

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

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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

Italy has a national AMR plan which covers the surveillance, detection and reporting of priority AMR pathogens.

Called the National Plan for Confronting Antimicrobial Resistance (Piano Nazionale di Contrasto dell'Antimicrobico-Resistenza (PNCAR) 2017-2020), or PNCAR for short, it has two general objectives: 1) reducing the frequency of infections caused by antibiotic-resistant microorganisms, and 2) reducing the frequency of hospital and community healthcare-associated infections. The PNCAR focuses on six areas of interest: Antibiotic resistance surveillance and prevention; appropriate use and surveillance of antimicrobial consumption; surveillance, prevention and control of healthcare-associated infections; training of healthcare staff; information and education of the population; and research and innovation. [1]

An example of a combined surveillance, detection and reporting mandate in Italy described in and supported by the PNCAR is the AR-ISS voluntary sentinel-surveillance network, made up of around 50 hospital laboratories nationwide. Operating since 2001, it collects AMR data on 8 pathogens (*Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Acinetobacter* spp., *Staphylococcus aureus*, *Enterococcus faecalis*, *Enterococcus faecium* and *Streptococcus pneumoniae*) in a manner consistent with that of the EARS-Net European surveillance network, which receives this data annually. The PNCAR notes that the hospitals served by the laboratories participating in the network represent only around 15% of the beds of the National Health Service; thus, a major aim of the plan is to boost participation in such activities. [1]

The PNCAR is implemented through 67 central-government actions and 59 regional- and local-government actions, and embodies both human and veterinary strategies. The so-called "strong points" of the strategy for the human sector are: control of healthcare-associated infections (HAIs); and appropriate use of antibiotics in humans. The strong points of the veterinary strategy are: complete digitization of veterinary medicinal products; and Integrating a risk categorization system for livestock farms. [1]

[1] Ministry of Health of Italy. October 24 2017. "National Plan for Confronting Antimicrobial Resistance (PNCAR) (Piano Nazionale di Contrasto dell'Antimicrobico-Resistenza (PNCAR) 2017-2020."

[http://www.salute.gov.it/imgs/C_17_pubblicazioni_2660_allegato.pdf] Accessed September 2020 Other sources: Ministry of Health of Italy. 2017. "PNCAR National Action Plan on Antimicrobial Resistance." Plan synopsis in English.

[http://www.salute.gov.it/imgs/C_17_opuscoliPoster_362_ulterioriallegati_ulterioreallegato_0_alleg.pdf] Accessed September 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

Italy has a national laboratory system which tests for all the 7 + 1 listed priority AMR pathogens, but under several protocols.

Under one protocol, Italy's National Plan to Confront Antimicrobial Resistance 2017-2020 (Piano Nazionale di Contrasto dell'Antimicrobico-Resistenza 2017-2020--PNCAR), the system routinely tests several but not all of the 7+1 priority AMR pathogens as defined by the WHO. AMR is monitored nationwide through a network of sentinel laboratories known as AR-ISS operating as a surveillance system under the National Institute of Health (ISS). AR-ISS collects AMR data on 8 pathogens, which include some of the WHO priority pathogens (Escherichia coli, Klebsiella pneumoniae, Staphylococcus aureus and Streptococcus pneumoniae among others). [1]

Under different protocols, N. gonorrhoeae and Mycobacterium tuberculosis are also subject to national-level surveillance. Two sentinel surveillance systems for STIs are active in Italy, both coordinated by the AIDS Operational Center (CoA) of the ISS: one uses a sentinel network of 12 public clinical centers specialized in STIs; the other a sentinel network of 13 clinical microbiology laboratories. As the ISS indicates, these sentinel surveillance systems do not have national coverage but sampling methods allow overall trends to be measured. [2, 3] Data on drug-resistant mycobacterium tuberculosis are collected by a network of 46 sentinel laboratories under the direction of the Supranational Reference Laboratory (SRL) network of the World Health Organization (WHO) for the surveillance of tuberculosis resistance at the Department of Infectious Diseases of the ISS. [4]

In addition, Salmonellosis is subject to mandatory notification under Italian law, and the ISS oversees a surveillance system called Enter-net Italia, which among others, also collects isolates of drug-resistant Salmonella spp. from environmental sources. [5] There is also evidence that routine testing for Shigella spp is undertaken in several hospital laboratories. [6]

[1] Republic of Italy. Ministry of Health. 2017. "National Plan to Confront Antimicrobial Resistance (PNCAR) 2017-2020 (Piano Nazionale di Contrasto dell'Antimicrobico-Resistenza (PNCAR) 2017-2020).

[http://www.salute.gov.it/imgs/C_17_pubblicazioni_2660_allegato.pdf] Accessed September 2020

[2] Republic of Italy. National Institute of Health (ISS). EpiCentro. Undated. "Gonorrhea (or blenorragia): Epidemiological aspects in Italy (Gonorrhea (o blenorragia): Aspetti epidemiologici in Italia)."

[<https://www.epicentro.iss.it/gonorrhea/epidemiologia-italia>] Accessed September 2020

[3] Republic of Italy. National Institute of Health (ISS). EpiCentro. Undated. "Sexually transmitted infections: Epidemiological aspects in Italy (Infezioni sessualmente trasmesse: Aspetti epidemiologici in Italia)."

[<https://www.epicentro.iss.it/ist/epidemiologia-italia>] Accessed September 2020

[4] Republic of Italy. National Institute of Health (ISS). EpiCentro. Undated. "Initiatives and projects: Tuberculosis - News (Iniziative e progetti in Italia: Tubercolosi - News)." [<https://www.epicentro.iss.it/tubercolosi/iniziative-italia>] Accessed September 2020

[5] Republic of Italy. National Institute of Health (ISS). EpiCentro. Undated. "salmonella: Epidemiological aspects (salmonella: Aspetti epidemiologici)". [<http://www.epicentro.iss.it/problemi/salmonella/epid.asp>] Accessed September 2020

[6] Luca Busani. Undated, possibly 2010. "Epidemiology and surveillance of Infectious gastroenteritis and episodes of foodborne illnesses (Epidemiologia e sorveglianza di gastroenteriti infettive e episodi di MTA)". National Institute of Health (ISS). PowerPoint presentation.

[http://www.izsto.it/images/stories/allegati_eventi/pdf%20pubblicabili%204%20e%205%20ottobre/busani.pdf] Accessed

September 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

Available evidence does not indicate that an Italian government agency currently implements a national policy to conduct detection or surveillance activities for antimicrobial residues or AMR organisms in the natural environment. For instance, the Ministry for Environment, Land and Sea Protection does conduct environmental risk assessments, but on such products as GMOs, endocrine disruptors and chemicals bearing risk to the environment. [4]

By contrast, Italy's National Plan to Confront Antimicrobial Resistance 2017-2020 (PNCAR) does not specifically mandate a government entity to conduct AMR detection or surveillance activities in the natural environment, but does require relevant AMR detection or surveillance activities to be carried out in two strategy areas: human and veterinary. [1] In the human strategy area, detection and surveillance is carried out in the medical context, through the national network of sentinel laboratories known as AR-ISS. [2] In the veterinary strategy area, detection of residuals and contaminants is already carried out through another mechanism, the National Plan on Residuals (Piano Nazionale Residui (PNR)). [1]

In its visit to Italy in early January 2017, the European Centre for Disease Control and Prevention (ECDC) concluded that "...the AMR situation in Italian hospitals and regions poses a major public health threat to the country," adding that there appeared to be "...little sense of urgency about the current AMR situation from most stakeholders and a tendency by many stakeholders to avoid taking charge of the problem..." [3]

[1] Republic of Italy. Ministry of Health. 2017. "PNCAR National Action Plan on Antimicrobial Resistance."

[http://www.salute.gov.it/imgs/C_17_opuscoliPoster_362_ulterioriallegati_ulterioreallegato_0_alleg.pdf] Accessed September 2020

[2] Republic of Italy. Ministry of Health. 2017. "National Plan to Confront Antimicrobial Resistance (PNCAR) 2017-2020 (Piano Nazionale di Contrasto dell'Antimicrobico-Resistenza (PNCAR) 2017-2020).

[http://www.salute.gov.it/imgs/C_17_pubblicazioni_2660_allegato.pdf] Accessed September 2020

[3] European Centre for Disease Control and Prevention (ECDC). January 9-13 2017. "ECDC country visit to Italy to discuss antimicrobial resistance issues". [<https://ecdc.europa.eu/sites/portal/files/documents/AMR-country-visit-Italy.pdf>] Accessed September 2020

[4] Republic of Italy. Ministry for Environment, Land and Sea Protection. January 25 2016. "Environmental Risk Assessment (ERA) (Valutazione del Rischio Ambientale (VRA))". <http://www.minambiente.it/pagina/valutazione-del-rischio-ambientale-vra>] Accessed September 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

Italy's laws require prescriptions for antibiotic use by humans and mandate good pharmaceutical practice and classification rules for the disbursement of medicines. However, there is some evidence of gaps in enforcement. [1, 2, 4].

Numerous Italian decree-laws support pharmacovigilance, some by transposing into national law the European Union regulations on the subject, such as those mandating good pharmacovigilance practices (GVP) by the health authorities of the Member States. [3] Nevertheless, Italy is among the five EU Member States with the highest levels of outpatient antibiotic consumption. A pattern where the use of leftover antibiotics is the prevailing source of nonprescription use, is also seen in Italy. [1]

While sales of over-the-counter (OTC) antibiotics at pharmacies without a prescription from a GP are illegal in Italy except for creams and eye drops, survey research has indicated that most pharmacists (69%) have sold Amoxicillin over the counter. [1]

[1] John Paget, Dominique Lescure, Ann Versporten, Herman Goossens, François Schellevis, Liset van Dijk. April 2017. "Antimicrobial resistance and causes of non-prudent use of antibiotics in human medicine in the EU". European Commission Directorate-General for Health and Food Safety.

[https://ec.europa.eu/health/amr/sites/amr/files/amr_arna_report_20170717_en.pdf] Accessed September 2020

[2] Ann Versporten, John Paget, Dominique Lescure, François Schellevis, Liset Van Dijk, Herman Goossens. 2016. "Regulation and authorization of antibiotics in the ambulatory care sector in Europe". European Society of Clinical Microbiology and Infectious Diseases (ESCMID). [https://www.escmid.org/escmid_publications/escmid_elibrary/material/?mid=48979] Accessed September 2020

[3] Italian Medicines Agency (AIFA). 2020. "Pharmacovigilance (Farmacovigilanza)." [<https://www.aifa.gov.it/en/normativa-di-riferimento-farmacovigilanza>] Accessed September 2020

[4] World Health Organisation (WHO). February 2017. "Italy: European Region". [<http://www.who.int/health-laws/countries/ita-en.pdf>] Accessed September 2020

1.1.2b

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

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

Current Year Score: 2

Italy has national legislation in place requiring prescriptions for antibiotic use for animals. Available evidence indicates that gaps in enforcement are few in Italy, as the use of antibiotics in animals is declining markedly there.

This requirement is embodied in Italy's main law on veterinary medicines, Legislative Decree n. 193 dated 06.04.2006 and called "Veterinary medical prescriptions." This decree strictly regulates the use of such medicines, stipulating that they may be sold only by pharmacies and licensed pharmacists. The pharmacological classes under which veterinary medicines are dispensed by means of prescriptions are: chemotherapeutics, antibiotics, antiparasitics, corticosteroids, hormones, anti-inflammatories, psychotropic substances, neurotropics, tranquilizers and beta-agonists. Such medicines containing active substances are dispensed according to whether the animal subjects are intended for the production of food for humans, or are animals kept not for human food production, such as domestic pets. [3]

Italy's national plan to combat AMR, National Plan to Confront Antimicrobial Resistance, contains a veterinary strategy as well as one for humans. [1] The veterinary strategy has several overarching goals, among which are to reduce the consumption of orally administered antibiotics by more than 30% and of so-called Critically Important Antimicrobials by more than 10%. [1]

Effective April 16 2019, the use of electronic veterinary prescriptions became mandatory in Italy, replacing the paper format.

The aim is to improve the traceability of veterinary medicines, particularly as pertains to the supply of food derived from animals such as livestock. [4]

Finally, according to the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) program of the European Medicines Agency, the use of several key antibiotics has declined markedly in Italy in recent years; for example, the use of tetracyclines has fallen from around 150 mg/PCU in 2010 to just over 70 mg/PCU in 2018. [5]

[1] Republic of Italy. Ministry of Health. 2017. "PNCAR National Action Plan on Antimicrobial Resistance 2017-2020." [http://www.salute.gov.it/imgs/C_17_opuscoliPoster_362_ulterioriallegati_ulterioreallegato_0_alleg.pdf] Accessed September 2020

[2] Republic of Italy. Ministry of Health. 2017. "National Plan to Confront Antimicrobial Resistance (PNCAR) 2017-2020 (Piano Nazionale di Contrasto dell'Antimicrobico-Resistenza (PNCAR) 2017-2020)." [http://www.salute.gov.it/imgs/C_17_pubblicazioni_2660_allegato.pdf] Accessed September 2020

[3] Riunite Municipal Pharmacies (Farmacie Comunal Riunite). 2019. "Veterinary medical prescription (Prescrizione medico veterinaria)." [http://www.fcr.re.it/prescrizione-medico-veterinaria] Accessed September 2020

[4] Republic of Italy. Ministry of Health. April 15 2019. "Electronic veterinary prescriptions mandatory from April 16, 2019 (Ricetta elettronica veterinaria, è obbligatoria dal 16 aprile 2019)." [http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=3709] Accessed September 2020

[5] European Medicines Agency. 2021. "European Surveillance of Veterinary Antimicrobial Consumption (ESVAC)." [https://www.ema.europa.eu/en/veterinary-regulatory/overview/antimicrobial-resistance/european-surveillance-veterinary-antimicrobial-consumption-esvac#trends-by-country-section] Accessed April 2021

[6] European Medicines Agency. 2019. "ITALY: CHANGES IN SALES (MG/PCU) ACROSS YEARS." [https://www.ema.europa.eu/en/documents/report/italy-trends-sales-veterinary-antibiotics-between-2010-2018_en.pdf] Accessed April 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

Italy has a national strategy for zoonotic diseases. It is guided by the Ministry of Health's latest Integrated National Plan of Controls (Piano Nazionale Integrato dei Controlli--PNI) which was implemented from 2015 to 2019. [1, 2] The PNI embraces two key rules on the issue: Ministerial Decree of 15 December 1990 , on public health and on the notification of infectious diseases, and Legislative Decree 4 April 2006 no. 191 , on food safety and veterinary public health, which regulates zoonoses surveillance and the epidemiology of food-borne outbreaks. [2]

There are other related, stand-alone national plans and strategies for the control of at least five specific zoonoses: Brucellosis, bovine spongiform encephalopathy (BSE), avian salmonellosis, trichinosis and bovine tuberculosis. [1, 2]

The health ministry's new National Prevention Plan for 2020-2025 (Piano Nazionale della Prevenzione 2020-2025--PNP), adopted on August 6 2020, also addresses zoonoses; one of its six macro objectives is to combat so-called priority infective

diseases, of which zoonoses are one priority category. In this regard, the plan's focus is on ensuring food safety and veterinary public health, but reducing the incidence of "non-alimentary" zoonoses is also a key objective. [3] At the forefront of executing these policies are the regional health authorities, the local health committees (Aziende Sanitarie Locali --ASL) and the veterinary labs known as Experimental Zooprohylactic Institutes (Istituti Zooprofilattici Sperimentali --IZS). [4]

Finally, Italy's national plan to combat AMR, known as the PNCAR, aims to strengthen the control of infectious diseases and zoonoses--particularly in livestock farms--such as through the use of alternative treatments to antimicrobials (immunising and non-immunising devices). [5]

[1] Republic of Italy. Ministry of Health. January 1 2015. "INTEGRATED NATIONAL PLAN 2015-2019: ANIMAL HEALTH - INFECTIOUS DISEASES (PIANO NAZIONALE INTEGRATO 2015-2019: SANITÀ ANIMALE - MALATTIE INFETTIVE)."

