal Emergency Management Agency (FEMA) issued a restriction on exports of certain PPE, in response to the COVID-19 pandemic. [1] On August 6, 2020, a temporary final rule extended and modified the restrictions issued in April, which was again extended and modified on December 31, 2020. [2, 3] The rule as of December 31, 2020 list of PPE subject to this restriction include surgical N95 respirators, nitrile gloves and exam glove, and surgical gowns and surgical isolation gowns, and includes certain exemptions, such as sealed, sterile medical kits and diagnostic testing kits and shipments to Overseas U.S. Military Addresses, Foreign Service Posts. [3, 4] However, there is no evidence—including from media outlets—that these have international/bilateral support.

[1] Federal Register. 10 April 2020. "Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic Use." [https://www.federalregister.gov/documents/2020/04/10/2020-07659/prioritization-and-allocation-of-certain-scarce-or-threatened-health-and-medical-resources-for]. Accessed 9 January 2021.
[2] Sanctions and Export Controls Update, a blog by Baker McKenzie. 10 August 2020. "FEMA Extends the Duration of Restrictions on Exports of PPE Products from the United States and Modifies PPE Products Covered."[https://sanctionsnews.bakermckenzie.com/fema-extends-the-duration-of-restrictions-on-exports-of-ppe-products-from-the-united-states-and-modifies-ppe-products-covered/#:~:text=The%20original%20restrictions%20on%20exports,earlier%20by%20the%20FEMA%20Administrator.]. Accessed 9 January 2021.

[3] Federal Emergency Management Agency. 31 December 2021. "Allocation Rule on Exports of Personal Protective Equipment." [https://www.fema.gov/fact-sheet/allocation-rule-personal-protective-equipment-exports]. Accessed 9 January 2021.
[4] Federal Register. 31 December 2021. "Prioritization and Allocation of Certain Scarce and Critical Health and Medical Resources for Domestic Use." [https://www.federalregister.gov/documents/2020/12/31/2020-29060/prioritization-and-allocation-of-certain-scarce-and-critical-health-and-medical-resources-for]. Accessed 9 January 2021.

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, the United States has issued a restriction, without international/bilateral support, on the export/import of non-medical goods due to an infectious disease outbreak. In April 2020, the news agency Reuters reported a list of countries that had applied for or were considering trade restrictions on food or agriculture products due to the coronavirus, and the list did not include the United States. [1] In June 2020, the Secretary of Agriculture and FDA Commissioner issued a statement regarding food export restrictions pertaining to COVID-19, concluding, “There is no evidence that people can contract COVID-19 from food or from food packaging. The U.S. food safety system, overseen by our agencies, is the global leader in ensuring the safety of our food products, including product for export.” [2] The International Trade Center maintains a list of COVID-19 Temporary Trade Measures the identifies what restrictions countries have imposed for medical and non-medical supplies due to the COVID-19 pandemic, and this list does not mention the US posing any restrictions on the export/import of non-medical goods. [3] The Foreign Agricultural Service of the US Department of Agriculture (USDA) reported in December 2020 that US exports to Mexico declined by five percent from the previous fiscal year, due to the COVID-19 pandemic, but there is no evidence that there were any restrictions invovled. [4] The US Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC), USDA, and US Department of States have no additional information on restrictions of export/import of non-medical goods due to coronavirus or another infectious disease outbreak. [5, 6, 7, 8]

[1] Reuters Staff. 3 April 2020. “Trade restrictions on food exports due to the coronavirus pandemic.” Reuters. [https://www.reuters.com/article/us-health-coronavirus-trade-food-factbox/trade-restrictions-on-food-exports-due-to-the-coronavirus-pandemic-idUSKBN21L332]. Accessed 10 January 2021.
[2] US Food and Drug Administration. 24 June 2020. “Coronavirus (COVID-19) Update: Joint Statement from USDA and FDA on Food Export Restrictions Pertaining to COVID-19.” [https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-joint-statement-usda-and-fda-food-export-restrictions-pertaining-covid]. Accessed 10 January 2021.
[3] Internaional Trade Centre. 7 December 2020. "COVID-19 Temporary Trade Measures." [https://www.macmap.org/covid19].Accessed 10 January 2021.
[4] US Department of Agriculture, Foreign Agricultural Service. 16 December 2020. "Mexico: US Exports to Mexico Down on Reduced Demand Due to COVID 19 Effects." [https://www.fas.usda.gov/data/mexico-us-exports-mexico-down-reduced-demand-due-covid-19-effects].Accessed 10 January 2021.
[5] US Department of Health and Human Services. [https://www.hhs.gov/]. Keyword search. Accessed 10 January 2021.
[6] US Centers for Disease Control and Prevention. [https://www.cdc.gov/]. Keyword search. Accessed 10 January 2021.
[7] US Department of Agriculture. [https://www.usda.gov/]. Keyword search. Accessed 10 January 2021.
[8] US Department of State. [https://www.state.gov/]. Keyword search. Accessed 10 January 2021.

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, the United States has implemented restrictions, without international/bilateral support, on travelers arriving from a specific country or countries due to an infectious disease outbreak. Between January 31, 2020 and September 14, 2020, there have been several Presidential proclamations restricting the entry of certain travelers into the United States in an effort to help slow the spread of coronavirus disease 2019 (COVID-19). According to the Centers for Disease Control and Prevention (CDC), as of September 14, 2020, "with specific exceptions, foreign nationals who have been in any of the following countries during the past 14 days may not enter the United States", with China, Iran, European Schengen area, United Kingdom, Republic of Ireland, and Brazil listed. [1] In March 2020, the US established mutual agreements with Canada and Mexico to limit non-essential travel at land ports of entry and ferry terminals to reduce the spread of COVID-19 bteween the US and these bordering countries. [2, 3] However, there is no evidence, including from media outlets, that there was international/bilateral support reached with other countries for which the US issued travel restrictions on arriving travelers. The CDC also publishes travel health notices for travel to other countries. A level 3 warning is the most serious, and advises against non-essential travel, but does not ban it. The CDC had one level 3 warnings as of January 4, 2021. [4] Separately, the CDC publishes a list of COVID-19 Travel Recommendations for travel to other countries during the COVID-19 pandemic, ranging from Level 4, very high, to Level 1, low, as well as "level unknown." As of January 4, 2021, the majority of countries listed fall under Level 4. [5] An October 2020 article in The Washington Post describes the travel restrictions in place during the COVID-19 pandemic, both by the US and other countries, as ineffective at stopping or slowing the spread of the virus. [6]

[1] Centers for Disease Control and Prevention (CDC), COVID-19. 2020. “Travelers Prohibited from Entry to the United States.” [https://www.cdc.gov/coronavirus/2019-ncov/travelers/from-other-countries.html]. Accessed 10 January 2021.
[2] US Department of Homeland Security. 20 March 2020. "Joint Statement on US-Canada Joint Initiative: Temporary Restriction of Travelers Crossing the US-Canada Land Border for Non-Essential Purposes." [https://www.dhs.gov/news/2020/03/20/joint-statement-us-canada-joint-initiative-temporary-restriction-travelers-crossing]. Accessed 30 January 2021.
[3] US Department of Homeland Security. 20 March 2020. "Joint Statement on US-Mexico Joint Initiative to Combat the COVID-19 Pandemic." [https://www.dhs.gov/news/2020/03/20/joint-statement-us-mexico-joint-initiative-combat-covid-19-pandemic]. Accessed 30 January 2021.
[4] Centers for Disease Control and Prevention (CDC). 2021. “Travel health notices.” [https://wwwnc.cdc.gov/travel/notices]. Accessed 10 January 2021.
[5] Centers for Disease Control and Prevention (CDC). 2021. “COVID-19 Travel Recommendations.” [https://wwwnc.cdc.gov/travel/noticescovid19]. Accessed 10 January 2021.
[6] Bollyky, T.J., Nuzzo, J.B. 1 October 2020. "Trump’s ‘early’ travel ‘bans’ weren’t early, weren’t bans and didn’t work." The Washington Post. [https://www.washingtonpost.com/outlook/2020/10/01/debate-early-travel-bans-china/]. Accessed 10 January 2021.

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: 261.2

2017

WHO; national sources

4.1.1b

Nurses and midwives per 100,000 people

Input number

Current Year Score: 1454.8

2017

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: 1

The United States has a health workforce strategy in place, updated in the past five years, to identify fields where there is an insufficient workforce and strategies to address these shortcomings. The US Department of Health and Human Services (HHS) has a strategy in place for 2018-2022. The 2016 Joint External Evaluation (JEE) self-assessment noted that "while public health workforce tracking is not comprehensive in the United States, there are systems in place to monitor the numbers of epidemiologists and clinical health professionals around the country." The National Center for Health Workforce Analysis at the Health Resources and Services Administration (HRSA) leads on healthcare workforce data collection, analysis and projections. [1] Under the HHS' strategic plan for financial years 2018-2022, workforce analysis and planning is addressed under "Strategic Objective 1.4: Strengthen and expand the healthcare workforce to meet America's diverse needs". [2, 3] While this draws on some HRSA data and analysis which is older than five years, such as the 2013 US health workforce chartbook, it also makes use of HRSA projections on human resources needs. [4] The latter are published regularly, focussing

on different occupational areas, and a number have been published in the 2016-2018 period. [5] Strategic Objective 1.4 of the HHS strategic plan covers strategies to address workforce shortages. For example, it aims to expand the healthcare workforce in line with rising and changing demand through the training and engagement of emerging health occupations, such as community health workers and community partners to enhance the provision of culturally, linguistically, and disability-appropriate services; and aims to better serve the aging population by integration geriatrics and primary care; and lists several strategies for reducing provider shortages in rural and underserved communities. [3]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 29 December 2020.
[2] Department of Health and Human Services (HHS). 2019. "Strategic plan FY 2018-2022." [https://www.hhs.gov/about/strategic-plan/index.html]. Accessed 29 December 2020.
[3] Department of Health and Human Services (HHS). 2020. "Strategic Goal 1: Reform, strengthen, and modernize the nation's healthcare system." Strategic plan FY 2018-2022. [https://www.hhs.gov/about/strategic-plan/strategic-goal-1/index.html]. Accessed 29 December 2020.
[4] Health Resources and Services Administration (HRSA). 2020. "Review Health Workforce Research." [https://bhw.hrsa.gov/health-workforce-analysis/research]. Accessed 29 December 2020.
[5] Health Resources and Services Administration (HRSA). 2020. "Projecting Health Workforce Supply and Demand." [https://bhw.hrsa.gov/health-workforce-analysis/research/projections]. Accessed 29 December 2020.