[<http://www.salute.gov.it/pianoNazionaleIntegrato2015/sezionePianoNazionaleIntegrato2015.jsp?cap=capitolo3&sez=pni-cap3-sanitaanimale-malattieinfettive>] Accessed September 2020

[2] Republic of Italy. Ministry of Health. January 1 2015. "INTEGRATED NATIONAL PLAN 2015-2019: TRANSVERSAL ACTIVITIES - ZOOSES (PIANO NAZIONALE INTEGRATO 2015-2019: ATTIVITÀ TRASVERSALI - ZONOSI)."

[<http://www.salute.gov.it/pianoNazionaleIntegrato2015/sezionePianoNazionaleIntegrato2015.jsp?cap=capitolo3&sez=pni-cap3-trasversali-zoonosi>] Accessed September 2020

[3] Republic of Italy. Ministry of Health. 2020. National Prevention Plan 2020-2025 (Piano Nazionale della Prevenzione 2020-2025---PNP)." [http://www.salute.gov.it/imgs/C_17_notizie_5029_0_file.pdf] Accessed September 2020

[4] Republic of Italy. Ministry of Health. December 22 2014. "Prevention, control and eradication of animal diseases (Prevenzione, controllo ed eradicazione malattie animali)".

[http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=1561&area=sanitaAnimale&menu=malattie] Accessed September 2020

[5] Republic of Italy. Ministry of Health. 2017. "PNCAR National Action Plan on Antimicrobial Resistance 2017-2020".

[http://www.salute.gov.it/imgs/C_17_opuscoliPoster_362_ulterioriallegati_ulterioreallegato_0_alleg.pdf] Accessed September 2020

1.2.1b

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

Yes = 1 , No = 0

Current Year Score: 1

Italy has national legislation, plans and strategy document(s) which include measures for risk identification and reduction for zoonotic disease spillover events from animals to humans.

Italy's overall national strategy for zoonotic diseases is guided by the Ministry of Health's latest Integrated National Plan of Controls (Piano Nazionale Integrato dei Controlli--PNI) which was implemented from 2015 to 2019. [1, 2] The PNI embraces two key rules on the issue: Ministerial Decree of 15 December 1990 , on public health and on the notification of infectious diseases, and Legislative Decree 4 April 2006 no. 191 , on food safety and veterinary public health, which regulates zoonoses surveillance and the epidemiology of food-borne outbreaks. The PNI puts heavy emphasis on risk identification, management and control. It recognizes two key types of zoonotic transmission: direct contact with infected animals, and indirect contact such as through the ingestion of contaminated food, through the contaminated environment (water, air, soil, etc), or by biological vectors (mosquitoes and other insects). The PNI prioritizes controlling the risks from foodborne zoonoses, and it mandates specific risk-reduction measures, mainly the strict monitoring and control of food-production facilities such as slaughterhouses. Reporting responsibilities are incumbent on all stakeholders in the food supply chain, ranging from

company veterinarians to food transporting personnel. [2]

There are other related, stand-alone national plans and strategies for the control of at least five specific zoonoses: Brucellosis, bovine spongiform encephalopathy (BSE), avian salmonellosis, trichinosis and bovine tuberculosis. All have risk-management and risk-reduction components. [1, 2]

The health ministry's new National Prevention Plan for 2020-2025 (Piano Nazionale della Prevenzione 2020-2025--PNP), adopted on August 6 2020, places considerable stress on managing and reducing risk. It does address zoonoses and their risks; one of the plan's six macro objectives is to combat so-called priority infective diseases, of which zoonoses are one priority category. To that end, this section of the plan stresses the need for risk valuation and management strategies in ensuring food safety and veterinary public health. The main zoonotic risk stated in the plan is that of food poisoning in the restaurant-supply and catering industries. In this regard, risk-reduction is based on ensuring the health of food animals, the tracing of food supply chains and the activation of the national alert system for withdrawing or recalling dangerous or potentially dangerous food from markets. Reducing the incidence of "non-alimentary" zoonoses is also a key objective. [3]

Finally, Italy's national plan to combat AMR, known as the PNCAR, aims to strengthen the control of infectious diseases and zoonoses--particularly in livestock farms--such as through the use of alternative treatments to antimicrobials (immunising and non-immunising devices). In that regard, one of its hallmarks is the use of an integrated risk-categorization system for livestock farms. [4]

[1] Republic of Italy. Ministry of Health. January 1 2015. "INTEGRATED NATIONAL PLAN 2015-2019: ANIMAL HEALTH - INFECTIOUS DISEASES (PIANO NAZIONALE INTEGRATO 2015-2019: SANITÀ ANIMALE - MALATTIE INFETTIVE)."

[<http://www.salute.gov.it/pianoNazionaleIntegrato2015/sezionePianoNazionaleIntegrato2015.jsp?cap=capitolo3&sez=pni-cap3-sanitaanimale-malattieinfettive>] Accessed September 2020 and April 2021

[2] Republic of Italy. Ministry of Health. January 1 2015. "INTEGRATED NATIONAL PLAN 2015-2019: TRANSVERSAL ACTIVITIES - ZOOSES (PIANO NAZIONALE INTEGRATO 2015-2019: ATTIVITÀ TRASVERSALI - ZONOSI)."

[<http://www.salute.gov.it/pianoNazionaleIntegrato2015/sezionePianoNazionaleIntegrato2015.jsp?cap=capitolo3&sez=pni-cap3-trasversali-zoonosi>] Accessed September 2020 and April 2021

[3] Republic of Italy. Ministry of Health. 2020. National Prevention Plan 2020-2025 (Piano Nazionale della Prevenzione 2020-2025---PNP)." [http://www.salute.gov.it/imgs/C_17_notizie_5029_0_file.pdf] Accessed September 2020

[4] Republic of Italy. Ministry of Health. 2017. "PNCAR National Action Plan on Antimicrobial Resistance 2017-2020".

[http://www.salute.gov.it/imgs/C_17_opuscoliPoster_362_ulterioriallegati_ulterioreallegato_0_alleg.pdf] Accessed September 2020

1.2.1c

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

Yes = 1 , No = 0

Current Year Score: 1

Italy has national legislation, plans and guidelines that account for the surveillance and control of multiple zoonotic pathogens of public health concern.

Italy's overall national strategy for zoonotic diseases is guided by the Ministry of Health's latest Integrated National Plan of Controls (Piano Nazionale Integrato dei Controlli--PNI) which was implemented from 2015 to 2019. [1, 2] The PNI embraces two key rules on the issue: Ministerial Decree of 15 December 1990, on public health and on the notification of infectious

diseases, and Legislative Decree 4 April 2006 no. 191, on food safety and veterinary public health, which regulates zoonoses surveillance and the epidemiology of food-borne outbreaks. The plan does not limit its scope to specific zoonoses but its framework encompasses stand-alone national plans and strategies for the control of at least five specific zoonoses: Brucellosis, bovine spongiform encephalopathy (BSE), avian salmonellosis, trichinosis and bovine tuberculosis. The plan also applies to over a dozen other animal-borne diseases, such as African swine fever and blue-tongue disease. [1, 2]

The health ministry's new National Prevention Plan for 2020-2025 (Piano Nazionale della Prevenzione 2020-2025--PNP), adopted on August 6 2020, addresses zoonoses and their risks; one of the plan's six macro objectives is to combat so-called priority infective diseases, of which zoonoses are one priority category. To that end, this section of the plan stresses the need for risk valuation and management strategies in ensuring food safety and veterinary public health. Reducing the incidence of "non-alimentary" zoonoses is also a key objective. [3] At the forefront of executing these policies are the regional health authorities, the local health committees (Aziende Sanitarie Locali --ASL) and the veterinary labs known as Experimental Zooprophyllactic Institutes (Istituti Zooprofilattici Sperimentali --IZS). [4]

Finally, Italy's national plan to combat AMR, known as the PNCAR, aims to strengthen the control of infectious diseases and zoonoses--particularly in livestock farms--such as through the use of alternative treatments to antimicrobials (immunising and non-immunising devices). In that regard, one of its hallmarks is the use of an integrated risk-categorization system for livestock farms. [5]

[1] Republic of Italy. Ministry of Health. January 1 2015. "INTEGRATED NATIONAL PLAN 2015-2019: ANIMAL HEALTH - INFECTIOUS DISEASES (PIANO NAZIONALE INTEGRATO 2015-2019: SANITÀ ANIMALE - MALATTIE INFETTIVE)."

[<http://www.salute.gov.it/pianoNazionaleIntegrato2015/sezionePianoNazionaleIntegrato2015.jsp?cap=capitolo3&sez=pni-cap3-sanitaanimale-malattieinfettive>] Accessed September 2020

[2] Republic of Italy. Ministry of Health. January 1 2015. "INTEGRATED NATIONAL PLAN 2015-2019: TRANSVERSAL ACTIVITIES - ZOOSES (PIANO NAZIONALE INTEGRATO 2015-2019: ATTIVITÀ TRASVERSALI - ZONOSI)."

[<http://www.salute.gov.it/pianoNazionaleIntegrato2015/sezionePianoNazionaleIntegrato2015.jsp?cap=capitolo3&sez=pni-cap3-trasversali-zoonosi>] Accessed September 2020

[3] Republic of Italy. Ministry of Health. 2020. National Prevention Plan 2020-2025 (Piano Nazionale della Prevenzione 2020-2025---PNP). [http://www.salute.gov.it/imgs/C_17_notizie_5029_0_file.pdf] Accessed September 2020

[4] Republic of Italy. Ministry of Health. December 22 2014. "Prevention, control and eradication of animal diseases (Prevenzione, controllo ed eradicazione malattie animali)".

[http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=1561&area=sanitaAnimale&menu=malattie] Accessed September 2020

[5] Republic of Italy. Ministry of Health. 2017. "PNCAR National Action Plan on Antimicrobial Resistance 2017-2020".

[http://www.salute.gov.it/imgs/C_17_opuscoliPoster_362_ulterioriallegati_ulterioreallegato_0_alleg.pdf] Accessed September 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

Available evidence does not indicate that Italy has a stand-alone agency dedicated to zoonotic disease that functions across ministries. Although Italy has national agencies with responsibility for zoonoses, they are not truly cross-ministerial in structure.

The Ministry of Health is responsible for administering national policy on animal health. It has at least two departments that have responsibility for policy on zoonotic disease. One, the Directorate-General for Animal Health and Veterinary Medicines (Direzione generale della sanità animale e dei farmaci veterinari), coordinates and funds the work of the experimental zooprophyllactic institutes (the IZSs). It also cooperates with its sister agency, the Ministry's Directorate General for Food Hygiene and Food Safety and Nutrition (Direzione generale per l'igiene e la sicurezza degli alimenti e la nutrizione). The other, the National Center for the Control and Emergency of Animal Diseases (Centro nazionale di lotta ed emergenza contro malattie animali), is a policymaking body that "...defines the objectives and strategies for the prevention, control and eradication of animal diseases for the entire national territory, in collaboration with the veterinary services of the Regions and Autonomous Provinces." [1]

Evidence does not indicate that either of these bodies is structured to cooperate on policy laterally, across other ministries or departments of the public administration, rather than with other units of the ministry itself. Otherwise, there is no evidence of a different cross-ministerial agency via the Ministry of Health or the Ministry of Agriculture. [2, 3]

[1] Republic of Italy. Ministry of Health. 2020. "Animal health (Sanità animale).

[http://www.salute.gov.it/portale/temi/p2_4.jsp?lingua=italiano&tema=Animali&area=sanitaAnimale] Accessed September 2020

[2] Republic of Italy. Ministry of Health. 2020. Website [<http://www.salute.gov.it>] Accessed September 2020

[3] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website.