4.1.2 Facilities capacity

4.1.2a

Hospital beds per 100,000 people

Input number

Current Year Score: 287

2017

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

The United States has 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. US has several facilities with the capacity to isolate patients with highly-communicable diseases in biocontainment units, and other isolation facilities suitable for highly-communicable diseases are common in hospitals across the country. At the time of the Ebola outbreak in 2014 there were high-level containment care (HLCC) facilities at 4 locations: Emory University in Atlanta, Georgia; the University of Nebraska Medical Center in Omaha, Nebraska; the National Institutes of Health (NIH) facility in Bethesda, Maryland; and the Care and Isolation Unit at St. Patrick Hospital in Missoula, Montana. HLCC facilities involve for instance negative pressure, restricted access, enclosed bathrooms, closed-circuit video cameras and observation windows, emergency decontamination showers,

and on-site autoclaves. [1] In 2015, Johns Hopkins Hospital in Maryland also opened a biocontainment unit for HLCC. [2] HLCC facilities received more attention in the wake of the Ebola outbreak, and the Centers for Disease Control and Prevention (CDC) established a system under which 55 hospitals were certified as Ebola treatment centres by the end of the outbreak in 2015. It is not clear whether these hospitals have maintained their facilities since the crisis, but the CDC continues to recommend that states maintain them and to provide guidance on doing so. [1, 3] According to the 2016 Joint external evaluation (JEE) of the United States of America: Self-assessment report, isolation rooms (or rooms that can be adapted for isolation) are commonly available in tertiary and acute care hospitals throughout the country, set up with guidance from the CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). [4] Isolation facilities are not addressed in the 2016 JEE mission report. [5] The COVID-19 pandemic is prompting more institutions to invest in new biocontainment facilities. [6] The US Department of Defense announced in September 2020 that the Army has partnered with the University of Pittsburgh Medical Center to develop "an individual biocontainment unit [IBU] that uses negative pressure to suction the air from around a patient to filter out viral particles. This prevents environmental contamination and limits exposure to SARS-CoV-2" and the FDA is considering an emergency use authorization for the IBUs. [7]

[1] Kortepeter, M, et al. 2016. “Containment care units for managing patients with highly hazardous infectious diseases: A concept whose time has come.” The Journal of Infectious Diseases, 214 (supp_3), 15 Oct 2016. [https://academic.oup.com/jid/article/214/suppl_3/S137/2218714]. Accessed 9 Jaunary 2021.
[2] Johns Hopkins Medicine. 2020. “Biocontainment Unit (BCU)/BCU news.” [https://www.hopkinsmedicine.org/biocontainment-unit/news.html]. Accessed 9 Jaunary 2021.
[3] Centers for Disease Control and Prevention (CDC). 2018. “Interim guidance for U.S. hospital preparedness for patients under investigation (PUIs) or with confirmed Ebola virus disease (EVD): A framework for a tiered approach.” [https://www.cdc.gov/vhf/ebola/healthcare-us/preparing/hospitals.html]. Accessed 9 Jaunary 2021.
[4] Department of Health and Human Services. 20 Sep 2016. “International health regulations - Joint external evaluation of the United States of America: Self-assessment report.” [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 9 Jaunary 2021.
[5] World Health Organisation (WHO). 2017. “Joint external evaluation of IHR core capacities of the United States of America – Mission report: June 2016.” Geneva: World Health Organisation. [http://apps.who.int/iris/bitstream/10665/254701/1/WHO-WHE-CPI-2017.13-eng.pdf?ua=1&ua=1]. Accessed 9 Jaunary 2021.
[6] Allen, J. 11 November 2020. “The Evolving Role of Biocontainment Facilities in Response to COVID-19.” Tradeline.[https://www.tradelineinc.com/reports/2020-11/evolving-role-biocontainment-facilities-response-covid-19]. Accessed 9 Jaunary 2021.
[7] Conant, J. 10 September 2020. “Innovative Biocontainment Unit Shows Promise.” US Department of Defense, Army.[https://www.defense.gov/Explore/Features/Story/Article/2340471/innovative-biocontainment-unit-shows-promise/]. Accessed 9 Jaunary 2021.

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 United States has demonstrated capacity to expand isolation capacity in response to an infectious disease outbreak in the past two years. There are multiple examples of the United States expanding isolation capacity to respond to the COVID-19 outbreak. Some examples include the following. In September 2020, the US Department of Defense announced that the Army has partnered with the University of Pittsburgh Medical Center to develop "an individual biocontainment unit [IBU] that uses negative pressure to suction the air from around a patient to filter out viral particles. This prevents environmental contamination and limits exposure to SARS-CoV-2" and the FDA is considering an emergency use authorization for the IBUs. [1] The 2016 Joint External Evaluation (JEE) self-assessment notes that the Centers for Disease Control and Prevention's (CDC) Healthcare Infection Control Practices Advisory Committee (HICPAC) has guidelines for establishing and controlling isolation rooms in U.S. hospitals. [2] This "2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings", last updated in July 2019, include recommendations to "Provide ventilation systems required for a sufficient number of airborne infection isolation rooms (AIIR)s (as determined by a risk assessment) and Protective Environments in healthcare facilities that provide care to patients for whom such rooms are indicated." [3, 4] The Army Corps started building more than 30 field hospitals (for covid-19 patients), retrofitting convention centers and erecting climate-controlled tents, in mid-March 2020. At Chicago's McCormick Place, workers scrambled in April to transform the convention center into a massive temporary hospital with 3,000 beds — more than the biggest hospital in Illinois. [5]

[1] Conant, J. 10 September 2020. “Innovative Biocontainment Unit Shows Promise.” US Department of Defense, Army.[https://www.defense.gov/Explore/Features/Story/Article/2340471/innovative-biocontainment-unit-shows-promise/]. Accessed 24 April 2021.
[2] Department of Health and Human Services. 20 Sep 2016. “International health regulations - Joint external evaluation of the United States of America: Self-assessment report.” [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 24 April 2021.
[3] Centers for Disease Control and Prevention. 2019. "Isolation Precautions." [https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html]. Accessed 24 April 2021.
[4] Centers for Disease Control and Prevention. July 2019. "2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings." [https://www.cdc.gov/infectioncontrol/pdf/guidelines/isolation-guidelines-H.pdf]. Accessed 24 April 2021.
[5] NPR. "U.S. Field Hospitals Stand Down, Most Without Treating Any COVID-19 Patients" May 7, 2020. [https://www.npr.org/2020/05/07/851712311/u-s-field-hospitals-stand-down-most-without-treating-any-covid-19-patients]. Accessed 26 June 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

There is a national procurement protocol in place in the United States which can be utilized by the Departments of Health and Human Services (HHS) and Agriculture (USDA) for the acquisition of laboratory supplies and medical supplies for routine

needs. The US has federal regulations covering all types of government procurement, including chapters specifically relating to HHS and USDA. Government procurement is regulated by the Federal Acquisition Regulation (FAR). [1] As part of the implementation of the FAR, 48 CFR Chapter 3 contains the HHS Acquisition Regulations, and 48 CFR Chapter 4 contains the Agriculture Acquisition Regulation (AGAR). These set out protocols for procuring goods and services, implicitly including laboratory supplies and medical supplies for routine needs. [2, 3, 4] The General Services Administration (GSA) publishes schedules of approved suppliers, including Schedule 66: Scientific equipment and services. This lists suppliers of items needed by health and other laboratories. [5, 6]

[1] General Services Administration, Department of Defense and National Aeronautics and Space Administration. 2020. "Federal Acquisition Regulation: Vol I – Parts 1-51."
[https://www.acquisition.gov/sites/default/files/current/far/pdf/FAR.pdf]. Accessed 9 January 2021.
[2] Department of Health and Human Services. 2018. "HHS Acquisition Regulation (HHSAR): 48 CFR Chapter 3."
[https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html]. Accessed 9 January 2021.
[3] Department of Health and Human Services. 18 Nov 2015. "48 CFR Chapter 3: Health and Human Services Acquisition Regulations; final rule." Federal Register. [https://www.hhs.gov/sites/default/files/hhsar final rule-2016.pdf]. Accessed 9 January 2021.
[4] Office of Procurement and Property Management, Department of Agriculture. 2021. "Policy and regulations."
[https://www.dm.usda.gov/procurement/policy/index.htm]. Accessed 9 January 2021.
[5] General Services Administration (GSA). 2016. "Scientific Equipment and Services: Now Get More Choices and Flexibility from GSA." [https://www.gsa.gov/cdnstatic/General_Supplies__Services/17-00212_AOSchedule66Slipsheet_final508.pdf]. Accessed 9 January 2021.
[6] US General Services Administration, Federal Acquisition Service. 2018. "Schedule 66: Scientific equipment and services." eLibrary record.
[https://www.gsaelibrary.gsa.gov/ElibMain/searchResults.do;jsessionid=3361DCE912F6550DA2D903D01E4637BF.prd1pweb?searchText=Laboratory+Instruments&searchType=allWords&x=12&y=10]. Accessed 9 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

The United States has a stockpile of medical supplies (e.g. MCMs, medicines, vaccines, medical equipment, PPE) for national use during a public health emergency. The US Centers for Disease Control and Prevention (CDC) under the Department of Health and Human Services (HHS) maintains the Strategic National Stockpile (SNS) for use during a public health emergency. The SNS includes critical medical equipment, such as ventilators, and personal protective equipment (PPE), as well as antibiotics, chemical antidotes, antitoxins, and other life-sustaining medications. [1, 2, 3] The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), under the Assistant Secretary for Preparedness and Response (ASPR) at the HHS, determines the content of the SNS and produces annual plans addressing procurement of countermeasures. [1, 4] The Biomedical Advanced Research and Development Authority (BARDA) within ASPR, together with the CDC, "maintains contracts with medical countermeasure manufacturers and distributors for the procurement of medical countermeasures for stockpiling prior to a public health emergency as well as for the rapid surge production and delivery of countermeasures during a public health emergency". [1, 5] Amidst the COVID-19 pandemic, a September 2020 article titled "Why the U.S. Still Has a Severe Shortage of Medical Supplies" in the Harvard Business Review described the SNS as "not designed to handle a

pandemic on this scale" and suggests the SNS needs a higher profile and greater influence within the federal government and better information and expertise. [6] Similarly, PBS Frontline—in partnership with the Associated Press and the Global Reporting Centre—reported in October 2020 that critical PPE shortages experienced in the US during the COVID-19 pandemic are related to the US "neglecting to substantially replenish the [SNS]." [7]

[1] Department of Health and Human Services. 20 Sep 2016. “International health regulations - Joint external evaluation of the United States of America: Self-assessment report.” [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 9 January 2021.
[2] US Department of Health and Human Services, Public Health Emergency. 2020. "Strategic National Stockpile." [https://www.phe.gov/about/sns/Pages/default.aspx]. Accessed 9 January 2021.
[3] Congressional Research Service. 15 June 2020. "National Stockpiles: Background and Issuesfor Congress." [https://fas.org/sgp/crs/natsec/IF11574.pdf]. Accessed 9 January 2021.
[4] Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HSS). 2017. “2017-2018 PHEMCE Strategy and Implementation Plan.” [https://www.phe.gov/Preparedness/mcm/phemce/Pages/strategy.aspx]. Accessed 9 January 2021.
[5] Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HSS). 2018. “Biomedical Advanced Research and Development Authority.” [https://www.phe.gov/about/barda/Pages/default.aspx]. Accessed 9 January 2021.
[6] Finkenstadt, D.J., Handfield, R., Guinto, P.. 17 September 2020. “Why the U.S. Still Has a Severe Shortage of Medical Supplies.” Harvard Business Review. [https://hbr.org/2020/09/why-the-u-s-still-has-a-severe-shortage-of-medical-supplies]. Accessed 9 January 2021.
[7] Taddonio, P. 6 October 2020. “Depleted National Stockpile Contributed to COVID PPE Shortage: ‘You Can’t Be Prepared If You’re Not Funded to Be Prepared’.” PBS Frontline. [https://www.pbs.org/wgbh/frontline/article/depleted-national-stockpile-contributed-to-covid-ppe-shortage/]. Accessed 9 January 2021.