[<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202>] Accessed September 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

Italy has a national mechanism for owners of livestock to conduct and report on disease surveillance to the central government. Italy has a very well-developed system for the reporting of animal diseases; it is grounded in laws--several of which are transposed European Union directives--mandating the notification of animal diseases within the European Community by the relevant veterinary offices of the Member States. [1]

According to the Ministry of Health's general consumer-protection plan, known as the Integrated National Plan 2015-2019 (Piano Nazionale Integrato 2015-2019), there are Veterinary Police Regulations in places since 1954 that mandate veterinary vigilance in the form of passive surveillance. [4] Data reporting obligations are placed, first and foremost, on the official veterinarian(s) in the relevant region, and then on "professional figures who interact directly or indirectly with [the animal] breeding [process]." Among these are: company veterinarians, owners and handlers of animals --including animals in transit, and directors of the experimental zooprophyllactic institutes (IZSs). [2]

The Ministry of Health is in charge of collecting such data via its dedicated animal disease information systems (the earlier SINzoo and the current SIMAN). [1] As concerns zoonoses found in livestock (in terms of national policy the main vector of concern), veterinarians report incidences of animal disease into the SIMAN system through the ministry's Vetinfo online portal of the national livestock registry (Banca Dati Nazionale dell'Anagrafe Zootecnica). Vetinfo has separate modules for

the reporting of diseases in cows, sheep horses and swine. [3]

- [1] Republic of Italy. Ministry of Health. 2020. "Disease notification (Notifica malattie)." (http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=1559&area=sanitaAnimale&menu=malattie) Accessed September 2020
- [2] Ministry of Health of Italy. 1 January 2015. "INTEGRATED NATIONAL PLAN 2015-2019: ANIMAL HEALTH - INFECTIOUS DISEASES (PIANO NAZIONALE INTEGRATO 2015-2019: SANITÀ ANIMALE - MALATTIE INFETTIVE)". (<http://www.salute.gov.it/pianoNazionaleIntegrato2015/sezionePianoNazionaleIntegrato2015.jsp?cap=capitolo3&sez=pni-cap3-sanitaanimale-malattieinfettive>) Accessed September 2020
- [3] Republic of Italy. Ministry of Health. 2020. Vetinfo. (<https://www.vetinfo.it/>) Accessed September 2020

1.2.2b

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

Yes = 1 , No = 0

Current Year Score: 0

Available evidence indicates that the Italian national surveillance system for zoonotic diseases does not mandate confidentiality in data collection, distribution and storage by owners of animals or other relevant parties per se. Nevertheless the system permits only authorised persons to process the relevant data from point of entry to final reporting to the European Food Safety Authority (EFSA). [6] The Italian national information system for zoonoses data collection, known as SIMAN, [1] complies with European Union (EU) directives, such as 82/894/EEC of December 21 1982 as amended and Directive (EC) 2003/99, which oblige EU Member States such as Italy to collect data on zoonoses and the like. [2, 3, 4] But these directives do not specifically mandate the confidentiality of collected data. [2, 3, 4]

Data collected on zoonoses flow from veterinarians of the Local Health Units-- Aziende Locali Sanitari e (ASL) to the regional veterinary services and Experimental Zooprofilactic Institutes (Istituti Zooprofilattici Sperimentali-IZSs), up to the Ministry of Health, and end at the European Commission and the EFSA. Data entry and validation are carried out in the SIMAN system only by authorised personnel, and only validated data is used in the reports intended for transmission to EFSA. [2, 3, 4, 6]

No additional evidence is available from the agriculture ministry or from the health ministry. [1, 5, 6]

- [1] Republic of Italy. Ministry of Health. 2020. "Disease notification (Notifica malattie)." (http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=1559&area=sanitaAnimale&menu=malattie) Accessed September 2020
- [2] Patrizia Colangeli, Simona Iannetti, Angelo Cerella, Carla Ippoliti, Alessio Di Lorenzo, Ugo Santucci, Pasquale Simonetti, Paolo Calistri & Rossella Lelli. July 2011. "The national information system for the notification of animal diseases in Italy." *Veterinaria italiana*. (https://www.researchgate.net/publication/299017979_National_System_for_Animals_Disease_Notification?enrichId=rgreq-1e979505b02f866953df6fa8d6d12ce8-XXX&enrichSource=Y292ZXJYWDlOZl50TAxNzk3OTtBUzo1NzExMjI4ODYzNzc0NzJAMTUxMzE3NzcxNTMyNg%3D%3D&el=1_x_2&_esc=publicationCoverPdf) Accessed September 2020
- [3] Daniela Cioci. October 2016. "THE ZOONOSSES: Lesson on: Information system for data collection on zoonoses (LE ZOONOSI: Lezione su: Sistema informativo per la raccolta dati sulle zoonosi)": ISZAM Institute (Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise "G. Caporale"). (http://www.izs.it/IZS/Engine/RAServeFile.php/f/Formazione_corsi_-_convegni/2016/Corso_EST_e_uso_dei_sistemi_informativi_nazionali_veterinari/Cioci_Sistema_informativo_per_la_raccolta)

_dati_sulle_zoonosi.pdf] Accessed September 2020

[4] Iannetti S., Cioci D., Falcone M.G. and Colangeli P. 2017. "The Zoonoses Data Collection in Italy: An Expert System for Data Quality Management and Improvement". Journal of Veterinary Science & Technology. Volume 8, Issue 2.

[<https://www.omicsonline.org/open-access/the-zoonoses-data-collection-in-italy-an-expert-system-for-data-qualitymanagement-and-improvement-2157-7579-1000431.pdf>] Accessed September 2020

[5] Republic of Italy. Ministry of Agriculture (Mipaaf), 2020. "National policies (Politiche nazionali)".

[<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/7681>] Accessed September 2020

[6] Republic of Italy. Ministry of Health. 2020. Vetinfo. [<https://www.vetinfo.it/>] Accessed September 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

Italy conducts some surveillance of zoonotic disease in wildlife, but lacks a national plan.

The Ministry of Health's animal disease control and surveillance policy focuses on livestock and the like, and it gives no indication that it makes monitoring of wildlife a priority. [1] The ministry's new National Prevention Plan (Piano Nazionale della Prevenzione---PNP) for the 2020-2025 period does cite the management of populations of wild animals as key to one of its central objectives, the prevention of zoonoses. Yet it is not evident that a specific plan for this purpose has been implemented. [2]

Nevertheless, one region in particular, Emilia-Romagna, has a plan to monitor disease in wildlife including zoonoses, to comply with European Commission Regulation no. 2075/2005 on diseases such as trichinosis in wild game. [3] Under that regulation, the European Food Safety Authority (EFSA) has developed a matrix "pick list", sorted by type of animal and designated place of testing. But the process is problematic for wild animals, as sampling is limited to game-handling establishments and the like. [5]

The Ministry of Health's annual National Plan for Research of Residuals (Piano Nazionale per la Ricerca dei Residui---PNR) looks for three types of substances (veterinary medicines, pesticides and environmental contaminants) in samples taken during food production that uses animals including farmed "wild" game (selvaggina allevata) and hunted game (selvaggina cacciata). Recent PNR data on trichinella from hunted wild game have been gathered from samplings of wild boar meat. [5]

[1] Republic of Italy. Ministry of Health. 2020. "Prevention, control and eradication of diseases (Prevenzione controllo ed eradicazione malattie)."

[http://www.salute.gov.it/portale/temi/p2_5.jsp?lingua=italiano&area=sanitaAnimale&menu=malattie] Accessed September 2020

[2] Republic of Italy. Ministry of Health. 2020. National Prevention Plan 2020-2025 (Piano Nazionale della Prevenzione 2020-2025---PNP)." [http://www.salute.gov.it/imgs/C_17_notizie_5029_0_file.pdf] Accessed September 2020

[3] Experimental Zooprophyllactic Institute of Lombardy and Emilia Romagna "Bruno Ubertini". Undated. "Wildlife monitoring plan (Piano di monitoraggio della fauna selvatica)".

[https://www.izsler.it/pls/izs_bs/v3_s2ew_consultazione.mostra_pagina?id_pagina=2652] Accessed September 2020

[4] Experimental Zooprophyllactic Institute of Lazio and Tuscany "M. Aleandri." 2019. "NATIONAL RESIDUALS PLAN (PIANO NAZIONALE RESIDUI)." [<http://www.izslt.it/piano-nazionale-residui/>] Accessed September 2020

[5] Iannetti S., Cioci D., Falcone M.G. and Colangeli P. 2017. "The Zoonoses Data Collection in Italy: An Expert System for Data Quality Management and Improvement". Journal of Veterinary Science & Technology. Volume 8, Issue 2.

[<https://www.omicsonline.org/open-access/the-zoonoses-data-collection-in-italy-an-expert-system-for-data-qualitymanagement-and-improvement-2157-7579-1000431.pdf>] Accessed September 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: 37.59

2018

OIE WAHIS database

1.2.4b

Number of veterinary para-professionals per 100,000 people

Input number

Current Year Score: 5.72

2018

OIE WAHIS database

1.2.5 Private sector and zoonotic

1.2.5a

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

Yes = 1, No = 0

Current Year Score: 0

Available evidence via the Ministry of Agriculture, National Institute of Health or Ministry of Health does not indicate that Italy's national plans on zoonotic disease substantially incorporate the private sector. [2, 5, 6, 7, 8, 9, 10]

Italy's national zoonotic disease prevention policy is a top-down, public-sector initiative. It is driven by a hierarchy of key actors, with the European Food Safety Authority (EFSA) acting as the supranational regulator at the top, the Italian Ministry of Health's Directorate-General for Animal Health and Veterinary Medicines coordinating between departments [8] at the national level, the regional veterinary services processing data and designing strategies at the regional level, the local health units (the ASLs) collecting data at the local level, and the experimental zooprophyllactic institutes (the IZSSs) providing epidemiological surveillance and technical support in the field. [1, 2]

The collection and analysis of zoonotic data necessitates some interaction with the private sector, such as through ASL veterinarians' inspections of food industry participants (livestock farms, feed companies, food producers and the like). [3, 4] Moreover, some European Commission funding made available to Member States' veterinary sectors for zoonoses prevention [5] may trickle down to private actors such as Italian livestock owners. Nevertheless, the Ministry of Health remains the "central competent authority" (autorità competente centrale) dealing with zoonoses in Italy, [1] and none of its relevant national plans or departments, such as the aforementioned Directorate-General, discusses a specific role for the private sector in combating zoonoses. [1, 5, 6, 7, 8]

[1] Republic of Italy. Ministry of Health. 2017. "National Plan to Confront Antimicrobial Resistance (PNCAR) 2017-2020 (Piano Nazionale di Contrasto dell'Antimicrobico-Resistenza (PNCAR) 2017-2020).

[http://www.salute.gov.it/imgs/C_17_pubblicazioni_2660_allegato.pdf] Accessed September 2020

[2] Republic of Italy. Ministry of Health. "The Italian Public Health System for Animal Health and Food Safety".

[http://www.salute.gov.it/imgs/C_17_EventiStampa_355_intervisteRelatori_itemInterviste_1_fileAllegatoIntervista.pdf] Accessed September 2020

[3] Daniela Cioci. October 2016. "THE ZOOONOSES: Lesson on: Information system for data collection on zoonoses (LE ZONOSI: Lezione su: Sistema informativo per la raccolta dati sulle zoonosi)": ISZAM Institute (Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise "G. Caporale"). [http://www.izs.it/IZS/Engine/RAServeFile.php/f/Formazione_corsi_-_convegni/2016/Corso_EST_e_uso_dei_sistemi_informativi_nazionali_veterinari/Cioci_Sistema_informativo_per_la_raccolta_dati_sulle_zoonosi.pdf] Accessed September 2020

[4] Iannetti S., Cioci D., Falcone M.G. and Colangeli P. 2017. "The Zoonoses Data Collection in Italy: An Expert System for Data Quality Management and Improvement". Journal of Veterinary Science & Technology. Volume 8, Issue 2.

[<https://www.omicsonline.org/open-access/the-zoonoses-data-collection-in-italy-an-expert-system-for-data-qualitymanagement-and-improvement-2157-7579-1000431.pdf>] Accessed September 2020

[5] Republic of Italy. Ministry of Health. 2020. "Prevention, control and eradication of diseases (Prevenzione controllo ed eradicazione malattie)."

[http://www.salute.gov.it/portale/temi/p2_5.jsp?lingua=italiano&area=sanitaAnimale&menu=malattie] Accessed September 2020

[6] Republic of Italy. Ministry of Health. January 1 2015. "INTEGRATED NATIONAL PLAN 2015-2019: ANIMAL HEALTH - INFECTIOUS DISEASES (PIANO NAZIONALE INTEGRATO 2015-2019: SANITÀ ANIMALE - MALATTIE INFETTIVE)".

[<http://www.salute.gov.it/pianoNazionaleIntegrato2015/sezionePianoNazionaleIntegrato2015.jsp?cap=capitolo3&sez=pni-cap3-sanitaanimale-malattieinfettive>] Accessed September 2020

[7] Republic of Italy. Ministry of Health. 2020. National Prevention Plan 2020-2025 (Piano Nazionale della Prevenzione 2020-2025---PNP). [http://www.salute.gov.it/imgs/C_17_notizie_5029_0_file.pdf] Accessed September 2020

[8] Republic of Italy. Ministry of Health. January 10 2018. Directorate-General for Animal Health and Veterinary Medicines (Direzione generale della sanità animale e dei farmaci veterinari).

[http://www.salute.gov.it/portale/ministro/p4_5_2_4_1.jsp?menu=organizzazione&label=uffCentrali&id=1156] Accessed September 2020

[9] Republic of Italy. National Institute of Health. EpiCentro. 2018. "Veterinary health care: General information (Sanità veterinaria: Informazioni generali). [<http://www.epicentro.iss.it/temi/veterinaria/veterinaria.asp>] September 2020

[10] Republic of Italy. Ministry of Agriculture (Mipaaf). 2018. "National policies (Politiche nazionali)." [https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/7681] Accessed September 2020

1.3 BIOSECURITY

1.3.1 Whole-of- government biosecurity systems

1.3.1a

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

Yes = 1 , No = 0

Current Year Score: 0

Publicly available evidence does not indicate that Italy has 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 of those facilities.

There is some evidence that Italy has processes in place to monitor dangerous pathogens. Italy has a biosafety and biosecurity system, whose official guidance points to the existence of national inventory and secure physical containment processes for biopathogens. [1, 2, 3, 10] Since 1992 the Presidency of the Council of Ministers has had a National Committee for Biosafety, Biotechnology and Life Sciences (Comitato Nazionale per la Biosicurezza, le Biotecnologie e le Scienze per la Vita-- CNBBSV), acting upon EU biosafety directives, such as genetically modified micro-organisms. [3, 4] The CNBBSV's guidelines on accreditation of so-called "biobanks" (biobanche), facilities holding biological materials for research, inventory control and traceability are key factors in determining their accreditation. [1, 2]

In its 2010 Code of Conduct for Biosecurity/Safety, the CNBBSV distinguishes between "biosafety" and "biosecurity", for the latter mandating controlled access and barriers for laboratory facilities, security measures taken on employees, stringent procedures on transport and traceability of biological agents inside and above all outside the laboratory, and controls to prevent the loss or theft of stored agents and toxins. [3] Group 4 pathogens, the most dangerous, may can be grown only in special containment facilities (called P4 or BSL-4), of which only one exists in Italy. [3] The CNBBSV also states that it hosts a National Observatory for Biosafety, Biotechnologies and Life Sciences which continuously maps "biotechnological activities" in the country and operates a database on biotechnologies. Details on its activities are not readily available. [4]

Among other key Italian government entities, neither the ministries of defense, health, or agriculture indicate the existence of a policy on safeguarding dangerous pathogens. [5, 6, 7]

Finally, although Italy has submitted Confidence Building Measures for 2020 and preceding years under the Biological Weapons Convention, access to the documents is restricted and they are not publicly available. [8] The biological weapons legislation database of VERTIC (the Verification Research, Training and Information Centre) shows no legislation by Italy directly concerning the security of dangerous pathogens. [9]

[1] Republic of Italy. Presidency of the Council of Ministers. National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV). 21 November 2008. "BIOBANKS AND CENTERS FOR BIOLOGICAL RESOURCES OF HUMAN SAMPLES, ESTABLISHED FOR RESEARCH PURPOSES (BIOBANCHE E CENTRI PER LE RISORSE BIOLOGICHE DI CAMPIONI UMANI, ISTITUITI A FINI DI RICERCA)*. [http://cnbbsv.palazzochigi.it/media/1644/2008-11-febbraio-accreditamento_20080211.pdf] Accessed September 2020

- [2] Republic of Italy. Presidency of the Council of Ministers. National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV). 19 April 2006. "GUIDELINES FOR THE CERTIFICATION OF BIOBANKS: ATTACHMENTS (LINEE GUIDA PER LA CERTIFICAZIONE DELLE BIOBANCHE: ALLEGATI)". [http://cnbbsv.palazzochigi.it/media/1629/2006-19-aprile-biobanche_1.pdf] Accessed September 2020
- [3] Republic of Italy. Presidency of the Council of Ministers. National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV). 15 June 2010. "Code of Conduct for Biosecurity/Safety (Codice di Condotta per la Biosicurezza)". [http://cnbbsv.palazzochigi.it/media/1653/2010-15-giugno-codici_condotta_biosicurezza-1.pdf] Accessed September 2020
- [4] Republic of Italy. Presidency of the Council of Ministers. "CNBBSV-National Committee for Biosafety, Biotechnology and Life Sciences (CNBBSV-Comitato Nazionale per la Biosicurezza, le Biotechnologie e le Scienze della Vita)". [<http://cnbbsv.palazzochigi.it/it/>] Accessed September 2020
- [5] Republic of Italy. Ministry of Defense. Website. [www.difesa.it] Accessed September 2020
- [6] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website. [<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202>] Accessed September 2020
- [7] Republic of Italy. Ministry of Health. Website. [www.salute.gov.it] Accessed September 2020
- [8] United Nations Office at Geneva (UNOG). Biological Weapons Convention Implementation Support Unit. "Confidence-Building Measures." [<https://bwc-ecbm.unog.ch/state/italy>] Accessed September 2020
- [9] VERTIC (Verification Research, Training and Information Centre). 2020. BWC Legislation Database. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/>] Accessed September 2020
- [10] National Labor Inspectorate (Ispettorato Nazionale Lavoro). May 2018. "Legislative Decree of 9 April 2008, n. 81. Text coordinated with Legislative Decree of 3 August 2009, n. 106. SINGLE TEXT ON HEALTH AND SAFETY AT WORK (D.lgs. 9 aprile 2008, n. 81. Testo coordinato con il D.Lgs. 3 agosto 2009, n. 106. TESTO UNICO SULLA SALUTE E SICUREZZA SUL LAVORO)". [<https://www.gruppocmb.com/wp-content/uploads/2018/05/Dlgs-81-08-Maggio-2018.pdf>] Accessed September 2020 Other sources: Republic of Italy. Ministry for Environment, Land and Sea Protection. "Italian Biosafety Clearing-House (Biosafety Clearing-House Italiana)". [<http://bch.minambiente.it/index.php/it/bch-italiana>] Accessed September 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: 0

There is insufficient evidence that Italy has regulations on biosecurity that stipulate measures to specifically address the deliberate misuse of high-consequence biological agents and toxins--as opposed to regulations on biosafety.

For example, the labor ministry's Legislative Decree No. 81 of 9 April 2008, (text coordinated with Legislative Decree no. 106 of 3 August 2009) on workplace safety addresses in some detail the issue of containment of group 2, 3 and 4 biological agents, but not explicitly in the context of their deliberate or malicious misuse. [1]

In its 2010 Code of Conduct for "Biosicurezza" (Biosecurity/Biosafety), Italy's cabinet-level National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV) does distinguish--in English--between "biosafety" and "biosecurity", for the latter mandating controlled access and barriers for laboratory facilities, security measures taken on employees, stringent procedures on transport and traceability of biological agents inside and above all outside the laboratory, and controls to prevent the loss or theft of stored agents and toxins. The Code of Conduct outlines practices for containment of dangerous pathogens. For example, Group 4 pathogens, the most dangerous, may be grown only in special containment facilities (called

P4 or BSL-4), of which evidence indicates two exist in Italy, at the "Lazzaro Spallanzani" National Infectious Disease Institute in Rome and at the CLIMVIB laboratory of the L.Sacco University Hospital in Milan. [5, 6] The document also notes that Legislative Decree 12 April 2001, n. 206 of Italy requires that laboratories conducting research involving the genetic manipulation of biological agents notify the Ministry of Health, and receive a prior assessment of its physical and structural containment capabilities. [2]

Italy also has comprehensive biosecurity/biosafety legislation, with many laws transposing European Union directives on these topics. Some of these laws relate to the release of genetically modified organisms and others focus on biosafety and -security in the workplace, such as in laboratories. [4] But in the published Italian legislation overall it is unclear what specific measures are to be taken in such facilities in the event that dangerous biological agents are deliberately misused.

Among other key Italian government entities, neither the ministries of defense, health, or agriculture indicate the existence of a policy on safeguarding dangerous pathogens. [7, 8, 9]

Finally, although Italy has submitted Confidence Building Measures for 2020 and preceding years under the Biological Weapons Convention, access to the documents is restricted and they are not publicly available. [10] The biological weapons legislation database of VERTIC (the Verification Research, Training and Information Centre) shows no legislation by Italy directly concerning the security of dangerous pathogens. [11]

[1] Republic of Italy. Ministry of Labor, Health and Social Policies. 2009. "LEGISLATIVE DECREE OF 9 APRIL 2008, No. 81 Text coordinated with the Legislative Decree 3 August 2009, n. 106 (DECRETO LEGISLATIVO 9 APRILE 2008, N. 81 Testo coordinato con il Decreto Legislativo 3 agosto 2009, n. 106)." [<http://www.ego-gw.it/public/about/VIR-0558A-09.pdf>] Accessed September 2020

[2] Republic of Italy. Presidency of the Council of Ministers. National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV). 15 June 2010. "Code of Conduct for Biosecurity/Safety (Codice di Condotta per la Biosicurezza)". [http://cnbbsv.palazzochigi.it/media/1653/2010-15-giugno-codici_condotta_biosicurezza-1.pdf] Accessed September 2020

[3] Republic of Italy. Presidency of the Council of Ministers. "CNBBSV-National Committee for Biosafety, Biotechnology and Life Sciences (CNBBSV-Comitato Nazionale per la Biosicurezza, le Biotecnologie e le Scienze della Vita)". [<http://cnbbsv.palazzochigi.it/it/>] Accessed September 2020

[4] University of Padua (Università degli Studi di Padova). Vallisneri Biomedical Library (Biblioteca Biomedica Vallisneri). Biosecurity/safety (Biosicurezza). "Current Regulations (Normativa Vigente)". [http://www.bio.unipd.it/safety/man/norme.html#SICUREZZA_BIOLOGICA] Accessed September 2020

[5] James leDuc. 2012. "REQUIREMENTS FOR AND CHALLENGES ASSOCIATED WITH BSL-4 LABS (PLENARY SESSION)." In "Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories: Summary of a Workshop (2012)." The National Academies Press. [<https://www.nap.edu/read/13315/chapter/10>] Accessed September 2020

[6] L. Sacco University Hospital, Milan. CLIMVIB Laboratory of Clinical Microbiology. "BSL-4 Facilities." [<http://climvib.eu/the-laboratory/bsl-4/>] Accessed September 2020

[7] Republic of Italy. Ministry of Defense. Website. [www.difesa.it] Accessed September 2020

[8] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website. [<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202>] Accessed September 2020

[9] Republic of Italy. Ministry of Health. Website. [www.salute.gov.it] Accessed September 2020

[10] United Nations Office at Geneva (UNOG). Biological Weapons Convention Implementation Support Unit. "Confidence-Building Measures." [<https://bwc-ecbm.unog.ch/state/italy>] Accessed September 2020

[11] VERTIC (Verification Research, Training and Information Centre). 2020. BWC Legislation Database. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/>] Accessed September 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: 0

There is insufficient evidence of a government agency in Italy with specific oversight for biosecurity, as opposed to biosafety, although there is official acknowledgement of the differences in the two concepts.

For example, in its 2010 Code of Conduct for "Biosicurezza" (Biosafety/Biosecurity), the cabinet-level National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV)--in charge of biosafety/biosecurity policy in the country [1]--does distinguish in English between "biosafety" and "biosecurity." [2] As regards the latter term, the Code of Conduct mandates controlled access and barriers for laboratory facilities, security measures taken on employees, stringent procedures on transport and traceability of biological agents inside and above all outside the laboratory, and controls to prevent the loss or theft of stored agents and toxins. It also outlines procedures for laboratories housing dangerous pathogens. [2] For example, Group 4 pathogens, the most dangerous, may be grown only in special containment facilities (called P4 or BSL-4). [2, 3, 4] Evidence indicates that two BSL-4 labs exist in Italy; at the "Lazzaro Spallanzani" National Infectious Disease Institute in Rome and at the CLIMVIB laboratory of the L.Sacco University Hospital in Milan. [5, 6]

The CNBBSV also guides the accreditation of so-called "biobanks" (biobanche), facilities holding biological materials for research purposes--inventory control and traceability are key factors in determining their accreditation. [3, 4] However, as in the published Italian legislation overall, it is unclear from this agency's Code of Conduct what specific measures are to be taken in such facilities in the event that dangerous biological agents are deliberately misused, or whether the CNBBSV itself is to direct relevant biosecurity policy. [2, 7] Tellingly, while this entity by all evidence remains in operation, its function with regard to biosecurity is unclear. For instance, its website provides a link to a page on bioterrorism policy, which contains no information. [1]

Among other key Italian government entities, neither the ministries of defense, health, or agriculture indicate the existence of a policy on safeguarding dangerous pathogens. [8, 9,10]

Finally, although Italy has submitted Confidence Building Measures for 2020 and preceding years under the Biological Weapons Convention, access to the documents is restricted and they are not publicly available. [11] The biological weapons legislation database of VERTIC (the Verification Research, Training and Information Centre) shows no legislation by Italy directly concerning the security of dangerous pathogens. [12]

[1] Republic of Italy. Presidency of the Council of Ministers. "CNBBSV-National Committee for Biosafety, Biotechnology and Life Sciences (CNBBSV-Comitato Nazionale per la Biosicurezza, le Biotecnologie e le Scienze della Vita)." Website.

[http://cnbbsv.palazzochigi.it/it/] Accessed September 2020

[2] Republic of Italy. Presidency of the Council of Ministers. National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV). 15 June 2010. "Code of Conduct for Biosecurity/Safety (Codice di Condotta per la Biosicurezza)".

[http://cnbbsv.palazzochigi.it/media/1653/2010-15-giugno-codici_condotta_biosicurezza-1.pdf] Accessed September 2020

[3] Republic of Italy. Presidency of the Council of Ministers. National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV). 21 November 2008. "BIOBANKS AND CENTERS FOR BIOLOGICAL RESOURCES OF HUMAN SAMPLES, ESTABLISHED FOR RESEARCH PURPOSES (BIOBANCHE E CENTRI PER LE RISORSE BIOLOGICHE DI CAMPIONI UMANI, ISTITUITI A FINI DI RICERCA)*. [http://cnbbsv.palazzochigi.it/media/1644/2008-11-febbraio-accreditamento_20080211.pdf] Accessed September 2020

[4] Republic of Italy. Presidency of the Council of Ministers. National Committee for Biosafety and Biotechnology and Life

Sciences (CNBBSV). 19 April 2006. "GUIDELINES FOR THE CERTIFICATION OF BIOBANKS: ATTACHMENTS (LINEE GUIDA PER LA CERTIFICAZIONE DELLE BIOBANCHE: ALLEGATI)". [http://cnbbsv.palazzochigi.it/media/1629/2006-19-aprile-biobanche_1.pdf] Accessed September 2020

[5] James leDuc. 2012. "REQUIREMENTS FOR AND CHALLENGES ASSOCIATED WITH BSL-4 LABS (PLENARY SESSION)." In "Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories: Summary of a Workshop (2012)." The National Academies Press. [<https://www.nap.edu/read/13315/chapter/10>] Accessed September 2020

[6] L. Sacco University Hospital, Milan. CLIMVIB Laboratory of Clinical Microbiology. "BSL-4 Facilities." [<http://climvib.eu/the-laboratory/bsl-4/>] Accessed September 2020

[7] University of Padua (Università degli Studi di Padova). Vallisneri Biomedical Library (Biblioteca Biomedica Vallisneri). Biosecurity/safety (Biosicurezza). "Current Regulations (Normativa Vigente)". [http://www.bio.unipd.it/safety/man/norme.html#SICUREZZA_BIOLOGICA] Accessed September 2020

[8] Republic of Italy. Ministry of Defense. Website. [www.difesa.it] Accessed September 2020

[9] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website. [<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202>] Accessed September 2020

[10] Republic of Italy. Ministry of Health. Website. [www.salute.gov.it] Accessed September 2020

[11] United Nations Office at Geneva (UNOG). Biological Weapons Convention Implementation Support Unit. "Confidence-Building Measures." [<https://bwc-ecbm.unog.ch/state/italy>] Accessed September 2020

[12] VERTIC (Verification Research, Training and Information Centre). 2020. BWC Legislation Database. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/>] Accessed September 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 public evidence that Italy has consolidated its inventories of especially dangerous pathogens and toxins.