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 the US has a stockpile of laboratory supplies for national use during a public health emergency. The US Centers for Disease Control and Prevention (CDC) under the Department of Health and Human Services (HHS) maintains the Strategic National Stockpile (SNS) of medical countermeasures for use during a public health emergency. The SNS includes antibiotics, chemical antidotes, antitoxins, other life-sustaining medications, critical medical equipment, and supplies. [1, 2] However, there is no specific mention of laboratory supplies, such as reagents and media, among the SNS supplies. [1, 2] In a US Government Accountability Office report to Congressional Committees on Urgent Actions Needed to Better Ensure an Effective Federal Response to COVID-19, an October 2020 "survey of senior state and territorial health and emergency management officials found that states and territories continue to report limitations in the availability of certain medical supplies," including reagents used for COVID-19 testing. Shortages were also reported in several states for testing instruments and rapid point-of-care tests. [3] In March 2020, the director of the CDC reported to the House Committee on Oversight and Reform that "some of the reagents essential to conducting coronavirus diagnostic tests? 'now are in short supply'." [4] An April 2020 article in RadioFreeEurope RadioLiberty, on supply of reagents during the COVID-19 pandemic, reported an official from the National Institute of Health stating, "We didn't stockpile it. We just relied on our regular testing platforms and they weren't ready for it." [5] The US Food and Drug Administration publishes a list of device shortages during the COVID-19 public health emergency, which includes laboratory supplies but does not mention stockpiling these supplies.

[6] There is no additional information on stockpiling of laboratory supplies for national use during a public health emergency from the Department of Health and Human Services, Department of Defense, Federal Emergency Management Agency, or the Food and Drug Administration. [7, 8, 9, 10]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 9 January 2021.
[2] US Department of Health and Human Services, Public Health Emergency. 2020. "Strategic National Stockpile." [https://www.phe.gov/about/sns/Pages/default.aspx]. Accessed 9 January 2021.
[3] US Government Accountability Office. 30 November 2020. "COVID-19: Urgent Actions Needed to Better Ensure an Effective Federal Response - Report to Congressional Committees." [https://www.gao.gov/reports/GAO-21-191/]. Accessed 9 January 2021.
[4] Slabodkin, G. 13 Marcy 2020. "CDC chief: Reagents critical to coronavirus tests? 'now are in short supply'". MedTech Dive. [https://www.medtechdive.com/news/cdc-chief-reagents-critical-to-coronavirus-tests-in-short-supply/574074/]. Accessed 9 January 2021.
[5] Heil, A. 18 April 2020. "What's A 'Reagent' And Why Is It Delaying Expanded Coronavirus Testing?" RadioFreeEurope RadioLiberty (RFE/RL). [https://www.rferl.org/a/coronavirus-reagent-delaying-expanded-coronavirus-testing-/30563198.html]. Accessed 9 January 2021.
[6] US Food and Drug Administration. Content current as of 23 December 2020. "Medical Device Shortages During the COVID-19 Public Health Emergency." [https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency]. Accessed 9 January 2021.
[7] US Department of Health and Human Services. [https://www.hhs.gov/]. Keyword search. Accessed 9 January 2021.
[8] US Department of Defense. [https://www.defense.gov/]. Keyword search. Accessed 9 January 2021.
[9] Federal Emergency Management Agency. [https://www.fema.gov/]. Keyword search. Accessed 9 January 2021.
[10] US Food and Drug Administration. [https://www.fda.gov/home]. Keyword search. Accessed 9 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: 1

There is 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. The US Centers for Disease Control and Prevention (CDC) under the Department of Health and Human Services (HHS) maintains the Strategic National Stockpile (SNS) of medical supplies for use during a public health emergency. The SNS includes antibiotics, chemical antidotes, antitoxins, and other life-sustaining medications. [1, 2] The SNS undergoes an annual review of inventory of all products. According to HHS, the SNS Annual Review "is the process by which the PHEMCE [the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), led by the Assistant Secretary for Preparedness and Response] recommends the most risk-balanced and sustainable portfolio of holdings for the SNS. The SNS Annual Review process supports more effective decision making and resource allocation for maintaining this critical stockpile. The PHEMCE SIP [annual PHEMCE Strategy and Implementation Plan] and SNS Annual Review are mandated by the Pandemic and All-Hazards Preparedness Reauthorization Act." [3, 4] The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), under the Assistant Secretary for Preparedness and Response (ASPR) at the HHS, determines the content of the SNS and produces annual plans addressing procurement of countermeasures. [1, 5]

[1] Department of Health and Human Services. 20 Sep 2016. “International health regulations - Joint external evaluation of the United States of America: Self-assessment report.” [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 9 January 2021.
[2] US Department of Health and Human Services, Public Health Emergency. 2020. "Strategic National Stockpile." [https://www.phe.gov/about/sns/Pages/default.aspx]. Accessed 9 January 2021.
[3] US Department of Health and Human Services, Public Health Emergency. 2020. "Strategic National Stockpile - Sustaining the Stockpile." [https://www.phe.gov/about/sns/Pages/sustaining.aspx]. Accessed 24 April 2021.
[4] US Department of Health and Human Services, Public Health Emergency. 2020. "About the Division of Medical Countermeasures Strategy and Requirements." [https://www.phe.gov/about/OPP/mcsr/Pages/about.aspx]. Accessed 20 June 2021.
[5] Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HSS). 2017. “2017-2018 PHEMCE Strategy and Implementation Plan.” [https://www.phe.gov/Preparedness/mcm/phemce/Pages/strategy.aspx]. Accessed 9 January 2021

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: 1

There is evidence of a plan/agreement to leverage domestic manufacturing capacity to produce medical supplies (e.g. MCMs, medicines, vaccines, equipment, PPE) and evidence of a plan/mechanism to procure medical supplies for national use during a public health emergency.

The US joint external evaluation (JEE) self-assessment report states that, among other things, the 2015 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan "leverages multiple U.S. Government capacities and creates incentives for private industry to [i]dentify, create, develop, manufacture, and procure critical medical countermeasures [(MCMs)]." [1] The PHEMCE was updated in 2017, and define MCMs as inclusive of "...nonpharmaceutical interventions (e.g., ventilators, diagnostics, personal protective equipment, and patient decontamination) that are used to prevent, mitigate, or treat the adverse health effects of a deliberate, an unintentional, or naturally occurring public health emergency." as well as "...pharmaceutical interventions (e.g., vaccines, antimicrobials, antidotes, and antitoxins)...that are used to prevent, mitigate, or treat the adverse health effects of a deliberate, an unintentional, or naturally occurring public health emergency." [2] Goal 1 of the 2017-2018 PHEMCE is to: " Identify, create, develop, manufacture, and procure critical MCMs", with objective 1.4 to: "Promote effective domestic and international partnerships with MCM developers and manufacturers, and support core services." [2]

The JEE self-assessment also states that the Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC) HHS CDC and Assistant Secretary for Preparedness and Response (ASPR) Biomedical Advanced Research and Development Authority (BARDA) "implement and maintain contracts with medical countermeasure manufacturers and distributors for the procurement of medical countermeasures for stockpiling prior to a public health emergency as well as for the rapid surge production and delivery of countermeasures during a public health emergency." [1]

In March 2020, HHS ASPR launched a public-private partnership, the consortium for Rapid Aseptic Packaging of Injectable Drugs (RAPID), to create a US-based "high-speed, high-volume emergency drug packaging solution using low-cost prefilled syringes" for vaccines and other therapeutic drugs, to enable the Strategic National Stockpile (SNS) to respond quickly to public health emergencies "such as the novel coronavirus outbreak." [3] In May 2020, HHS announced plans to work with private industry partners to improve the US capacity to produce active pharmaceutical ingredients, in particular for during the COVID-19 pandemic. [4] In June 2020, HHS announce Operation Warp Speed, a joint effort between HHS and the Department of Defense "to increase domestic manufacturing capacity for vials that may be needed for vaccines and drugs to respond to the COVID-19 pandemic and future public health emergencies." [5] On August 6, 2020, the President issued Executive Order 13944 on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States. [6, 7] "This executive order directed the U.S. Food and Drug Administration (FDA) to identify a list of essential medicines, medical countermeasures and critical inputs that are medically necessary to have available at all times...The goal of this work is to ensure the American public is protected against outbreaks of emerging infectious diseases, such as COVID-19, as well as chemical, biological, radiological, and nuclear threats. To accomplish this goal, the executive order seeks to ensure sufficient and reliable, long-term domestic production of these products, and to minimize potential shortages by reducing our dependence on foreign manufacturers of these products." [7]

[1] Department of Health and Human Services. 20 Sep 2016. “International health regulations - Joint external evaluation of the United States of America: Self-assessment report.” [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 11 January 2021.
[2] Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HSS). 2017. “2017-2018 PHEMCE Strategy and Implementation Plan.” [https://www.phe.gov/Preparedness/mcm/phemce/Pages/strategy.aspx]. Accessed 11 January 2021.
[3] Department of Health and Human Services. 18 March 2020. “HHS Announces New Public-Private Partnership to Develop U.S.-Based, High-Speed Emergency Drug Packaging Solutions.” [https://www.hhs.gov/about/news/2020/03/18/hhs-announces-new-public-private-partnership-to-develop-us-based-high-speed-emergency-drug-packaging-solutions.html]. Accessed 11 January 2021.
[4] Department of Health and Human Services. 19 May 2020. “HHS, Industry Partners Expand U.S.-Based Pharmaceutical Manufacturing for COVID-19 Response.” [https://www.hhs.gov/about/news/2020/05/19/hhs-industry-partners-expand-us-based-pharmaceutical-manufacturing-covid-19-response.html]. Accessed 11 January 2021.
[5] Department of Health and Human Services. 11 June 2020. “Operation Warp Speed ramps up U.S.-based manufacturing capacity for vials for COVID-19 vaccines and treatments.” [https://www.hhs.gov/about/news/2020/06/11/operation-warp-speed-ramps-up-us-based-manufacturing-capacity-for-vials-for-covid-19-vaccines-and-treatments.html]. Accessed 11 January 2021.
[6] The White House. 6 August 2020. "Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States." [https://www.whitehouse.gov/presidential-actions/executive-order-ensuring-essential-medicines-medical-countermeasures-critical-inputs-made-united-states/]. Accessed 11 January 2021.
[7] US Food and Drug Administration. 2020. "Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs." [https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs]. Accessed 11 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 insufficient evidence of a plan/agreement to leverage domestic manufacturing capacity to produce laboratory supplies and insufficient evidence of a plan/mechanism to procure laboratory supplies for national use during a public health emergency. The US joint external evaluation (JEE) self-assessment report states that, among other things, the 2015 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan "leverages multiple U.S. Government capacities and creates incentives for private industry to [i]dentify, create, develop, manufacture, and procure critical medical countermeasures [(MCMs)]." [1] The PHEMCE was updated in 2017, and define MCMs as including pharmaceutical and nonpharmaceutical interventions that are used to prevent, mitigate, or treat the adverse health effects of a deliberate, an unintentional, or naturally occurring public health emergency." [2] However, there is no mention of a plan for manufacturing or procurement of laboratory suppplies for national use during a public health emergency. The JEE self-assessment also states that the Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC) HHS CDC and Assistant Secretary for Preparedness and Response (ASPR) Biomedical Advanced Research and Development Authority (BARDA) "implement and maintain contracts with medical countermeasure manufacturers and distributors for the procurement of medical countermeasures for stockpiling prior to a public health emergency as well as for the rapid surge production and delivery of countermeasures during a public health emergency" but does not mention laboratory supplies. [1] On August 6, 2020, the President issued Executive Order 13944 on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States. [3, 4] "This executive order directed the U.S. Food and Drug Administration (FDA) to identify a list of essential medicines, medical countermeasures and critical inputs that are medically necessary to have available at all times...The goal of this work is to ensure the American public is protected against outbreaks of emerging infectious diseases, such as COVID-19, as well as chemical, biological, radiological, and nuclear threats. To accomplish this goal, the executive order seeks to ensure sufficient and reliable, long-term domestic production of these products, and to minimize potential shortages by reducing our dependence on foreign manufacturers of these products." [4] However, there is no evidence that this specifically includes laboratory supplies. There is no additional evidence specific to manufacturing and procurement of laboratory supplies available through the Department of Health and Human Services, Centers for Disease Control and Prevention, Federal Emergency Mangament Agency, or Department of Defense. [5, 6, 7, 8]