While the 2010 Code of Conduct for "Biosicurezza" (Biosafety/Biosecurity) published by Italy's cabinet-level National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV) states that the most dangerous (Group 4) pathogens may be held only with prior authorisation of the Ministry of Health, in special containment facilities (called P4 or BSL-4), this document itself does not constitute a policy to consolidate such inventories. [1] In addition, the CNBBSV's guidelines on biobanks does not elucidate a specific policy for the storage and consolidation of top-level pathogens. [2, 3] Evidence indicates that Italy has two BSL-4 labs and therefore two locations where it might store such pathogens--the "Lazzaro Spallanzani" National Infectious Disease Institute in Rome and the CLIMVIB laboratory of the L.Sacco University Hospital in Milan. [4, 5]

Among other key Italian government entities, neither the ministries of defense, health, or agriculture indicate the existence of a policy on safeguarding dangerous pathogens. [6, 7, 8]

Finally, although Italy has submitted Confidence Building Measures for 2020 and preceding years under the Biological Weapons Convention, access to the documents is restricted and they are not publicly available. [9] The biological weapons legislation database of VERTIC (the Verification Research, Training and Information Centre) shows no legislation by Italy directly concerning the security of dangerous pathogens. [10]

- [1] Republic of Italy. Presidency of the Council of Ministers. National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV). 15 June 2010. "Code of Conduct for Biosecurity/Safety (Codice di Condotta per la Biosicurezza)". [http://cnbbsv.palazzochigi.it/media/1653/2010-15-giugno-codici_condotta_biosicurezza-1.pdf] Accessed September 2020
- [2] Republic of Italy. Presidency of the Council of Ministers. National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV). 21 November 2008. "BIOBANKS AND CENTERS FOR BIOLOGICAL RESOURCES OF HUMAN SAMPLES, ESTABLISHED FOR RESEARCH PURPOSES (BIOBANCHE E CENTRI PER LE RISORSE BIOLOGICHE DI CAMPIONI UMANI, ISTITUITI A FINI DI RICERCA)*". [http://cnbbsv.palazzochigi.it/media/1644/2008-11-febbraio-accreditamento_20080211.pdf] Accessed September 2020
- [3] Republic of Italy. Presidency of the Council of Ministers. National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV). 19 April 2006. "GUIDELINES FOR THE CERTIFICATION OF BIOBANKS: ATTACHMENTS (LINEE GUIDA PER LA CERTIFICAZIONE DELLE BIOBANCHE: ALLEGATI)". [http://cnbbsv.palazzochigi.it/media/1629/2006-19-aprile-biobanche_1.pdf] Accessed September 2020
- [4] James leDuc. 2012. "REQUIREMENTS FOR AND CHALLENGES ASSOCIATED WITH BSL-4 LABS (PLENARY SESSION)." In "Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories: Summary of a Workshop (2012)." The National Academies Press. [<https://www.nap.edu/read/13315/chapter/10>] Accessed September 2020
- [5] L. Sacco University Hospital, Milan. CLIMVIB Laboratory of Clinical Microbiology. "BSL-4 Facilities." [<http://climvib.eu/the-laboratory/bsl-4/>] Accessed September 2020
- [6] Republic of Italy. Ministry of Defense. Website. [www.difesa.it] Accessed September 2020
- [7] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website. [<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202>] Accessed September 2020
- [8] Republic of Italy. Ministry of Health. Website. [www.salute.gov.it] Accessed September 2020
- [9] United Nations Office at Geneva (UNOG). Biological Weapons Convention Implementation Support Unit. "Confidence-Building Measures." [<https://bwc-ecbm.unog.ch/state/italy>] Accessed September 2020
- [10] VERTIC (Verification Research, Training and Information Centre). 2020. BWC Legislation Database. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/>] Accessed September 2020
- Other sources: National Labor Inspectorate (Ispettorato Nazionale Lavoro). May 2018. "Legislative Decree of 9 April 2008, n. 81. Text coordinated with Legislative Decree of 3 August 2009, n. 106. SINGLE TEXT ON HEALTH AND SAFETY AT WORK (D.lgs. 9 aprile 2008, n. 81. Testo coordinato con il D.lgs. 3 agosto 2009, n. 106. TESTO UNICO SULLA SALUTE E SICUREZZA SUL LAVORO)". [<https://www.gruppocmb.com/wp-content/uploads/2018/05/Dlgs-81-08-Maggio-2018.pdf>] Accessed September 2020

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

Italy is capable of conducting Polymerase Chain Reaction (PCR)-based diagnostic testing for anthrax and Ebola.

According to EpiCentro, the epidemiological centre of the National Institute of Health (Istituto Superiore di Sanità--ISS), Ebola is subject to mandatory notification in the context of Class I diseases, and cases are confirmed through the use of PCR testing.

[1] The "Lazzaro Spallanzani" national institute of infectious diseases is a key resource in Italy for the identification and containment of such diseases. By contrast, EpiCentro indicates that anthrax is considered a zoonosis and is notifiable as a Class V disease in Italy—one of lower epidemiological reporting significance. Due to the sharp decline of animal cases of anthrax in recent years, and improved sanitation and food production procedures, the number of human cases has also sharply declined. [2]

Nevertheless, cases of anthrax continue to be diagnosed and reported. For example, a bacteriological examination and a reverse transcription-polymerase chain reaction (RT-PCR) test were performed on goats in July 2020 by the Experimental Zooprophyllactic Institute (IZS) of Puglia and Basilicata - Foggia (a national laboratory), both yielding positive results. [3]

[1] National Institute of Health (Istituto Superiore di Sanità--ISS). EpiCentro. August 1 2019. "Ebola virus disease (Malattia da virus Ebola)". [<https://www.epicentro.iss.it/ebola/>] Accessed September 2020

[2] National Institute of Health (Istituto Superiore di Sanità--ISS). EpiCentro. Undated, possibly 2012. "Anthrax: Epidemiological aspects (Antrace: Aspetti epidemiologici)." [<https://www.epicentro.iss.it/antrace/epidemiologia>] Accessed September 2020

[3] World Organisation for Animal Health (OIE). 31 August 2020. "Information received on 12/08/2020 from Dr Silvio Borrello, Chief Veterinary Officer, Food Safety and Collegial Bodies for Health Protection, Ministère de la Santé, Department for Veterinary Public Health, Rome, Italy."

[https://www.oie.int/wahis_2/public/wahid.php/Reviewreport/Review?page_refer=MapEventSummary&reportid=35406] Accessed September 2020

1.3.2 Biosecurity training and practices

1.3.2a

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

Yes = 1 , No = 0

Current Year Score: 0

While there is evidence that Italy requires biosecurity training for personnel in any facility working with especially dangerous pathogens, there is no evidence that it is done through a standardised approach.

In its 2010 Code of Conduct for "Biosicurezza" (Biosafety/Biosecurity), Italy's National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV) distinguishes in English between "biosafety" and "biosecurity", for the latter mandating controlled access and barriers for laboratory facilities, security measures taken on employees, stringent procedures on transport and traceability of biological agents inside and above all outside the laboratory, and controls to prevent the loss or theft of stored agents and toxins. In particular, facilities carrying out research on Group 3 biological agents with potential dual-use must provide adequate training for involved personnel, who must be accredited by the competent authority in the region housing the facility. The accreditation of personnel must be based on shared international standards and be renewed every five years. However, there is no mention of a set standardised national-level training curriculum which is to be followed or details on what the training must include. [1] The Code of Conduct also states that Group 4 pathogens, the most dangerous, may be grown only with prior authorisation of the Ministry of Health, in special containment facilities (called P4 or BSL-4), of which two exist in Italy. [3, 4]

Other Italian laws mandating training of personnel in facilities using biological agents, such as Title X of Legislative Decree No. 81 of 9 April 2008, pertain more to biosafety rather than to biosecurity. [2]

Among other key Italian government entities, neither the ministries of defense, health, nor agriculture indicate the existence of a policy on biosecurity training. [5, 6, 7]

Finally, although Italy has submitted Confidence Building Measures for 2020 and preceding years under the Biological Weapons Convention, access to the documents is restricted and they are not publicly available. [8] The biological weapons legislation database of VERTIC (the Verification Research, Training and Information Centre) shows no legislation by Italy directly concerning the security of dangerous pathogens. [9]

- [1] Republic of Italy. Presidency of the Council of Ministers. National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV). 15 June 2010. "Code of Conduct for Biosecurity/Safety (Codice di Condotta per la Biosicurezza)". [http://cnbbsv.palazzochigi.it/media/1653/2010-15-giugno-codici_condotta_biosicurezza-1.pdf] Accessed September 2020
- [2] National Labor Inspectorate (Ispettorato Nazionale Lavoro). May 2018. "Legislative Decree of 9 April 2008, n. 81. Text coordinated with Legislative Decree of 3 August 2009, n. 106. SINGLE TEXT ON HEALTH AND SAFETY AT WORK (D.lgs. 9 aprile 2008, n. 81. Testo coordinato con il D.Lgs. 3 agosto 2009, n. 106. TESTO UNICO SULLA SALUTE E SICUREZZA SUL LAVORO)". [<https://www.gruppocmb.com/wp-content/uploads/2018/05/Dlgs-81-08-Maggio-2018.pdf>] Accessed September 2020
- [3] James leDuc. 2012. "REQUIREMENTS FOR AND CHALLENGES ASSOCIATED WITH BSL-4 LABS (PLENARY SESSION)." In "Biosecurity Challenges of the Global Expansion of High-Containment Biological Laboratories: Summary of a Workshop (2012)." The National Academies Press. [<https://www.nap.edu/read/13315/chapter/10>] Accessed September 2020
- [4] L. Sacco University Hospital, Milan. CLIMVIB Laboratory of Clinical Microbiology. "BSL-4 Facilities." [<http://climvib.eu/the-laboratory/bsl-4/>] Accessed September 2020
- [5] Republic of Italy. Ministry of Defense. Website. [www.difesa.it] Accessed September 2020
- [6] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website. [<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202>] Accessed September 2020
- [7] Republic of Italy. Ministry of Health. Website. [www.salute.gov.it] Accessed September 2020
- [8] United Nations Office at Geneva (UNOG). Biological Weapons Convention Implementation Support Unit. "Confidence-Building Measures." [<https://bwc-ecbm.unog.ch/state/italy>] Accessed September 2020
- [9] VERTIC (Verification Research, Training and Information Centre). 2020. BWC Legislation Database. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/>] Accessed September 2020

1.3.3 Personnel vetting: regulating access to sensitive locations

1.3.3a

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

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

Current Year Score: 0

Available evidence does not indicate that regulations or licensing conditions in Italy 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.

Italy's key published document addressing the treatment of personnel with access to especially dangerous biological agents is not specific on the nature of controls to be taken with regard to such personnel. In its 2010 Code of Conduct for "Biosicurezza" (Biosafety/Biosecurity), Italy's National Committee for Biosafety and Biotechnology and Life Science (CNBBSV) distinguishes in English between "biosafety" and "biosecurity", for the latter mandating that "security/safety measures on the personnel employed" (misure di sicurezza sul personale impiegato) be instituted in facilities with dangerous biological agents.

Furthermore, the CNBBSV stipulates that laboratories and personnel working specifically with biological agents of risk Group 3 with potential dual use should be monitored through special accreditation by the competent regional authorities, or by the military health authorities in the case of the Defense Administration. Such accreditation must be renewed every five years and be based on shared international standards. But this document does not discuss the specific measures to be taken, such as background checks or psychological tests. [1]

Article 279 of Title X of Italy's main law-decree on health and safety at work, No. 81 of April 9 2008/ No. 106 of August 3 2009, discusses controls but states only that personnel working with biological agents should be subject to health surveillance--in other words, be given protective equipment, vaccinations and health exams due to the risk of exposure to those agents, rather than because of the risk that the personnel themselves might pose to working with such agents. [2]

Furthermore, there is little evidence that other government entities in Italy require background checks on personnel at risk of exposure to dangerous biological material, with respect to biosecurity. The ministries of defense, health, or agriculture give no indication of the existence of a policy on screening of biosecurity personnel. [3, 4, 5]

Finally, although Italy has submitted Confidence Building Measures for 2020 and preceding years under the Biological Weapons Convention, access to the documents is restricted and they are not publicly available. [6] The biological weapons legislation database of VERTIC (the Verification Research, Training and Information Centre) shows no legislation by Italy directly concerning the security of dangerous pathogens. [7]

- [1] Republic of Italy. Presidency of the Council of Ministers. National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV). 15 June 2010. "Code of Conduct for Biosecurity/Safety (Codice di Condotta per la Biosicurezza)". [http://cnbbsv.palazzochigi.it/media/1653/2010-15-giugno-codici_condotta_biosicurezza-1.pdf] Accessed September 2020
- [2] National Labor Inspectorate (Ispettorato Nazionale Lavoro). May 2018. "Legislative Decree of 9 April 2008, n. 81. Text coordinated with Legislative Decree of 3 August 2009, n. 106. SINGLE TEXT ON HEALTH AND SAFETY AT WORK (D.lgs. 9 aprile 2008, n. 81. Testo coordinato con il D.Lgs. 3 agosto 2009, n. 106.TESTO UNICO SULLA SALUTE E SICUREZZA SUL LAVORO". [<https://www.gruppocmb.com/wp-content/uploads/2018/05/Dlgs-81-08-Maggio-2018.pdf>] Accessed September 2020
- [3] Republic of Italy. Ministry of Defense. Website. [www.difesa.it] Accessed September 2020
- [4] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website. [<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202>] Accessed September 2020
- [5] Republic of Italy. Ministry of Health. Website. [www.salute.gov.it] Accessed September 2020
- [6] United Nations Office at Geneva (UNOG). Biological Weapons Convention Implementation Support Unit. "Confidence-Building Measures." [<https://bwc-ecbm.unog.ch/state/italy>] Accessed September 2020
- [7] VERTIC (Verification Research, Training and Information Centre). 2020. BWC Legislation Database. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/>] Accessed September 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

There is publicly available information on national regulations on the safe and secure transport of infectious substances (Categories A and B).