[1] Department of Health and Human Services. 20 Sep 2016. “International health regulations - Joint external evaluation of the United States of America: Self-assessment report.” [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 11 January 2021.
[2] Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HSS). 2017. “2017-2018 PHEMCE Strategy and Implementation Plan.” [https://www.phe.gov/Preparedness/mcm/phemce/Pages/strategy.aspx]. Accessed 11 January 2021.
[3] The White House. 6 August 2020. "Executive Order on Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States." [https://www.whitehouse.gov/presidential-actions/executive-order-ensuring-essential-medicines-medical-countermeasures-critical-inputs-made-united-states/]. Accessed 11 January 2021.
[4] US Food and Drug Administration. 2020. "Executive Order 13944 List of Essential Medicines, Medical Countermeasures, and Critical Inputs." [https://www.fda.gov/about-fda/reports/executive-order-13944-list-essential-medicines-medical-countermeasures-and-critical-inputs]. Accessed 11 January 2021.
[5] US Department of Health and Human Services. 2021. [https://www.hhs.gov/]. Keyword search. Accessed 11 January 2021.
[6] Centers for Disease Control and Prevention. 2021. [https://www.cdc.gov/]. Keyword search. Accessed 11 January 2021.
[7] Federal Emergency Management Agency. 2021. [https://www.fema.gov/]. Keyword search. Accessed 11 January 2021.
[8] US Department of Defense. 2021. [https://www.defense.gov/]. Keyword search. Accessed 11 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: 1

The United States has a plan in place for dispensing medical countermeasures for national use during a public health emergency. The Centers for Disease Control and Prevention (CDC) deploys medical countermeasures from the Strategic National Stockpile in line with the SNS Emergency Operations Plan. This contains threat-specific planning considerations and logistical requirements associated with the medical countermeasures. Additional CDC guidance to state and local partners (Receiving Distributing and Dispensing SNS Assets V.11) provides specific requirements for receiving, distributing, and dispensing medical countermeasures, and each state and locality is required to have jurisdiction-specific plans for carrying out these functions. [1]

[1] Department of Health and Human Services. 20 Sep 2016. “International health regulations - Joint external evaluation of the United States of America: Self-assessment report.” [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 31 December 2020.

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 the US has a plan which outlines procedures for receiving health personnel from other countries during a public health emergency, though a sub-national plan exists. The "International Assistance System: Concept of operations (IAS/CONOPS)", published in 2015 by the Federal Emergency Management Agency (FEMA), describes the International Assistance System (IAS). The IAS is used to receive, review, and manage incoming offers of assistance (including medical) from international partners during a domestic disaster, and is managed by the International Resources Coordination Group. The IAS/CONOPS states a preference for financial assistance, and that "Government-to-government offers of foreign nationals to assist in emergencies should generally be declined, unless specifically requested by FEMA for explicit purposes. Where requested by FEMA, offers of foreign nationals should be coordinated with the CBP's Office of Field Operations". More specifically to medical personnel, it states that first responders are on a "No-Go list" of "resources that cannot readily enter the U.S. without significant regulatory review, waivers, and/or changes." The plan contains operational procedures for the participation of foreign Urban Search and Rescue (US&R) teams to support US teams, but not medical personnel. [1, 2] The 2016 Joint External Evaluation (JEE) self-assessment states that the Department of Health and Human Services (HHS) is "in the process of developing a companion framework to the IAS that will describe the roles, responsibilities, and processes that HHS will use to manage international offers of public health and medical assistance." [1] The HHS's Public Health Emergency website states that work has been carried out on "Developing guidelines for HHS to receive foreign

medical and public health assistance from international partners in response to emergencies in the United States when national capacities are overwhelmed", but there is no link to these guidelines. [3] The latest information from the HHS on response coordination does not mention a new framework, and neither this nor the HHS' plans on medical surge capacity have not been updated since the JEE self-assessment. They do not cover procedures for receiving foreign personnel, but focus on assistance from federal to state/local level and mutual assistance among states. [4, 5] Various guidance documents and agreements have been put in place to encourage mutual aid among North American countries in a public health emergency. These include suggested provisions for mutual aid agreements which address exchange of medical personnel, and commitments at both federal and state level to identify ways of sharing medical personnel. Examples at the federal level include a 2007 letter of intent between the US, Canada and Mexico, and a 2008 agreement between the US and Canada on emergency management cooperation. There is no evidence of federal-level documents which take forward the commitments these agreements contain regarding planning for the deployment of foreign medical personnel. [6] The 2016 Joint External Evaluation report for the United States of America notes that strategies for receiving public health professionals in an emergency need strengthening, as they are not as well developed as those for sending personnel abroad. [7] A New York Times' article from April 2020 described challenges healthcare workers faced when trying to enter the US to work in support of the coronavirus pandemic response and described an "apparent lack of coordination between the various government agencies involved." [8]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 9 January 2021.
[2] Federal Emergency Management Agency (FEMA), Department of Homeland Security. 2015. "International Assistance System: Concept of operations (IAS/CONOPS)." [https://www.fema.gov/sites/default/files/2020-08/fema_IAS_CONOPS_2015.pdf]. Accessed 9 January 2021.
[3] Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HSS). 15 Feb 2017. "International Assistance and Response Policy Branch." [https://www.phe.gov/about/OPP/dihs/Pages/response.aspx]. Accessed 9 January 2021.
[4] Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HSS). 2012. "HHS concept of operations plan (CONOPs)." [https://www.phe.gov/Preparedness/planning/mscc/handbook/chapter1/Pages/conops.aspx]. Accessed 9 January 2021.
[5] Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HSS). 2010. "Medical Surge Capacity Handbook." [https://www.phe.gov/Preparedness/planning/mscc/handbook/Pages/default.aspx]. Accessed 9 January 2021.
[6] Stier, D. and Thombley, M. 2007. "Public health mutual aid agreements - A menu of suggested provisions." Centers for Disease Control and Prevention. [https://www.cdc.gov/phlp/docs/Mutual_Aid_Provisions.pdf]. Accessed 9 January 2021.
[7] World Health Organisation (WHO). 2017. "Joint external evaluation of IHR core capacities of the United States of America - Mission report: June 2016." Geneva: World Health Organisation. [http://apps.who.int/iris/bitstream/10665/254701/1/WHO-WHE-CPI-2017.13-eng.pdf?ua=1&ua=1]. Accessed 9 January 2021.
[8] Jordan, M., Correal, A. 13 April 2020, Updated 3 July 2020. "Foreign Doctors Could Help Fight Coronavirus. But U.S. Blocks Many." The New York Times. [https://www.nytimes.com/2020/04/13/us/coronavirus-foreign-doctors-nurses-visas.html]. Accessed 9 January 2021.

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: 99.1

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: 1126.35

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: 1

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

The United States has federal guidance in place calling for subnational healthcare authorities to ensure timely, but not prioritised, treatment for exposed healthcare workers during an emergency. These are in addition to general occupational safety standards ensuring timely and free treatment for healthcare workers who are exposed to bloodborne pathogens in any healthcare context. The Office of the Assistant Secretary for Preparedness and Response (ASPR) under the Department of Health and Human Services (HHS) published guidance in 2012, which addresses preparedness for responder safety and health during a public health emergency. States should: "Develop, refine, and sustain processes to assist healthcare organizations to provide the timely distribution of critical medication such as prophylaxis or immediate treatment for healthcare workers and their families during an exposure incident." [1] Prioritised treatment for healthcare workers is not directly addressed in the Pandemic and All Hazards Preparedness Act (2006) and the Reauthorization of this Act in 2013, [2, 3] or in the National health security strategy and implementation plan published by the ASPR in 2019. [4, 5] There are regulations ensuring timely access to vaccines and prophylaxis for healthcare workers exposed to bloodborne pathogens in any healthcare context. The Occupational Safety and Health Administration (OSHA)'s Bloodborne Pathogens standard (29 CFR 1910.1030), and similar OSHA State Plan standards, require employers to provide vaccinations and post-exposure follow-up (including prophylaxis) for healthcare workers who have had an occupational exposure incident involving blood or other infectious materials. These must be provided at no cost to the employee. [6] The standard applies to healthcare workers in any healthcare context, including emergencies. [6, 7] Some disease-specific HHS guidance, including for Zika virus, refers to the Bloodborne Pathogens standard. [8] In 2018, the Centers for Disease Control and Prevention (CDC) under the HHS published guidance on allocating influenza vaccines during a pandemic. Critical healthcare workers fall into the highest-priority group. [9]

[1] Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HSS). 2012. "National guidance for healthcare system preparedness." [http://www.phe.gov/preparedness/planning/hpp/reports/documents/capabilities.pdf]. Accessed 31 December 2020.
[2] Government of the US. 2006. "Pandemic and All Hazards Preparedness Act, Public law 109-417." [https://www.gpo.gov/fdsys/pkg/PLAW-109publ417/pdf/PLAW-109publ417.pdf]. Accessed 31 December 2020.
[3] Government of the US. 2013. "Pandemic and All-Hazards Preparedness Reauthorization Act, Public law 113–5." [https://www.govinfo.gov/content/pkg/PLAW-113publ5/pdf/PLAW-113publ5.pdf]. Accessed 31 December 2020.
[4] Department of Health and Human Services. 2019. "National Health Security Strategy 2019-2022." [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/NHSS-Strategy-508.pdf]. Accessed 31 December 2020.
[5] Department of Health and Human Services. 2019. "National Health Security Strategy: Implementation plan 2019-2022." [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/2019-2022-nhss-ip-v508.pdf]. Accessed 31 December 2020.
[6] Occupational Safety and Health Administration (OSHA), Department of Labor. 2012. "Bloodborne Pathogens standard (29 CFR 1910.1030)." Occupational Safety and Health Standards, Toxic and Hazardous Substances. [https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051]. Accessed 31 December 2020.
[7] Occupational Safety and Health Administration (OSHA), Department of Labor. 2018. "Quick reference guide to the Bloodborne Pathogens standard" (29 CFR 1910.1030)

[https://www.osha.gov/SLTC/bloodbornepathogens/bloodborne_quickref.html]. Accessed 31 December 2020.
[8] Centers for Disease Control and Prevention (CDC). 2017. "Interim guidance for managing occupational exposures to Zika virus for healthcare personnel." [https://www.cdc.gov/zika/hc-providers/infection-control/managing-occupational-exposures.html]. Accessed 31 December 2020.
[9] Centers for Disease Control and Prevention (CDC). 2018. "Interim updated planning guidance on allocating and targeting pandemic influenza vaccine during an influenza pandemic." [https://www.cdc.gov/flu/pandemic-resources/pdf/2018-Influenza-Guidance.pdf]. Accessed 31 December 2020.

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: 1

There are systems in place for public health officials and healthcare workers to communicate during a public health emergency in the United States. The Department of Health and Human Services (HHS), Centers for Disease Control and Prevention's (CDC) Health Alert Network (HAN) enables cleared information about public health emergencies to be rapidly shared with public health practitioners and clinicians at federal, state and local level. [1, 2] There are four types of HAN messages. The most urgent is a "Health Alert", which "provides vital, time-sensitive information for a specific incident or situation; warrants immediate action or attention by health officials, laboratorians, clinicians, and members of the public; and conveys the highest level of importance." [2] The CDC also runs the Clinician Outreach and Communication Activity (COCA), which "prepares clinicians to respond to emerging health threats and public health emergencies by communicating relevant, timely information related to disease outbreaks, disasters, terrorism events, and other health alerts." COCA serves physicians, nurses, physician's assistants, pharmacists, paramedics, veterinarians, epidemiologists, public health practitioners, and state and local health department officials. COCA communication methods include conference calls/webinars, newsletters and clinical support via direct email for questions and feedback, among others. [3, 4] Healthcare workers report notifiable diseases to state and local health departments, which feeds into the National Notifiable Diseases Surveillance System (NNDSS). [5, 6] Additionally, the CDC maintains a telephone support line (800-CDC-INFO) for healthcare providers to reach out with urgent inquiries. [7]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 31 December 2020.
[2] Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS). 2020. "Health alert network (HAN)." Emergency preparedness and response. [https://emergency.cdc.gov/HAN/index.asp]. Accessed 31 December 2020.
[3] Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS). 2018. "Clinician Outreach and Communication Activity (COCA)." [https://www.emergency.cdc.gov/coca/index.asp]. Accessed 31 December 2020.
[4] Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS). 2018. "About COCA." [https://www.emergency.cdc.gov/coca/about.asp]. Accessed 31 December 2020.

[5] Centers for Disease Control and Prevention (CDC). 2021. "National Notifiable Diseases Surveillance System (NNDSS)." [https://www.cdc.gov/nndss/index.html]. Accessed 24 April 2021.
[6] Centers for Disease Control and Prevention (CDC). 2018. "National Notifiable Diseases Surveillance System (NNDSS): Data collection and reporting." [https://wwwn.cdc.gov/nndss/data-collection.html]. Accessed 24 April 2021.
[7] Centers for Disease Control and Prevention (CDC). 2021. "CDC-INFO." [https://www.cdc.gov/cdc-info/index.html]. Accessed 24 April 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: 1

The systems for public health officials and healthcare workers to communicate during an emergency in the United States encompass healthcare workers in both the public and private sector. In the US, healthcare is primarily delivered by the private sector even where it is publicly financed. [1] Facilities may be owned privately and operated as for-profit or non-profit entities, or may be owned and operated by a local government. [2] Public health officials here refers to those employed by federal agencies such as the Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC), as well as state-level health departments. The CDC's Health Alert Network (HAN) enables cleared information about public health emergencies to be rapidly shared with public health practitioners and clinicians at federal, state and local level. [3, 4] The CDC also runs the Clinician Outreach and Communication Activity (COCA), which "prepares clinicians to respond to emerging health threats and public health emergencies by communicating relevant, timely information related to disease outbreaks, disasters, terrorism events, and other health alerts." COCA serves physicians, nurses, physician's assistants, pharmacists, paramedics, veterinarians, epidemiologists, public health practitioners, and state and local health department officials. [5, 6] Both HAN and COCA are available to public and private sector healthcare workers. [7]

[1] Department for Professional Employees. 2016. "The U.S. Health Care System: An International Perspective." [http://dpeaflcio.org/programs-publications/issue-fact-sheets/the-u-s-health-care-system-an-international-perspective/]. Accessed 31 December 2020.
[2] University of Colorado. N.d. "What you need to know about healthcare in the US: A guide for international scholars." [https://www.ucdenver.edu/docs/librariesprovider190/default-document-library/healthcare_in_us.pdf?sfvrsn=b722eeb9_6]. Accessed 31 December 2020.
[3] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 31 December 2020.
[4] Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS). 2020. "Health alert network (HAN)." Emergency preparedness and response. [https://emergency.cdc.gov/HAN/index.asp]. Accessed 31 December 2020.
[5] Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS). 2018. "Clinician Outreach and Communication Activity (COCA)." [https://www.emergency.cdc.gov/coca/index.asp]. Accessed 31 December 2020.
[6] Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS). 2018. "About COCA." [https://www.emergency.cdc.gov/coca/about.asp]. Accessed 31 December 2020.
[7] Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS). 2018. "Public-Private Partnerships and CDC." [https://www.cdc.gov/partners/index.html]. Accessed 31 December 2020.

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 public health system in the United States is monitoring for and tracking the number of healthcare associated infections (HCAI) that take place in healthcare facilities. According to the 2016 Joint External Evaluation (JEE) self-assessment, the Department of Health and Human Services (HHS) Office of Disease Prevention and Health Promotion released the "National action plan to prevent health care-associated infections" in 2013. It also states that "the National and State Healthcare-Associated Infections Progress Report is released annually by the CDC [Centers for Disease Control and Prevention]. Data includes central-line associated bloodstream infections, catheter-associated urinary tract infections, selected surgical site infections, hospital-onset Clostridium difficile infections, and hospital-associated MRSA infections." [1] The data comes from two HAI surveillance systems, the National Healthcare Safety Network (NHSN) and the Emerging Infections Program Healthcare-Associated Infections Community-Interface (EIP HAIC). [2] The latest annual progress report provides national- and state-level HAI incidence data for calendar year 2019. [3]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 31 December 2020.
[2] Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HSS). 2018. "HAI data and statistics." [https://www.cdc.gov/hai/surveillance/index.html]. Accessed 31 December 2020.
[3] Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HSS). 2020. "Healthcare-associated Infections (HAI) Progress Report." [https://www.cdc.gov/hai/surveillance/progress-report/index.html]. Accessed 31 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 in the United States for ethical review before beginning a clinical trial. Both the Office of Human Subjects Research Protection and the Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS) have regulations requiring ethical review by an institutional review board (IRB) before beginning a clinical trial. In the Code of Federal Regulations, the relevant regulations are 45 CFR Part 46 (Protection of human subjects) by the HHS, and 21 Part 56 (Institutional review boards) by the FDA. [1, 2, 3, 4] Clinical trials involving products reviewed and approved by the FDA must comply with FDA regulations; those which are federally funded, supported or conducted must comply with HHS regulations. If both criteria apply, they must comply with both sets of regulations. [5, 6]

[1] Food and Drug Administration (FDA), Department of Health and Human Services. 2018. "Comparison of FDA and HHS human subject protection regulations." [https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/EducationalMaterials/ucm112910.htm]. Accessed 31 December 2020.
[2] Office for Human Research Protections, Department of Health and Human Services. 2016. "45 CFR 46." [https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116]. Accessed 31 December 2020.
[3] Code of Federal Regulations. 2020. "Title 45: Public welfare, Subtitle A, Subchapter A, Part 46: Protection of human subjects." [https://ecfr.federalregister.gov/current/title-45/subtitle-A/subchapter-A/part-46]. Accessed 31 December 2020.
[4] Code of Federal Regulations. 2020. "Title 21: Food and drugs, Chapter I, Subchapter A, Part 56: Institutional review boards." [https://ecfr.federalregister.gov/current/title-21/chapter-I/subchapter-A/part-56]. Accessed 31 December 2020.
[5] Food and Drug Administration (FDA), Department of Health and Human Services. 2019. "Institutional review boards frequently asked questions - information sheet." [https://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm]. Accessed 31 December 2020.
[6] National Institutes of Health (NIH), Department of Health and Human Services. 2019. "Learn about clinical studies." ClinicalTrials.gov, US National Library of Medicine. [https://www.clinicaltrials.gov/ct2/about-studies/learn#HowAreParticipants]. Accessed 31 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) during a public health emergency in the United States. According to the Department of Health and Human Services (HHS), recognising that "[r]apid IRB [institutional review board] evaluation and approval of scientific research involving human subjects plays a critical role in advancing research during a public health or medical emergency", the Public Health Emergency Research Review Board (PHERRB) was created as "a specialized IRB established under the auspices of the National Institutes of Health (NIH) … to carry out ethical review of research protocols involving human subjects that address public health emergencies." PHERRB reviewed protocols are conducted, supported, or regulated by the HHS and subject to regulations 45 CFR 46 and/or 21 CFR 50 and 56, which address protection of human subjects. [1] Any of the NIH intramural IRBs can serve as the PHERRB, depending on the nature of the protocol. [2]

[1] Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS). 2015. "Research infrastructure." [https://www.phe.gov/Preparedness/planning/science/Pages/infrastructure.aspx]. Accessed 31 December 2020.
[2] National Institutes of Health (NIH), Department of Health and Human Services (HHS). N.d. "Public Health Emergency

Research Review Board (PHERRB)." [https://ohsr.od.nih.gov/pherrb.php]. Accessed 31 December 2020.