Italy has a publicly available national regulation on the safe and secure transport of infectious substances that refers to IATA Categories A and B, however, only indirectly. This is the Ministry of Health's Circular No. 5 of 8 May 2003 on the transport of infectious materials and diagnostic samples. This circular was designed to be in accordance with the United Nations' classification system for the transport of dangerous goods, dividing these into three categories: 1) biological products such as sera and vaccines; 2) diagnostic samples, such as tissues and tissue fluids; and 3) infectious substances, such as cultures or samples of live microorganisms known or believed to be the probable cause of infectious disease in humans or animals. The guide discusses the packaging and shipment/transport of such materials in compliance with IATA Division 6.2 standards on infectious substances, and corresponding to the IATA PI 602 instructions. [1] The Division 6.2 standards contain Categories A and B infectious substances. [2]

Title X of Legislative Decree No. 81 of 9 April 2008 of the Ministry of Labor and Social Policy on health and safety in the workplace contains rules to protect workers against risks of exposure to potentially pathogenic biological agents. Article 272 obligates employers to "agree procedures for safe handling and transportation of biological agents inside and outside the workplace." However, the regulation does not describe any applicable protocols. [3]

Furthermore, there is little evidence that other government entities in Italy have made available regulations on the transport of Category A and B infectious substances. The ministries of defense, health, or agriculture give no indication of having policies on securing the transport of such substances. [4, 5, 6]

Finally, the biological weapons legislation database of VERTIC (the Verification Research, Training and Information Centre) shows no legislation by Italy directly concerning the security and transport of dangerous pathogens. [7]

[1] Ministry of Health (Ministero della Salute). May 8 2003. "Recommendations for the safe transport of infectious materials and diagnostic samples (Raccomandazioni per la sicurezza del trasporto di materiali infettivi e di campioni diagnostici)". [http://www.salute.gov.it/imgs/C_17_normativa_394_allegato.pdf] Accessed September 2020

[2] International Air Transport Association (IATA). January 1 2020. "3.6.2 Division 6.2—Infectious Substances." [<https://www.iata.org/contentassets/b08040a138dc4442a4f066e6fb99fe2a/dgr-61-en-3.6.2.pdf>] Accessed September 2020

[3] National Labor Inspectorate (Ispettorato Nazionale Lavoro). May 2018. "Legislative Decree of 9 April 2008, n. 81. Text coordinated with Legislative Decree of 3 August 2009, n. 106. SINGLE TEXT ON HEALTH AND SAFETY AT WORK (D.lgs. 9 aprile 2008, n. 81. Testo coordinato con il D.Lgs. 3 agosto 2009, n. 106. TESTO UNICO SULLA SALUTE E SICUREZZA SUL LAVORO".

[<https://www.gruppocmb.com/wp-content/uploads/2018/05/Dlgs-81-08-Maggio-2018.pdf>] Accessed September 2020

[4] Republic of Italy. Ministry of Defense. Website. [www.difesa.it] Accessed September 2020

[5] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website.

[<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202>] Accessed September 2020

[6] Republic of Italy. Ministry of Health. Website. [www.salute.gov.it] Accessed September 2020

[7] VERTIC (Verification Research, Training and Information Centre). 2020. BWC Legislation Database.

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

Italy has regulations in place to oversee the cross-border transfer and end-user screening of especially dangerous pathogens, toxins, and pathogens with pandemic potential.

As a Member State of the European Union, Italy applies the EU's regulations on cross-border transfers and end-user screening. These concepts are covered by the EU's Regulation No 428/2009 Setting up a Community Regime for the Control of Exports, Transfer, Brokering and Transit of Dual-Use Items. In its list of items encompassed by the term "dual-use", the regulation includes 91 pathogens and toxins: 32 human viruses, 17 animal viruses, 4 rickettsiae, 15 bacteria, 19 toxins, 2 fungi and 2 mycoplasmas. [1]

Among others, this includes the pathogens and toxins associated with plague, cholera, encephalitis, Ebola, dengue fever, anthrax, salmonellosis, brucellosis, shigellosis, yellow fever and botulism. However, the list omits pathogens and toxins associated with some major infectious diseases, such as influenza and tuberculosis. The regulation states that export authorization is subject to identification of the end-user and intended use. It further states that dual-use items may not be exported when the exporter is informed by member state authorities that they are intended for the production of weapons of mass destruction, or for military use more broadly where the destination country is subject to an arms embargo imposed by the Organisation for Security and Co-operation in Europe (OSCE) or United Nations Security Council. [1]

Regulations issued by the European Council are legally binding legislative acts in all EU Member States [2].

[1] European Council. 2009. Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items. EUR-Lex. [<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32009R0428>]. Accessed September 2020

[2] European Union. 2019. "Regulations, Directives and other acts." Europa.eu. [https://europa.eu/european-union/eu-law/legal-acts_en]. Accessed September 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

Italy has national legislation on biosafety (biosicurezza). While this word means both biosafety (prevention of accidental release) and biosecurity (prevention of deliberate release), much relevant legislation refers to accidental rather than deliberate release. Many of Italy's laws on biosafety transpose the relevant European Union directives, such as Legislative Decree No. 277 of 15 August 1991, which implements EU directives n. 80/1107/EEC, n. 82/605/EEC, n. 83/477/EEC,

n.86/188/EEC, and 88/642/EEC on exposure to biological and other agents. [1]

In Italy, these EU directives led to the creation of a cabinet-level agency, the CNBBSV, in charge of biosafety oversight in the country. [2, 3] In parallel, the Italian node of the Biosafety Clearing-House (BCH) works to implement the Cartagena Protocol on Biosafety, and to conform national legislation with EU rules, such as Directive 2001/18/EC (on the deliberate release of GMOs into the environment) and Regulation (EC) No. 1829/2003 (on genetically modified food and feed). [4]

The environment ministry's decree of November 8th 2017 creates a master plan to supervise the deliberate release of GMOs. [5] The Ministry of Labor plays a parallel role, by enforcing laws on biological risks in the workplace. For example, Title X of the Legislative Decree No 81 of 9 April 2008/ Legislative Decree No 106 of August 3 2009 on Health and Safety at Work specifically addresses exposure to biological agents and the attendant responsibilities of employers. This combined decree-law also transposes EU directives on biological substances and workplace safety, but it mainly concerns accidental release, referring to deliberate release only in the context of GMOs. [6]

Finally, the Italian Institute for Environmental Protection and Research, (Istituto Superiore per la Protezione e la Ricerca Ambientale--ISPRa) lays out guidelines on biohazards in institutional laboratories, created for the use of employees of the country's national, regional and provincial environmental agencies. [7] Other laws, such as on accident prevention and waste disposal, only tangentially address biosafety. [1]

[1] University of Padua (Università degli Studi di Padova). Vallisneri Biomedical Library (Biblioteca Biomedica Vallisneri). Biosecurity/safety (Biosicurezza). "Current Regulations (Normativa Vigente)".

[http://www.bio.unipd.it/safety/man/norme.html#SICUREZZA_BIOLOGICA] Accessed September 2020

[2] Republic of Italy. Presidency of the Council of Ministers. National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV). 15 June 2010. "Code of Conduct for Biosecurity/Safety (Codice di Condotta per la Biosicurezza)".

[http://cnbbsv.palazzochigi.it/media/1653/2010-15-giugno-codici_condotta_biosicurezza-1.pdf] Accessed September 2020

[3] Republic of Italy. Presidency of the Council of Ministers. "Decree establishing the National Committee for Biosafety, Biotechnology and Life Sciences (DPCM 14.XI.2001) (Decreto istitutivo del Comitato Nazionale per la Biosicurezza, le Biotecnologie e le Scienze della Vita (DPCM 14.XI.2001))".

[http://presidenza.governo.it/biotecnologie/fonti_normative/legge_istitutiva.html] Accessed September 2020

[4] Republic of Italy. Ministry for Environment, Land and Sea Protection. 2020. Italian Biosafety Clearing-House (Biosafety Clearing-House Italiana--BCH). 2020. "General plan for supervisory activity (Piano generale per l'attività di vigilanza)".

<http://bch.minambiente.it/index.php/en/ita-biosafety-clearing-house/legislation/2-non-categorizzato/431-piano-generale-vigilanza-ogm>] Accessed September 2020

[5] Official Gazette of the Italian Republic. 3 January 2018. "Ministry for Environment, Land and Sea Protection of Italy. Ministry of the environment and protection of the territory and the sea. DECREE 8 November 2017. General plan for supervisory activities on the deliberate release into the environment of genetically modified organisms (Ministero dell'ambiente e della tutela del territorio e del mare. DECRETO 8 novembre 2017. Piano generale per l'attività di vigilanza sull'emissione deliberata nell'ambiente di organismi geneticamente modificati.

[<http://bch.minambiente.it/images/pdf/it/DECRETO%208%20novembre%202017%20-%20vigilanza%20OGM.pdf>] Accessed September 2020

[6] National Labor Inspectorate (Ispettorato Nazionale Lavoro). May 2018. "Legislative Decree of 9 April 2008, n. 81. Text coordinated with Legislative Decree of 3 August 2009, n. 106. SINGLE TEXT ON HEALTH AND SAFETY AT WORK (D.lgs. 9 aprile 2008, n. 81. Testo coordinato con il D.Lgs. 3 agosto 2009, n. 106. TESTO UNICO SULLA SALUTE E SICUREZZA SUL LAVORO".

[<https://www.gruppocmb.com/wp-content/uploads/2018/05/Dlgs-81-08-Maggio-2018.pdf>] Accessed September 2020

[7] Italian Institute for Environmental Protection and Research, (Istituto Superiore per la Protezione e la Ricerca Ambientale--ISPRa). July 2013. "Criteria and guidelines for the protection of health and safety in terms of biological risk assessment in the institutional activities of the Environmental Protection Agencies. Manual and guideline 93/2013 (Manuale e linee guida.

Criteri ed indirizzi per la tutela della salute e sicurezza in tema di valutazione del rischio biologico nelle attività istituzionali delle Agenzie per la Protezione dell' Ambiente 93/2013)". [http://www.isprambiente.gov.it/files/pubblicazioni/manuali-lineeguida/MLG93_13.pdf] Accessed September 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

Italy has an established agency responsible for the enforcement of biosafety legislation and regulations. National oversight on biosafety issues is by a cabinet-level agency, the CNBBSV. [1, 2] It oversees biosafety policy but is not an enforcing body, [2] such powers usually being the purview of the state entities underwriting the relevant laws. While the Italian term "biosicurezza" covers both biosafety (prevention of accidental release) and biosecurity (prevention of deliberate release), most relevant legislation is presented in the context of accidental, rather than deliberate, release. When deliberate release is addressed, it is primarily in the context of genetically modified organisms (GMOs). [3]

Aside from the CNBBSV, several other entities are pivotal actors in national biosafety policy. One is the Italian node of the Biosafety Clearing-House (BCH), which works to implement the Cartagena Protocol on Biosafety and conform national laws with EU regulations on biosafety and biosecurity, such as apply to GMOs. [4] Another is the Italian Institute for Environmental Protection and Research (ISPRA), which lays out guidelines on biohazards in institutional laboratories, created for the use of employees of the country's national, regional and provincial environmental agencies. [5, 6]

As regards enforcement, the Ministry of Labour is a key actor in enforcing biosafety rules; ie, Title X of the Legislative Decree No 81 of 9 April 2008/ Legislative Decree No 106 of August 3 2009 on Health and Safety at Work addresses exposure to biological agents, and mandates procedures to reduce the risk of such exposure. [7] Finally, the Ministry of Health is also pivotal in enforcing biosafety rules. Its Circular No. 5 of May 8 2003, mandates United Nations' and IATA standards for the transport on the transport of dangerous biological materials. [8]

[1] Republic of Italy. Presidency of the Council of Ministers. National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV). 15 June 2010. "Code of Conduct for Biosecurity/Safety (Codice di Condotta per la Biosicurezza)". [http://cnbbsv.palazzochigi.it/media/1653/2010-15-giugno-codici_condotta_biosicurezza-1.pdf] Accessed September 2020

[2] Republic of Italy. Presidency of the Council of Ministers. "Decree establishing the National Committee for Biosafety, Biotechnology and Life Sciences (DPCM 14.XI.2001) (Decreto istitutivo del Comitato Nazionale per la Biosicurezza, le Biotecnologie e le Scienze della Vita (DPCM 14.XI.2001))".

[http://presidenza.governo.it/biotecnologie/fonti_normative/legge_istitutiva.html] Accessed September 2020

[3] University of Padua (Università degli Studi di Padova). Vallisneri Biomedical Library (Biblioteca Biomedica Vallisneri). Biosecurity/safety (Biosicurezza). "Current Regulations (Normativa Vigente)".

[http://www.bio.unipd.it/safety/man/norme.html#SICUREZZA_BIOLOGICA] Accessed September 2020

[4] Republic of Italy. Ministry for Environment, Land and Sea Protection. 2020. Italian Biosafety Clearing-House (Biosafety Clearing-House Italiana--BCH). 2020. "General plan for supervisory activity (Piano generale per l'attività di vigilanza)". <http://bch.minambiente.it/index.php/en/ita-biosafety-clearing-house/legislation/2-non-categorizzato/431-piano-generale-vigilanza-ogm>] Accessed September 2020

[5] Official Gazette of the Italian Republic. 3 January 2018. "Ministry for Environment, Land and Sea Protection of Italy. Ministry of the environment and protection of the territory and the sea. DECREE 8 November 2017. General plan for supervisory activities on the deliberate release into the environment of genetically modified organisms (Ministero dell'ambiente e della tutela del territorio e del mare. DECRETO 8 novembre 2017. Piano generale per l'attività di vigilanza

sull'emissione deliberata nell'ambiente di organismi geneticamente modificati.

[<http://bch.minambiente.it/images/pdf/it/DECRETO%208%20novembre%202017%20-%20vigilanza%20OGM.pdf>] Accessed September 2020

[6] Italian Institute for Environmental Protection and Research, (Istituto Superiore per la Protezione e la Ricerca Ambientale--ISPRa). July 2013. "Criteria and guidelines for the protection of health and safety in terms of biological risk assessment in the institutional activities of the Environmental Protection Agencies. Manual and guideline 93/2013 (Manuale e linee guida. Criteri ed indirizzi per la tutela della salute e sicurezza in tema di valutazione del rischio biologico nelle attività istituzionali delle Agenzie per la Protezione dell' Ambiente 93/2013)". [http://www.isprambiente.gov.it/files/pubblicazioni/manuali-lineeguida/MLG93_13.pdf] Accessed September 2020

[7] National Labor Inspectorate (Ispettorato Nazionale Lavoro). May 2018. "Legislative Decree of 9 April 2008, n. 81. Text coordinated with Legislative Decree of 3 August 2009, n. 106. SINGLE TEXT ON HEALTH AND SAFETY AT WORK (D.lgs. 9 aprile 2008, n. 81. Testo coordinato con il D.Lgs. 3 agosto 2009, n. 106. TESTO UNICO SULLA SALUTE E SICUREZZA SUL LAVORO)". [<https://www.gruppocmb.com/wp-content/uploads/2018/05/Dlgs-81-08-Maggio-2018.pdf>] Accessed September 2020

[8] Ministry of Health (Ministero della Salute). 8 May 2003. "Recommendations for the safe transport of infectious materials and diagnostic samples (Raccomandazioni per la sicurezza del trasporto di materiali infettivi e di campioni diagnostici)". [http://www.salute.gov.it/imgs/C_17_normativa_394_allegato.pdf] Accessed September 2020

1.4.2 Biosafety training and practices

1.4.2a

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

Yes = 1 , No = 0

Current Year Score: 0

Italy does not use a single, national standard for biosafety training. Instead, applicable training is context-specific.