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

There is a government agency responsible for approving new medical countermeasures (MCM) for humans in the United States. The Food and Drug Administration (FDA), Department of Health and Human Services (HHS) is responsible for approving new medicines for humans and has a special programme for developing and approving medical countermeasures for use in a chemical, biological, radiological, and nuclear (CBRN) event. The FDA's Center for Drug Evaluation and Research (CDER) reviews and approves all new medicines for human use. [1] The FDA Medical Countermeasures Initiative (MCMi), launched in 2010, is responsible for promoting, developing and regulating medical countermeasures such as drugs, vaccines, diagnostic tests, and PPE to protect humans against CBRN threats. [2]

[1] Food and Drug Administration (FDA), Department of Health and Human Services (HSS). 2019. "Development and approval process (drugs)." [https://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm]. Accessed 31 December 2020.
[2] Food and Drug Administration (FDA), Department of Health and Human Services (HSS). 2020. "MCMi program update, fiscal year 2019." FDA Medical Countermeasure Initiative. [https://www.fda.gov/media/136121/download]. Accessed 31 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

There is an expedited process for approving medical countermeasures (MCM) for human use during public health emergencies in the United States. According to the Food and Drug Administration (FDA), Department of Health and Human Services (HHS), which is responsible for approving new medicines: "The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) establishes streamlined mechanisms to facilitate certain MCM preparedness and response activities without FDA having to issue an Emergency Use Authorization (EUA, which can be a time- and resource-intensive process). One tool, which is applicable only to eligible FDA-approved medical products intended for use during a Chemical, Biological, Radiological and Nuclear (CBRN) emergency, allows the Centers for Disease Control and Prevention (CDC) to create and issue, and government stakeholders to disseminate, special emergency use instructions (EUI) (also referred to as fact sheets for recipients of an MCM and for health care professionals) about the FDA-approved conditions of use for such MCMs before aChemical, biological, radiological and nuclear CBRN event occurs." [1, 2] The FDA works closely with the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to approve, license, and clear medical countermeasures, or to authorise medical countermeasures for emergency use when appropriate. [3, 4] In addition, in January 2018 the FDA and the Department of Defense (DoD) announced a joint programme to expedite development and approval of medical products for deployed military personnel. [1]

[1] Food and Drug Administration (FDA), Department of Health and Human Services. 2019. "MCMi [Medical Countermeasures Initiatives] Collaborations." [https://www.fda.gov/emergency-preparedness-and-response/about-mcmi/mcmi-collaborations]. Accessed 31 December 2020.
[2] Government of the US. 2013. "Pandemic and All-Hazards Preparedness Reauthorization Act, Public law 113-5." [https://www.govinfo.gov/content/pkg/PLAW-113publ5/pdf/PLAW-113publ5.pdf]. Accessed 31 December 2020.
[3] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 31 December 2020.
[4] Department of Health and Human Services (HSS). 2017. "Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan." [https://www.phe.gov/Preparedness/mcm/phemce/Documents/2017-phemce-sip.pdf]. Accessed 31 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: 1

In the United States, pandemics are integrated into the national risk reduction strategy and there is a standalone disaster risk reduction strategy for pandemics. Overall national risk evaluation is addressed by the National Preparedness System (NPS). [1, 2] Under the NPS, the National Response Framework (NRF), last updated 2016, includes an Emergency support function

annex (ESF #8) on public health and medical services, for which responsibility lies with the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS). It provides the mechanism for federal support to sub-national authorities to prepare for and respond to a public health emergency. [2] The Department for Homeland Security provides risk reduction guidance for use by local areas. The Comprehensive Preparedness Guide (CPG) 201 provides guidance on conducting a threat and hazard identification and risk assessment (THIRA), a common risk assessment process. It includes epidemics and pandemics among the threats to consider. [3] There is also a stand-alone risk reduction strategy for pandemics. The Pandemic and All-Hazards Preparedness Act (PAHPA) 2006 called for the establishment of a quadrennial National Health Security Strategy (NHSS). [4] The ASPR has published a NHSS for 2019-2022 and associated implementation plan. These address pandemic risk reduction measures such as planning for countermeasures and non-pharmaceutical interventions; surveillance and situational awareness to prepare for outbreaks; and coordination among stakeholders for preparedness and response. [5, 6]

[1] NSTC Subcommittee on Disaster Reduction. 2012. "National progress report on the implementation of the Hyogo Framework for Action (2011-2013) – Interim." PreventionWeb, HFA monitor report. [https://www.preventionweb.net/files/28816_usa_NationalHFAprogress_2011-13.pdf]. Accessed 5 January 2021.
[2] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 5 January 2021.
[3] Department of Homeland Security. 2018. "Threat and hazard identification and risk assessment guide (THIRA) and stakehold preparedness review (SPR) guide: Comprehensive Preparedness Guide (CPG) 201." 3rd edition, May 2018. [https://www.fema.gov/media-library-data/8ca0a9e54dc8b037a55b402b2a269e94/CPG201_htirag_2nd_edition.pdf]. Accessed 5 January 2021.
[4] Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services. 2019. "Pandemic and All Hazards Preparedness Act." [http://www.phe.gov/Preparedness/legal/pahpa/Pages/default.aspx]. Accessed 5 January 2021.
[5] Department of Health and Human Services. 2019. "National Health Security Strategy 2019-2022." [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/NHSS-Strategy-508.pdf]. Accessed 5 January 2021.
[6] Department of Health and Human Services. 2019. "National Health Security Strategy: Implementation plan 2019-2022." [https://www.phe.gov/Preparedness/planning/authority/nhss/Documents/2019-2022-nhss-ip-v508.pdf]. Accessed 5 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

The United States has cross-border agreements with neighbouring countries with regard to public health emergencies, and there is no evidence of gaps in implementation. The North American plan for animal and pandemic influenza (NAPAPI), issued by the presidents of Canada, Mexico and the US in 2012, outlines how the three countries will work together to prepare for and manage animal influenza or new strains of human influenza. Its aims include reducing the barriers to sharing medical

countermeasures across borders, and it commits the three countries to immediately sharing outbreak notifications directly with each other. [1, 2, 3] In 2012, the health secretaries of the US and Mexico signed a declaration adopting a shared set of technical guidelines for responding to public health events affecting both countries, the "Technical guidelines for United States - Mexico coordination on public health events of mutual interest". [1, 4] A US Department of State (DOS) fact sheet on US relations with Canada, from July 2020, includes a section on coordination on the fight against the COVID-19 pandemic, stating that the US with working closely with the Canadian government, including to discuss best practices to respond and working to ensure that PPE is available to frontline workers. [5] A similar DOS fact sheet on Mexico from September 2020 states that the US is working closely with the Mexican government to combat the pandemic, including coordination calls. [6]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 31 December 2020.
[2] Governments of Canada, Mexico and the US. 2012. "North American plan for animal and pandemic influenza." [http://www.phe.gov/Preparedness/international/Documents/napapi.pdf]. Accessed 31 December 2020.
[3] US Department of Health and Human Services (HHS), Public Health Emergency. 2017. "North American plan for animal and pandemic influenza." [https://www.phe.gov/Preparedness/international/Pages/napapi.aspx]. Accessed 31 December 2020.
[4] Centers for Disease Prevention and Control (CDC). 2017. "United States - Mexico guidelines and protocol for coordination." [https://www.cdc.gov/usmexicohealth/united-states-mexico-guidelines-cooperation.html]. Accessed 31 December 2020.
[5] US Department of State. 16 July 2020. "U.S. Relations With Canada." [https://www.state.gov/u-s-relations-with-canada/]. Accessed 31 December 2020.
[6] US Department of State. 29 September 2020. "U.S. Relations With Mexico." [https://www.state.gov/u-s-relations-with-mexico/]. Accessed 31 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: 2

The United States has cross-border agreements with neighbouring countries and groups of countries with regard to animal health emergencies, and there is no evidence of gaps in implementation. The North American plan for animal and pandemic influenza (NAPAPI), issued by the presidents of Canada, Mexico and the US in 2012, outlines how the three countries will work together to prepare for and manage animal influenza. Its aims include reducing the barriers to sharing medical countermeasures across borders, and it commits the three countries to immediately sharing outbreak notifications directly with each other. The plan includes agreements to share avian influenza vaccines and to provide veterinary assistance as needed. [1, 2] In 2012, the health secretaries of the US and Mexico signed a declaration adopting a shared set of technical guidelines for responding to public health events affecting both countries, the "Technical guidelines for United States - Mexico coordination on public health events of mutual interest". [1] The guidelines include "cases of disease identified in one country for which there is evidence or reason to suspect an epidemiologic link to the other country, including diseases detected in animals". [3]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 31 December 2020.

[2] Governments of Canada, Mexico and the US. 2012. "North American plan for animal and pandemic influenza." [http://www.phe.gov/Preparedness/international/Documents/napapi.pdf]. AAccessed 31 December 2020.
[3] Core Group on Epidemiologic Surveillance of the Health Working Group, US-Mexico Binational Commission; Centers for Disease Control and Prevention (CDC), US Department of Health and Human Services (HSS); and General Directorate of Epidemiology (DGE), Secretaria de Salud (SSA), Mexico. 2012. "Technical guidelines for United States-Mexico coordination on public health events of mutual interest." [https://www.cdc.gov/usmexicohealth/pdf/us-mexico-guidelines.pdf]. Accessed 31 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: 1

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: 0

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: 0

There is insufficient evidence that the United States has allocated national funds to improve capacity to address epidemic threats within the past three years. According to a June 2020 issue brief from The Heritage Foundation, "it is challenging to

get a complete picture of how much the federal government actually allocates to health security," including a clear answer from the government itself. Credible, non-govermental data from fiscal year 2019 estimates around $13.6 billion budgeted at the federal level for health security, which includes pandemic preparedness. [1] The Centers for Disease Control and Prevention (CDC) provides federal funding and support to local authorities through Public Health Emergency Preparedness (PHEP) cooperative agreements. Local authorities have applied for funding as needed and received annual grants since 2002. $612m was disbursed in 2017 and around $620m was available in both 2018 and 2019. [2, 3, 4, 5] However, findings from a Council on Foreign Relations (CFR) Independent Task Force Report found that since 2002 funding for the CDC's PHEP cooperative agreements has decreased by more than 25 percent. The CFR findings also describes a pandemic influenza outbreak simulation led by the Department of Health and Human Services in 2019 that concluded "that the national response to such a major public health emergency would be hindered by dangerous gaps in funding and inadequate coordination across government agencies." [6] Accompanying Recommendations from the CFR Task Force call for a comprehensive health security budget consistent with the threats the country faces regarding pandemic disease, "increased funding for the pandemic preparedness programs, projects, and activities of relevant U.S. agencies, including among others the CDC, the office of the HHS assistant secretary for preparedness and response, the National Institutes of Health, the Food and Drug Administration (FDA), the State Department, and USAID." [7] From 2014-2019 $20.3m was committed to the US by donors (primarily the Bill and Melinda Gates Foundation) to improve capacity to address epidemic threats, of which $15.9m has been disbursed. [8] There is no additional information available through the US Department of Health and Human Services, its CDC, or the US Department of Agriculture. [9, 10, 11]

[1] Bartels, F., Brookes, P. 1 June 2020. "Clear Lines of Responsibility Would Facilitate Implementation of the National Biodefense Strategy." The Heritage Foundation, Issue Brief No. 5079. [https://www.heritage.org/sites/default/files/2020-06/IB5079.pdf]. Accessed 31 December 2020.
[2] Centers for Disease Control and Prevention (CDC). 2018. "Public Health Emergency Preparedness (PHEP) cooperative agreement." [https://www.cdc.gov/phpr/readiness/phep.htm]. Accessed 31 December 2020.
[3] Centers for Disease Control and Prevention (CDC). 2020. "Final PHEP budget period 1 supplement (fiscal year 2018) funding."
[https://www.cdc.gov/cpr/readiness/00_docs/Final_PHEP_BP1_Supplement_FY_2018_Funding_Table_June_6_2018.pdf]. Accessed 31 December 2020.
[4] Centers for Disease Control and Prevention (CDC). 2019. "Final PHEP budget period 1 supplement (fiscal year 2019) funding." [https://www.cdc.gov/cpr/readiness/00_docs/PHEPBudgetPeriod-1_FiscalYear2019_Funding-Table_February212019.pdf]. Accessed 31 December 2020.
[5] Centers for Disease Control and Prevention (CDC). 2018. "Public health preparedness and response: 2018 national snapshot." Apr 2018. [https://www.cdc.gov/phpr/pubs-links/2018/documents/2018_Preparedness_Report.pdf]. Accessed 31 December 2020.
[6] Bollyky, J., Patrick, S.M. October 2020. "Improving Pandemic Preparedness: Lessons From COVID-19." Council on Foreign Relations, Independent Task Force Report - Findings. [https://www.cfr.org/report/pandemic-preparedness-lessons-COVID-19/findings/]. Accessed 31 December 2020.
[7] Bollyky, J., Patrick, S.M. October 2020. "Improving Pandemic Preparedness: Lessons From COVID-19." Council on Foreign Relations, Independent Task Force Report - Recommendations. [https://www.cfr.org/report/pandemic-preparedness-lessons-COVID-19/recommendations/]. Accessed 31 December 2020.
[8] Georgetown Infectious Disease Atlas. 2019. "Global Health Security Tracking Dashboard: United States – Recipient profile." [https://tracking.ghscosting.org/#analysis/US/r]. Accessed 31 December 2020.
[9] US Department of Health and Human Services. 2021. [https://www.hhs.gov/]. Keyword search. Accessed 27 January 2021.
[10] US Centers for Disease Control and Prevention. 2021. [https://www.cdc.gov/]. Keyword search. Accessed 27 January 2021.
[11] US Department of Agriculture. 2021. [https://www.usda.gov/]. Keyword search. Accessed 27 January 2021.

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: 1

There is a publicly identified special emergency public financing mechanism and funds which the United States can access in the face of a public health emergency. The US has emergency financing mechanisms for responding to any kind of major natural disaster, and for responding to public health emergencies specifically, though the Public Health Emergency Fund is not always immediately available. The Robert T. Stafford Disaster Relief and Emergency Assistance Act enables states and territories to apply to the president for federal funding if they are struck by any kind of natural disaster which exceeds their own ability to respond, including epidemics or pandemics. The president then has the option of making a “Stafford Act declaration”. Depending on severity, the president can declare a “major disaster”, for which funds are unlimited, or an “emergency”, for which funds are capped at $5m. [1, 2, 3] Section 319 of the Public Health Service Act also establishes a federal funding mechanism for public health emergencies, including epidemics or pandemics. States must request the Secretary of Health and Human Services (HHS) to declare a public health emergency in their state, and if a declaration is

made, funds can be allocated from the Public Health Emergency Fund. [3] However, this fund is not regularly allocated money and as experience in the past year with regard to the opioid crisis has shown, Congress may need to draft and pass a bill to approve appropriation of new funds before the emergency assistance can be provided. [3, 4, 5, 6]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 10 January 2021.
[2] Federal Emergency Management Agency (FEMA), Department of Homeland Security (DHS). 2020. "How a Disaster Gets Declared." [https://www.fema.gov/disasters/how-declared]. Accessed 10 January 2021.
[3] Katz, R, et al. 2017. "Funding public health emergency preparedness in the United States." American Journal of Public Health, 107 (suppl 2), Sep 2017. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5594396/]. Accessed 10 January 2021.
[4] Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS). 2019. "Public health emergency declaration Q&As." [https://www.phe.gov/Preparedness/legal/Pages/phe-qa.aspx#faq1]. Accessed 10 January 2021.
[5] Keith, T. 2017. "In opioid crisis, national emergency vs public health emergency." NPR, 26 Oct 2017. [https://www.npr.org/2017/10/26/560229103/in-opioid-crisis-public-health-emergency-vs-national-emergency]. Accessed 10 January 2021.
[6] Luthra, S. 2018. "Congress tackles the opioid epidemic. But how much will it help?" The Washington Post, 19 Mar 2018. [https://www.washingtonpost.com/national/health-science/congress-tackles-the-opioid-epidemic-but-how-much-will-it-help/2018/03/19/6f6e9502-2bb6-11e8-8dc9-3b51e028b845_story.html?utm_term=.ccd00c32144a]. Accessed 10 January 2021.

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 in the past three years, senior leaders in the US have made a public commitment to support other countries to improve their capacity to address epidemic threats by providing financing and technical support; but not that senior leaders have made a public commitment to improve the US' own capacity to address epidemic threats by expanding financing or requesting support to improve capacity. On 9 May 2019 a press release on behalf of President Trump announced that the US had committed to support partner countries to improve their capacity to address epidemic threats, through the US' new Global Health Security Strategy. The press release committed the US to "support select partner countries in areas such as emergency preparedness and disease surveillance". The press release does not contain any solid commitments to provide financial or technical support. However, the Strategy commits the Centers for Disease Control and Prevention (CDC) and USAID to provide technical support to partner countries to help them improve their Joint External Evaluation (JEE) scores; and notes that of the $149.8m requested for global public health protection in the 2020 President's Budget, $99.762m would support the Global Health Security Agenda (GHSA) and related CDC global health security programs. [1, 2] Furthermore, at the Global Health Security Ministerial Meeting in Indonesia in 2018, Secretary of Health and Human Services

Alex Azar emphasized the important of GHSA 2024, stating “to keep our people safe, we must strengthen our capacity to prevent, detect and respond to infectious diseases. As the continuing Ebola crisis in the Democratic Republic of the Congo reminds us, it is vital that we all work together to support countries struggling to combat these frightening threats.” [3] There is no evidence that senior leaders have made a public commitment to improve the US’ own capacity to address epidemic threats by expanding financing or requesting support to improve capacity, either from the White House, the Department of Health and Human Services, or US-relate health news from the World Health Organisation and the Pan-American Health Organisation. [4, 5, 6, 7]

[1] The White House. 9 May 2019. “President Donald J. Trump is protecting the homeland and the world from global health security threats.” [https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-protecting-homeland-world-global-health-security-threats/]. Accessed 10 January 2021.
[2] Government of the United States. 2019. “United States government Global health security strategy.” [https://www.whitehouse.gov/wp-content/uploads/2019/05/GHSS.pdf]. Accessed 10 January 2021.
[3] US Department of Health & Human Services. November 2018. "GHSA Ministerial Meeting: Secretary Alex Azar Plenary Video". [https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/ghsa-ministerial-meeting-secretary-alex-azar-plenary-video.html]. Accessed 10 January 2021.
[4] The White House. 2019. “News.” [https://www.whitehouse.gov/news/]. Accessed 10 January 2021.
[5] Department of Health and Human Services. 2019. “News releases.” [https://www.hhs.gov/about/leadership/secretary/news-releases/index.html]. AAccessed 10 January 2021.
[6] World Health Organisation. 2019. “United States of America.” [https://www.who.int/countries/usa/en/]. Accessed 10 January 2021.
[7] Pan-American Health Organisation/World Health Organisation United States. 2019. “Latest news.” [https://www.paho.org/us/index.php?lang=en]. Accessed 10 January 2021.

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 in the past three years, the United States has provided other countries with financing or technical support to improve capacity to address epidemic threats and has requested financing or technical support from donors to improve the country’s domestic capacity to address epidemic threats. Through the Global Health Security Agenda (GHSA), in 2015 the US committed US$1bn—part of a $5.4bn commitment to combat the Ebola outbreak and prevent further outbreaks—to build capacity to prevent, detect, and respond to future infectious disease outbreaks across the Caribbean Community and 31 countries, 17 of which received direct financial support and technical assistance from the Centers for Disease Control and Prevention (CDC), and 14 of which received only technical assistance. According to the GSHA, by the end of December 2017, the CDC had obligated $453.8m, and USAID had obligated $245.5m in support of this commitment. [1, 2, 3] According to the Global Health Security Tracking Dashboard, from 2014-2020 the US has committed $57.09bn to support other countries, of which $50.84bn has been disbursed. [4] For example, during this period, the country disbursed $699.30m in "US GHSA Support" to over 30 countries, and the US Agency for International Development (USAID) disbursed $166.41m for PREDICT II. [5] During the same period, $124.14m has been committed and $74.39m disbursed to the US. [6]

[1] Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS). 2017. "Advancing the Global Health Security Agenda: CDC achievements and early impact." [https://www.cdc.gov/globalhealth/healthprotection/resources/pdf/GHSAReport_final.pdf]. Accessed 10 January 2021.
[2] US Department of State. 17 April 2017. "Remarks at the Grand Challenges Annual Meeting." Remarks by the Secretary of State, Washington DC, 4 Oct 2017. [https://2017-2021.state.gov/secretary-tillerson-addresses-global-health-challenges-at-grand-challenges-annual-meeting/index.html]. Accessed 30 January 2021.
[3] PATH. 2017. "Healthier world, safer America: A roadmap for international action to prevent the next pandemic." [https://www.path.org/publications/files/APP_GH_Security_rpt_rev.pdf]. Accessed 10 January 2021.
[4] Georgetown Infectious Disease Atlas. 2020. "Global Health Security Tracking Dashboard: United States – Funder profile." [https://tracking.ghscosting.org/details/1078/funder]. Accessed 24 April 2021.
[5] Georgetown Infectious Disease Atlas. 2020. "Global Health Security Tracking Dashboard: United States – Funder table." [https://tracking.ghscosting.org/table/1078/funder]. Accessed 24 April 2021.
[6] Georgetown Infectious Disease Atlas. 2019. "Global Health Security Tracking Dashboard: United States – Recipient profile." [https://tracking.ghscosting.org/details/1078/recipient]. Accessed 21 May 2021.