The most relevant protocol followed by Italy in this regard is the Cartagena Protocol on Biosafety, Chapter 22 of which requires "...scientific and technical training in the proper and safe management of biotechnology", and in biosafety risk management. [1] To this end, the Italian node of the Cartagena Protocol's Biosafety Clearing-House (BCH) works to implement the Protocol and conform national laws with EU rules on biosafety and biosecurity, such as on the deliberate release of GMOs into the environment. [2] Training in biosafety is also mandated by Title X of the labour ministry's Legislative Decree of No 81 of April 9 2008/ No 106 of August 3 2009 on health and safety at work. It addresses exposure to biological agents, and its Article 278 mandates employers to provide workers--such as in laboratories--with training on a regular basis. [3] The National Plan for Confronting Antimicrobial Resistance (PNCAR) for 2017-2020 also mandates training for personnel in the fields of human and animal health, such as workers in Italy's veterinary and food-safety laboratories (IZSs), and the Local Health Units (ASLs) . [4, 5]

Training in biosecurity is mandated in the CNBBSV Code of Conduct for "Biosicurezza" (Biosecurity/Biosafety), which distinguishes in English between "biosafety" and "biosecurity", mandating training for involved employees specifically with regard to the latter. [6] No additional evidence of a national standard on biosecurity training is available from the agriculture, environment and health ministries, Labour Inspectorate, or the Cabinet. [2, 3, 4, 5, 6, 7, 8]

Finally, the biological weapons legislation database of VERTIC (the Verification Research, Training and Information Centre)

shows no legislation by Italy directly concerning the security and transport of dangerous pathogens. [9]

- [1] Convention of Biological Diversity. 16 July 2013. "Text of the Cartagena Protocol on Biosafety". [<https://bch.cbd.int/protocol/text/>] Accessed September 2020
- [2] Republic of Italy. Ministry for Environment, Land and Sea Protection. I2020. "Italian Biosafety Clearing-House (Biosafety Clearing-House Italiana)." [<http://bch.minambiente.it/index.php/it/bch-italiana>] Accessed September 2020
- [3] Republic of Italy. National Labor Inspectorate (Ispettorato Nazionale Lavoro). May 2018. "Legislative Decree of 9 April 2008, n. 81. Text coordinated with Legislative Decree of 3 August 2009, n. 106. SINGLE TEXT ON HEALTH AND SAFETY AT WORK (D.lgs. 9 aprile 2008, n. 81. Testo coordinato con il D.lgs. 3 agosto 2009, n. 106. TESTO UNICO SULLA SALUTE E SICUREZZA SUL LAVORO)". [<https://www.gruppocmb.com/wp-content/uploads/2018/05/Dlgs-81-08-Maggio-2018.pdf>] Accessed September 2020
- [4] Republic of Italy. Ministry of Health. 2017. "National Plan to Confront Antimicrobial Resistance (PNCAR) 2017-2020 (Piano Nazionale di Contrasto dell'Antimicrobico-Resistenza (PNCAR) 2017-2020)". [http://www.salute.gov.it/imgs/C_17_pubblicazioni_2660_allegato.pdf] Accessed September 2020
- [5] Republic of Italy. Ministry of Health. 10 April 2018. "Management of an outbreak of foot-and-mouth disease and biosafety standards (Gestione di un focolaio di afta epizootica e norme di biosicurezza)". [http://www.salute.gov.it/portale/temi/p2_6_corsi.jsp?lingua=italiano&id=220&area=formazione%20veterinaria&menu=formazione] Accessed September 2020
- [6] Republic of Italy. Presidency of the Council of Ministers. National Committee for Biosafety and Biotechnology and Life Sciences. 15 June 2010. "Code of Conduct for Biosecurity/Safety (Codice di Condotta per la Biosicurezza)". [http://presidenza.governo.it/biotecnologie/documenti/Codici_condotta_biosicurezza.pdf] Accessed September 2020
- [7] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website. [<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202>] Accessed September 2020
- [8] Republic of Italy. Ministry of Health. Website. [www.salute.gov.it] Accessed September 2020
- [9] VERTIC (Verification Research, Training and Information Centre). 2020. BWC Legislation Database. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/>] Accessed September 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: 0

Available evidence is insufficient that Italy conducts assessments on whether research is occurring on especially dangerous pathogens with the potential for dual use.

However, the country does discuss dual-use research in policy documents. For example, in its 2010 Code of Conduct for "Biosicurezza" (Biosafety/Biosecurity), Italy's Cabinet-level National Committee for Biosafety, Biotechnology and Life Sciences (CNBBSV) clearly states: "The CNBBSV considers it necessary that the laboratories, staff, [and] biological agents of risk group 3, with potential dual use, should be properly surveyed and controlled." [1] The Code of Conduct also states that Group 4

pathogens, the most dangerous, may be grown only with prior authorisation of the Ministry of Health, in special containment facilities (called P4 or BSL-4), of which two exist in Italy. [1] However, this document does not in itself constitute evidence that Italy maintains an ongoing policy to monitor dual-use research.

The key Italian ministries relevant to this issue provide very little information on their policies regarding dual-use research. For example, the Ministry of Defense in its 2018 policy white paper on Dual use and Resilience does not indicate any mandate to monitor research into materials with the potential for dual use. [2] Similarly, the Ministry of Agriculture gives no indication that it has a policy on overseeing or even engaging in such research. [3] The Ministry of Foreign Affairs, in charge of executing the European Union's rules--chiefly (EC) 428/2009--on controlling the export, transfer, brokering and transit of dual-use (including biological-chemical) technologies, has an elaborate protocol in this regard--including for military goods--but otherwise provides no information on a dual-goods research policy. [4] Whereas the EU has to-date relied on existing trade controls on such technologies to address the problem, evidence is gathering that such controls are insufficient to curb or monitor so-called dual-use research of concern (DURC) unrelated to export. [5, 6]

Finally, although Italy has submitted Confidence Building Measures for 2020 and preceding years under the Biological Weapons Convention, access to the documents is restricted and they are not publicly available. [8] Moreover, the biological weapons legislation database of VERTIC (the Verification Research, Training and Information Centre) shows no legislation by Italy directly concerning the security of dangerous pathogens. [7]

[1] Republic of Italy. Presidency of the Council of Ministers. National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV). 15 June 2010. "Code of Conduct for Biosecurity/Safety (Codice di Condotta per la Biosicurezza)".

[http://cnbbsv.palazzochigi.it/media/1653/2010-15-giugno-codici_condotta_biosicurezza-1.pdf] Accessed September 2020

[2] Republic of Italy. Ministry of Defense. 2018. "'Dual use and Resilience' CONCEPTUAL INTEGRATION DOCUMENT OF THE PROGRAMMATIC LINES OF THE DEPARTMENT ('Duplice uso e Resilienza' DOCUMENTO DI INTEGRAZIONE CONCETTUALE DELLE LINEE PROGRAMMATICHE DEL DICASTERO)".

[https://www.difesa.it/Content/Documents/2018_Ministero_Difesa_integrazione_linee_programmatiche.pdf] Accessed September 2020

[3] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website.

[<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202>] Accessed September 2020

[4] Republic of Italy. Ministry of Foreign Affairs and International Cooperation. 2020. "Dual-use Products (Prodotti a duplice uso)." [https://www.esteri.it/mae/resource/doc/2020/01/duplice_uso.pdf] Accessed September 2020

[5] Christos Charatsis. "Dual-use Research and Trade Controls: Opportunities and Controversies". STRATEGIC TRADE REVIEW, Volume 3, Issue 4, Spring 2017 pp. 47—68..[<http://www.str.ulg.ac.be/wp-content/uploads/2017/04/Dual-use-Research-and-Trade-Controls-Opportunities-and-Controversies.pdf>] Accessed September 2020

[6] Giorgio Palù. 24 Jan 2014. "Regulating Dual-Use Research in Europe" Abstract. "Science" Vol. 343, Issue 6169, pp. 368-369. [<http://science.sciencemag.org/content/343/6169/368.2>] Accessed September 2020

[7] VERTIC (Verification Research, Training and Information Centre). 2020. BWC Legislation Database:Italy.

[<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/>] Accessed September 2020

[8] United Nations Office at Geneva (UNOG). Biological Weapons Convention Implementation Support Unit. "Confidence-Building Measures." [<https://bwc-ecbm.unog.ch/state/italy>] Accessed October 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: 0

Available evidence does not indicate that Italy has regulations requiring oversight of research with especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research.

However, the country does discuss dual-use research in policy documents. For example, in its 2010 Code of Conduct for "Biosicurezza" (Biosafety/Biosecurity), Italy's Cabinet-level National Committee for Biosafety, Biotechnology and Life Sciences (CNBBSV) clearly states: "The CNBBSV considers it necessary that the laboratories, staff, [and] biological agents of risk group 3, with potential dual use, should be properly surveyed and controlled." [1] The Code of Conduct also states that Group 4 pathogens, the most dangerous, may be grown only with prior authorisation of the Ministry of Health, in special containment facilities (called P4 or BSL-4), of which two exist in Italy. [1] However, this document not in itself constitute evidence that Italy maintains an ongoing policy to monitor dual-use research.

The key Italian ministries relevant to this issue provide very little information on their policies regarding dual-use research. For example, the Ministry of Defense in its 2018 policy white paper on Dual use and Resilience does not indicate any mandate to monitor research into materials with the potential for dual use. [2] Similarly, the Ministry of Agriculture gives no indication that it has a policy on overseeing or even engaging in such research. [3] The Ministry of Foreign Affairs, in charge of executing the European Union's rules--chiefly (EC) 428/2009--on controlling the export, transfer, brokering and transit of dual-use (including biological-chemical) technologies, has an elaborate protocol in this regard--including for military goods--but otherwise provides no information on a dual-goods research policy. [4] Whereas the EU has to-date relied on existing trade controls on such technologies to address the problem, evidence is gathering that such controls are insufficient to curb or monitor so-called dual-use research of concern (DURC) unrelated to export. [5, 6]

Finally, although Italy has submitted Confidence Building Measures for 2020 and preceding years under the Biological Weapons Convention, access to the documents is restricted and they are not publicly available. [8] Moreover, the biological weapons legislation database of VERTIC (the Verification Research, Training and Information Centre) shows no legislation by Italy directly concerning the security of dangerous pathogens. [7]

[1] Republic of Italy. Presidency of the Council of Ministers. National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV). 15 June 2010. "Code of Conduct for Biosecurity/Safety (Codice di Condotta per la Biosicurezza)".

[http://cnbbsv.palazzochigi.it/media/1653/2010-15-giugno-codici_condotta_biosicurezza-1.pdf] Accessed September 2020

[2] Republic of Italy. Ministry of Defense. 2018. "'Dual use and Resilience' CONCEPTUAL INTEGRATION DOCUMENT OF THE PROGRAMMATIC LINES OF THE DEPARTMENT ('Duplice uso e Resilienza' DOCUMENTO DI INTEGRAZIONE CONCETTUALE DELLE LINEE PROGRAMMATICHE DEL DICASTERO)".

[https://www.difesa.it/Content/Documents/2018_Ministero_Difesa_integrazione_linee_programmatiche.pdf] Accessed September 2020

[3] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website.

[<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202>] Accessed September 2020

[4] Republic of Italy. Ministry of Foreign Affairs and International Cooperation. 2020. "Dual-use Products (Prodotti a duplice uso)." [https://www.esteri.it/mae/resource/doc/2020/01/duplice_uso.pdf] Accessed September 2020

[5] Christos Charatsis. "Dual-use Research and Trade Controls: Opportunities and Controversies". STRATEGIC TRADE REVIEW, Volume 3, Issue 4, Spring 2017 pp. 47—68. [<http://www.str.ulg.ac.be/wp-content/uploads/2017/04/Dual-use-Research-and-Trade-Controls-Opportunities-and-Controversies.pdf>] Accessed September 2020

[6] Giorgio Palù. 24 Jan 2014. "Regulating Dual-Use Research in Europe" Abstract. "Science" Vol. 343, Issue 6169, pp. 368-369. [<http://science.sciencemag.org/content/343/6169/368.2>] Accessed September 2020

[7] VERTIC (Verification Research, Training and Information Centre). 2020. BWC Legislation Database:Italy.

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

2020 8] United Nations Office at Geneva (UNOG). Biological Weapons Convention Implementation Support Unit. "Confidence-Building Measures." [https://bwc-ecbm.unog.ch/state/italy] Accessed October 2020

1.5.1c

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

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence that Italy has an agency responsible for oversight of research on especially dangerous pathogens, toxins, pathogens with pandemic potential and/or other dual-use research.