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: 0

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

The United States has a number of policies and systems for sharing genetic and epidemiological data with other countries that go beyond influenza. The 2016 Joint External Evaluation (JEE) self-assessment states that: "A leading practice is the sharing of samples and data, including whole genome sequence and associated metadata, in public repositories for public health agencies and researchers to use globally. This practice needs to be pursued and reinforced." [1] The United States is a member of the Global Health Security Initiative, 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 National Institutes of Health (NIH) under the Department of Health and Human Services (HHS) has published

a number of data sharing policies which encourage and sometimes require researchers to submit genetic data into relevant publicly-available databases, including databases available to the international community. An example relevant to infectious diseases is the "National Institute of Allergy and Infectious Diseases (NIAID)/Division of Microbiology and Infectious Diseases (DMID) data sharing and release guidelines", which "establishes … guidelines for data release plans across NIAID/DMID Omics Centers including Genomic Sequencing Centers for Infectious Diseases (GSCID) and other NIAID-funded large scale Centers and projects", and "indicates that plans should specify that genomic and other data types collected in NIAID-funded research will be submitted as rapidly as possible into publicly accessible and searchable international databases such as GenBank, dbGaP, the sequence read archive, the DMID Bioinformatics Resource Center, or other databases designated and approved by NIAID." [3] The Food and Drug Administration (FDA), HSS, operates the GenomeTrakr network, a network of over 60 domestic and international laboratories which shares genomic and geographic data from pathogens. It started with foodborne pathogens but is being expanded to include any pathogens affecting human health. The Centers for Disease Control and Prevention (CDC) feeds data into GenomeTrakr through its PulseNet system. 83 countries participate in PulseNet International. The FDA is working with the World Health Organization (WHO) and the United Nations' Food and Agriculture Organization (FAO) to make this technology available to developing nations. [4, 5, 6] Lastly, Mexico and the United States have agreed upon an Operational Protocol for Binational Communication and Coordination for the Notification of Diseases and Outbreaks. Appendix 5 of the protocol describes procedures for sharing specimens during public health events of mutual interest. The procedures include an option for Mexico to send specimens to the CDC for analysis. [7] The Technical Guides that support the protocol describe ongoing information exchange to follow up on binational outbreaks. In addition, they discuss resource sharing and which agency is responsible for which costs related to the investigation. The guides also call for the establishment of an expedited customs procedure for cross- border transport of specimens during outbreak investigations. [8]

[1] Department of Health and Human Services. 20 Sep 2016. "International health regulations - Joint external evaluation of the United States of America: Self-assessment report." [https://www.phe.gov/about/OPP/dihs/Documents/jee-self-assessment.pdf]. Accessed 10 January 2021.
[2] Global Health Security Initiative. "GHSI Members." [http://ghsi.ca/ghsi-members/]. Accessed 10 January 2021.
[3] Trans-NIH BioMedical Informatics Coordinating Committee (BMIC), National Institutes of Health (NIH). 2019. "NIH data sharing policies." [https://www.nlm.nih.gov/NIHbmic/nih_data_sharing_policies.html]. Accessed 10 January 2021.
[4] Food and Drug Administration (FDA), Department of Health and Human Services (HHS). 2020. "GenomeTrakr Network." [https://www.fda.gov/Food/FoodScienceResearch/WholeGenomeSequencingProgramWGS/ucm363134.htm]. Accessed 10 January 2021.
[5] Food and Drug Administration (FDA), Department of Health and Human Services (HHS). 2017. "Sharing whole genome sequencing with the world."
[https://www.fda.gov/Food/FoodScienceResearch/WholeGenomeSequencingProgramWGS/ucm554448.htm]. Accessed 10 January 2021.
[6] Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS). 2019. "About PulseNet." [https://www.cdc.gov/pulsenet/about/index.html]. Accessed 10 January 2021.
[7] Centers for Disease Control and Prevention. 2017. "Operational Protocol for U.S.-Mexico Binational Communication and Coordination on Disease Notifications and Outbreaks". [https://www.cdc.gov/usmexicohealth/pdf/us-mexico-protocol.pdf]. Accessed 10 January 2021.
[8] Centers for Disease Control and Prevention. 2017. "United States — Mexico Guidelines and Protocol for Coordination". [https://www.cdc.gov/usmexicohealth/united-states-mexico-guidelines-cooperation.html]. Accessed 10 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 evidence that the United States has not shared samples in accordance with the PIP framework in the past year. The Department of Health and Human Services (HHS) published an updated pandemic influenza plan in 2017, reiterating its commitment to a leading role in the PIP framework. It stated that "HSS will continue to coordinate domestic and international pandemic preparedness and response activities. This will include having clearly-defined mechanisms for rapid exchange of information, data, reagents and other resources needed domestically and globally." [1] This leading role was illustrated by the feedback provided by the US to the PIP framework review in 2016, which urged strengthening of the system. [2] There is no evidence on the World Health Organization (WHO) PIP Framework website that the US has not shared samples in accordance with the framework in the past year, nor are there any media reports indicating this. [3] Effective July 6, 2021, the US withdrew its membership from the World Health Organization. [4, 5] A July 2020 article in The Lancet mentions that "US agencies, pharmaceutical companies, and laboratories also rely on the WHO Pandemic Influenza Preparedness Framework to gain access to new influenza virus samples for research and development. Severing ties with WHO could impede US access to crucial tools for developing biological countermeasures to influenza." However, there is no mention of the US not sharing samples in accordance with the framework. [5]

[1] Department of Health and Human Services (HHS). 2017. "Pandemic influenza plan: 2017 update." [https://www.cdc.gov/flu/pandemic-resources/pdf/pan-flu-report-2017v2.pdf]. Accessed 5 January 2021.
[2] "United States Government feedback for the 2016 Pandemic Influenza Preparedness Framework review." 15 Jul 2016. [http://www.who.int/influenza/pip/2016-review/US_July2016.pdf]. Accessed 5 January 2021.
[3] World Health Organization (WHO). 2018. "Pandemic Influenza Preparedness (PIP) Framework." [http://www.who.int/influenza/pip/en/]. Accessed 5 January 2021.
[4] US Department of State. 3 September 2020. "Update on U.S. Withdrawal from the World Health Organization." [https://www.state.gov/update-on-u-s-withdrawal-from-the-world-health-organization/]. Accessed 5 January 2021.
[5] Gostin, L.O, Koh, H.H., Williams, M., et al. 9 July 2020. "US withdrawal from WHO is unlawful and threatens global and US health and security." [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736
[20] 31527-0/fulltext]. Accessed 5 January 2021.

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 the US has not shared pandemic pathogen samples during an outbreak in the past two years. In the cases of notifiable infectious disease outbreaks reported to the World Health Organisation (WHO) in the past two years, the WHO did not report any failure to share pathogen samples. [1, 2] In the cases of outbreaks reported to the World Organisation for Animal Health (OIE) in the past two years, the OIE did not report any failure to share pathogen samples. [3] There is no media reporting to suggest that the US has failed to share pandemic pathogen samples during an outbreak in the past two years. Effective July 6, 2021, the US withdrew its membership from the World Health Organization. [4, 5] A July 2020 article in The Lancet mentions that "US agencies, pharmaceutical companies, and laboratories also rely on the WHO Pandemic Influenza Preparedness Framework to gain access to new influenza virus samples for research and development. Severing ties with WHO could impede US access to crucial tools for developing biological countermeasures to influenza." However, there is no mention of the US not sharing samples, and there is no evidence that COVID-19 samples have not been shared. [5] The WHO Pan American Health Organization Regional Update, Influenza for Epidemiological Week 50 - December

22, 2020 includes an update on influenza and COVID-19 data from the United States, but does not refer to samples shared. [6]

[1] World Health Organisation (WHO). 2021. “Disease Outbreak News”. 2019 and 2020 pages. [https://www.who.int/csr/don/archive/year/2019/en/]; [https://www.who.int/csr/don/archive/year/2020/en/]. Accessed 5 January 2021.
[2] World Health Organisation (WHO). 20 Feb 2017. “Seoul virus – United States of America and Canada.” Disease Outbreak News. [https://www.who.int/csr/don/20-february-2017-seoulvirus-usa-and-canada/en/]. Accessed 5 January 2021.
[3] World Organisation for Animal Health (OIE). 2021. “Weekly Disease Information”. WAHIS Interface. [https://www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI]; [https://www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/reportarchive]. Accessed 5 January 2021.
[4] US Department of State. 3 September 2020. "Update on U.S. Withdrawal from the World Health Organization." [https://www.state.gov/update-on-u-s-withdrawal-from-the-world-health-organization/]. Accessed 5 January 2021.
[5] Gostin, L.O, Koh, H.H., Williams, M., et al. 9 July 2020. "US withdrawal from WHO is unlawful and threatens global and US health and security." [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736
[20] 31527-0/fulltext]. Accessed 5 January 2021.
[6] Pan American Health Organization, World Health Organization. 22 December 2020. "Regional Update, Influenza. Epidemiological Week 50 - December 22, 2020." [https://www.paho.org/en/documents/regional-update-influenza-epidemiological-week-50-december-22-2020]. Accessed 5 January 2021.

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: 2

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: 67

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: 3

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: 2

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: 2

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: 0

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: 0.82

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: 0.9

2016

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

There is no clear measurement or reporting of the share of employment in the informal sector in the United States. The Bureau of Labor Statistics (BLS) measures contingent work and alternative employment arragements, which was last collected in May 2017. According to BLS, 3.8 percent of workers held contingent jobs, defined as wokers who do not expect their jobs to last or report them as temporary. There were four cateogries of workers reported as a percentage of total employment with alternative employment arrangements: 6.9 percent as independent contractors, 1.7 percent as on-call wokers, 0.9 percent as temporary help agency wokers and 0.6 percent as workers provided by contract firms. [1] A Federal Reserve Report on the Economic Well-Being of U.S. Households in 2018—referring to informal, infrequent paid acvities as gig work—found that 3 in 10 adults engaged in at least one gig activity in the month before they were surveyed. [2] A survey conducted by the Federal Reserve Bank of Boston in 2013—sample of 1,218 individuals, ages 21 and older—found that approximately 44 percent of respondents reported participating in some informal paid work during 2011–2013. [3] No more data on share of employment in the informal sector is available for the United States through the ILOSTAT database and the World Bank. [4, 5]

[1] US Bureau of Labor Statistics. 7 June 2018. "Contingent and Alternative Employment Arrangements News Release." [https://www.bls.gov/news.release/archives/conemp_06072018.htm]. Accessed 7 January 2021.
[2] The Federal Reserve. May 2019. "Report on the Economic Well-Being of U.S. Households in 2018." [https://www.federalreserve.gov/publications/2019-economic-well-being-of-us-households-in-2018-employment.htm]. Accessed 7 January 2021.
[3] Bracha, A., Burke, M.A. 2014. "Informal Work Activity in the United States: Evidence from Survey Responses." Rederal Reserve Bank of Boston.[https://www.bostonfed.org/publications/current-policy-perspectives/2014/informal-work-in-the-united-states-evidence-from-survey-responses.aspx]. Accessed 7 January 2021.
[4] International Labour Organization (ILOSTAT). "Country Profiles". [https://ilostat.ilo.org/data/country-profiles/]. Accessed 7 January 2021.
[5] The World Bank. "Informal employment (% of total non-agricultural employment". [https://data.worldbank.org/indicator/SL.ISV.IFRM.ZS]. Accessed 7 January 2021.

6.2.3c

Coverage of social insurance programs (% of population)

Scored in quartiles (0-3, where 3=best)

Current Year Score: 3

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: 0

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: 2

2021

Economist Intelligence Democracy Index

6.2.6 Inequality

6.2.6a

Gini coefficient

Scored 0-1, where 0=best

Current Year Score: 0.41

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: 4

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: 4

2021

Economist Intelligence

6.4 ENVIRONMENTAL RISKS

6.4.1 Urbanization

6.4.1a

Urban population (% of total population)

Input number

Current Year Score: 82.46

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: 0.23

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: 3

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: 78.54

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: 407.9

2019

WHO

6.5.1c

Population ages 65 and above (% of total population)

Input number

Current Year Score: 16.21

2019

World Bank

6.5.1d

Prevalence of current tobacco use (% of adults)

Input number

Current Year Score: 25.1

2018

World Bank

6.5.1e

Prevalence of obesity among adults

Input number

Current Year Score: 36.2

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: 5355.79

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: 0

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