Italy has an entity, the Cabinet-level National Committee for Biosafety, Biotechnology and Life Sciences (CNBBSV), which oversees biosafety (biosicurezza) policy in Italy and mandates the adequate monitoring of laboratories, personnel, and biological agents in risk group 3 carrying the potential for dual use. Its 2010 Code of Conduct for "Biosicurezza" (Biosafety/Biosecurity) clearly states: "The CNBBSV considers it necessary that the laboratories, staff, [and] biological agents of risk group 3, with potential dual use, should be properly surveyed and controlled." [1] The Code of Conduct also states that Group 4 pathogens, the most dangerous, may be grown only with prior authorisation of the Ministry of Health, in special containment facilities (called P4 or BSL-4), of which two exist in Italy. [1]

By contrast, other key Italian ministries relevant to this issue provide very little information on their policies regarding dual-use research. For example, the Ministry of Defense in its 2018 policy white paper on Dual use and Resilience does not indicate any mandate to monitor research into materials with the potential for dual use. [2] Similarly, the Ministry of Agriculture gives no indication that it has a policy on overseeing or even engaging in such research. [3] The Ministry of Foreign Affairs, in charge of executing the European Union's rules--chiefly (EC) 428/2009--on controlling the export, transfer, brokering and transit of dual-use (including biological-chemical) technologies, has an elaborate protocol in this regard--including for military goods--but otherwise provides no information on a dual-goods research policy. [4] Whereas the EU has to-date relied on existing trade controls on such technologies to address the problem, evidence is gathering that such controls are insufficient to curb or monitor so-called dual-use research of concern (DURC) unrelated to export. [5, 6]

Finally, although Italy has submitted Confidence Building Measures for 2020 and preceding years under the Biological Weapons Convention, access to the documents is restricted and they are not publicly available. [8] Moreover, the biological weapons legislation database of VERTIC (the Verification Research, Training and Information Centre) shows no legislation by Italy directly concerning the security of dangerous pathogens. [7]

[1] Republic of Italy. Presidency of the Council of Ministers. National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV). 15 June 2010. "Code of Conduct for Biosecurity/Safety (Codice di Condotta per la Biosicurezza)". [http://cnbbsv.palazzochigi.it/media/1653/2010-15-giugno-codici_condotta_biosicurezza-1.pdf] Accessed September 2020

[2] Republic of Italy. Ministry of Defense. 2018. "'Dual use and Resilience' CONCEPTUAL INTEGRATION DOCUMENT OF THE PROGRAMMATIC LINES OF THE DEPARTMENT ('Duplici uso e Resilienza' DOCUMENTO DI INTEGRAZIONE CONCETTUALE DELLE LINEE PROGRAMMATICHE DEL DICASTERO)". [https://www.difesa.it/Content/Documents/2018_Ministero_Difesa_integrazione_linee_programmatiche.pdf] Accessed September 2020

[3] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website.

[https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202] Accessed September 2020

[4] Republic of Italy. Ministry of Foreign Affairs and International Cooperation. 2020. "Dual-use Products (Prodotti a duplice

uso). " [https://www.esteri.it/mae/resource/doc/2020/01/duplice_uso.pdf] Accessed September 2020

[5] Christos Charatsis. "Dual-use Research and Trade Controls: Opportunities and Controversies". STRATEGIC TRADE REVIEW, Volume 3, Issue 4, Spring 2017 pp. 47—68..[http://www.str.ulg.ac.be/wp-content/uploads/2017/04/Dual-use-Research-and-Trade-Controls-Opportunities-and-Controversies.pdf] Accessed September 2020

[6] Giorgio Palù. 24 Jan 2014. "Regulating Dual-Use Research in Europe" Abstract. "Science" Vol. 343, Issue 6169, pp. 368-369. [http://science.sciencemag.org/content/343/6169/368.2] Accessed September 2020

[7] VERTIC (Verification Research, Training and Information Centre). 2020. BWC Legislation Database:Italy.

[https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/] Accessed September 2020 8] United Nations Office at Geneva (UNOG). Biological Weapons Convention Implementation Support Unit.

"Confidence-Building Measures." [https://bwc-ecbm.unog.ch/state/italy] Accessed October 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

Although Italy restricts the release of genetically modified organisms (GMOs), there is insufficient evidence that the country specifically requires the screening of synthesized DNA against lists of known pathogens and toxins before it is sold.

The Cabinet-level National Committee for Biosafety, Biotechnology and Life Sciences (CNBBSV), oversees policy on synthesized DNA in Italy. Its 2010 Code of Conduct encompasses human, animal and plant genetics and specifically addresses synthetic DNA. With respect to synthetic biology the Code of Conduct promotes four principles: 1) a synthetic biological organism must not be able to survive accidental release into the environment; 2) long-term environmental impact studies should be conducted in case of the release of such an organism; 3) the production of substances obtained from a synthetic biological organism must be monitored when these substances are not identical to known equivalent substances; and 4) research on synthetic biological organisms should be prohibited when they fall under the prohibitions set by the BWC Convention. However, the Code of Conduct does not discuss the technical methods used, if any, to screen synthesized DNA for sequences related to dangerous agents. [1]

As a Member State of the European Union, Italy has transposed the EU's rules on synthesized DNA into national policy. One such law is Law-Decree No. 224 of July 8 2003, which transposes Directive 2001/18 / EC on the deliberate release of GMOs. The law-decree permits the government to limit or suspend the commercialization of GMOs found to present risks to humans, animals, or the environment. [2] This law-decree also mandates identification of the pathogenic characteristics of both the donor organism and its modification, but does not describe or mandate a process for comparing the synthesized DNA with existing pathogens. [3]

None of the key ministries relevant to the issue of screening synthesized DNA--those of transport, defense, agriculture and health--indicate that they have policies on this issue. [4, 5, 6, 7] Finally, the biological weapons legislation database of VERTIC (the Verification Research, Training and Information Centre) shows no legislation by Italy directly mandating the pre-release screening of synthesized DNA via comparison with existing pathogens and toxins. [8]

[1] Republic of Italy. Presidency of the Council of Ministers. National Committee for Biosafety and Biotechnology and Life Sciences (CNBBSV). 15 June 2010. "Code of Conduct for Biosecurity/Safety (Codice di Condotta per la Biosicurezza)".

[http://cnbbsv.palazzochigi.it/media/1653/2010-15-giugno-codici_condotta_biosicurezza-1.pdf] Accessed September 2020

[2] U.S. Library of Congress. March 2014, updated July 24 2020. "Restrictions on Genetically Modified Organisms: Italy". [<https://www.loc.gov/law/help/restrictions-on-gmos/italy.php>] Accessed September 2020

[3] Official Gazette of the Republic of Italy. No. 194 of 22 August 2003. "Legislative Decree 8 July 2003, n. 224 "Implementation of Directive 2001/18 / EC concerning the deliberate release into the environment of genetically modified organisms" (Decreto Legislativo 8 luglio 2003, n. 224 "Attuazione della direttiva 2001/18/CE concernente l'emissione deliberata nell'ambiente di organismi geneticamente modificati)". [<https://www.camera.it/parlam/leggi/deleghe/03224dl.htm>] Accessed September 2020

[4] Republic of Italy. Ministry of Infrastructure and Transport. 2020. Website. [www.mit.gov.it] Accessed September 2020

[5] Republic of Italy. Ministry of Defense. 2020. Website. [www.difesa.it] Accessed September 2020

[6] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website. [<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202>] Accessed September 2020

[7] Republic of Italy. Ministry of Health. 2020. Website. [www.salute.gov.it] Accessed September 2020

[8] VERTIC (Verification Research, Training and Information Centre). 2020. BWC Legislation Database. [<https://www.vertic.org/programmes/biological-weapons-and-materials/bwc-legislation-database/>] Accessed September 2020

1.6 IMMUNIZATION

1.6.1 Vaccination rates

1.6.1a

Immunization rate (measles/MCV2)

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

Current Year Score: 1

2019

World Health Organization

1.6.1b

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

Yes = 1 , No = 0

Current Year Score: 1

2020

OIE WAHIS database

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

2.1 LABORATORY SYSTEMS STRENGTH AND QUALITY

2.1.1 Laboratory testing for detection of priority diseases

2.1.1a

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

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

Current Year Score: 2

Italy can conduct at least five of the ten WHO core tests. While there is no readily available evidence of an official matrix of country-defined core tests for Italy, its national health care system has a network of laboratories that are capable of conducting the following tests:

1. Virus culture for poliovirus (polio): epidemiological information and clinical samples are sent to the main national reference laboratory (the National Health Institute--Istituto Superiore di Sanità--ISS) or sub-national labs. [1]
2. Polymerase chain reaction (PCR) testing for Influenza virus (flu): diagnostic lab tests conducted at the Torino Local Health Unit (ASLTO2 - Ospedale Amedeo di Savoia, Torino) include Real-time RT-PCR (A, B, A/H1N1/2009) testing according to WHO and CDC protocols. Epidemiological and virological surveillance of influenza is conducted nationally through the Influenza network of physicians and paediatricians, which coordinates weekly with the ISS. [2]
3. Serology for HIV: a national surveillance system exists for new diagnoses of HIV infection, and a test for specific HIV or anti-HIV antibodies is carried out through a normal blood sample. [3]
4. Microscopy for mycobacterium tuberculosis (tuberculosis/TB): the identification of mycobacteria, commonly through the use of the Mantoux test. [4]
5. Rapid diagnostic testing for plasmodium spp. (malaria): the Ministry of Health conducts testing for plasmodium spp., mandating microscopic diagnosis by laboratories. [5]
6. Bacterial culture for Salmonella enteritidis serotype Typhi (typhoid): the National Reference Laboratory for Zoonoses (Salmonella) (Laboratorio Nazionale di Riferimento per le Zoonosi (Salmonella)) conducts serotyping for this disease. [6] There is no publicly available information on the four country-defined tests.

[1] Republic of Italy. Ministry of Health. December 18 2019. "Acute flaccid paralysis surveillance (acute flaccid paralysis) (Sorveglianza paralisi flaccide acute)".

[<http://www.salute.gov.it/portale/malattieInfettive/dettaglioContenutiMalattieInfettive.jsp?lingua=italiano&id=820&area=Malattie%20infettive&menu=sorveglianza>] Accessed September 2020

[2] Isabella Donatelli, Simona Puzelli, Annapina Palmieri, Angela Di Martino, Marzia Facchini, Monica Meola, Concetta Fabiani, Laura Calzoletti, Tiziana Grisetti, Maria Rita Castrucci. 2015. "WHO NATIONAL CENTER FOR INFLUENZA Virological

surveillance of influenza in Italy (2013-2014 season) (CENTRO NAZIONALE OMS PER L'INFLUENZA Sorveglianza virologica dell'influenza in Italia (stagione 2013-2014))." National Health Institute (Istituto Superiore di Sanità).

[http://old.iss.it/binary/fluv/cont/15_21_web.pdf] Accessed September 2020

[3] Republic of Italy. Ministry of Health. 2020. "The HIV test (Il test Hiv).

[<http://www.salute.gov.it/portale/hiv/dettaglioContenutiHIV.jsp?lingua=italiano&id=185&area=aids&menu=vuoto>] Accessed September 2020

[4] Republic of Italy. Ministry of Health. 2020. "Tuberculosis: Diagnosis (Tubercolosi: Diagnosi)".

[<http://www.salute.gov.it/portale/malattieInfettive/dettaglioSchedeMalattieInfettive.jsp?lingua=italiano&id=208&area=Malattie%20infettive&menu=indiceAZ&tab=5>] Accessed September 2020

[5] Republic of Italy. Ministry of Health. 28 December 2016. "Malaria, prevention and control in Italy (Malaria, prevenzione e controllo in Italia)".

[http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=2785] Accessed September 2020

[6] Ministry of Health (Ministero della Salute). June 30 2016. "ZOOONOSIS (SALMONELLA) - NATIONAL REFERENCE LABORATORY (ZOOONOSI (SALMONELLA) - LABORATORIO NAZIONALE DI RIFERIMENTO))".

[<http://www.salute.gov.it/relazioneAnnuale2015/dettaglioRA2015.jsp?cap=capitolo3&sez=ra15-3-3b-lnr&id=1089>] Accessed September 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

Although Italy has at least two national-level plans to address public health emergencies of pandemic or epidemic origin, there is insufficient evidence that these plans include considerations for testing for novel pathogens, scaling capacity, and defining goals for testing.

These two plans are the National strategic-operational plan for preparation and response to a flu pandemic (PanFlu) 2021-2023 and the National Plan for Epidemic Emergencies, known as the "Itavet Plan" (2014). Both plans are unspecific as regards mandating actual testing for novel pathogens and scaling such activity. In defining its public health objectives during such a crisis, the 2021 influenza plan adopts a graded action framework, with individual actions corresponding to each one of four pandemic phases. The plan mandates epidemiological surveillance, beginning in the alert phase--to ensure the rapid identification of a new virus--which implies a mandate for testing--but it does not describe a testing system with goals or means for scaling such testing. [1]

Similarly, the 2014 Itavet Plan delineates five intervention phases (suspicion; investigation; confirmation; response; and containment and eradication), and thus at the earliest stages can be said to require field investigation and veterinary checks for suspected disease vectors both known and unknown. In suspect cases the local IZS (Experimental Prophylactic Institutes--veterinary health units) are to apply the relevant diagnostic tests and register results in the national veterinary reporting system (SIMAN). Many IZS serve as reference laboratories for specific veterinary diseases. Data thus collected, reported and recorded are the basis of the epidemiological outlook formed during the suspicion and outbreak periods. However, the plan does not describe a testing system with goals or means for scaling such testing. [2]

No other evidence was found via the Ministry of Health. [3]

[1] Republic of Italy. Ministry of Health. Directorate-General of Sanitary Prevention. January 25 2021. "National strategic-operational plan for preparation and response to a flu pandemic (PanFlu) 2021-2023 (Piano strategico-operativo nazionale di preparazione e risposta a una pandemia influenzale (PanFlu) 2021-2023)."

[<https://www.quotidianosanita.it/allegati/allegato4004886.pdf>] Accessed April 2021

[2] Republic of Italy. Ministry of Health. Directorate of Animal Health and Veterinary Drugs. 2014. "National Plan for Epidemic Emergencies. (PIANO NAZIONALE PER LE EMERGENZE DI TIPO EPIDEMICO ITALIAN VETERINARY CONTINGENCY PLAN 'ITAVETPLAN')." [http://www.quadernidellasalute.it/imgs/C_17_pagineAree_1670_listaFile_itemName_0_file.pdf] Accessed September 2020

[3] Republic of Italy. Ministry of Health. [<http://www.salute.gov.it/portale/home.html>] Accessed May 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

Italy's health care system has a regional structure, and sentinel systems for human diseases mainly rely on regional reference laboratories such as the Lazzaro Spallanzani National Institute of Infectious Diseases in Lazio, and the Centre for Tropical Diseases in Verona. [4, 5] The national government mandates accreditation of such regional laboratories.

Accredia, a non-profit organisation, was designated in December 2009 by the Italian Government as sole national accreditation body. It is supervised by the Ministry of Economic Development. [1] Its website lists hundreds of microbiology laboratories which it has accredited, including many of the so-called experimental zooprophyllactic institutes (IZSs) that are key facilities in combating zoonotic diseases. [2] Recently, the laboratories of one Italian region were the first in the country to be accredited under ISO 15189 standards; in October 2018 Accredia granted ISO 15189 accreditation to the clinical laboratories of the Health Agency of the Trentino-Alto Adige Region. [3]

[1] Accredia. December 2016. "ACCREDITIA--The Italian Accreditation Body".

[https://www.accredia.it/app/uploads/2016/12/6940_2_ACCREDITIA___The_Italian_Accreditation_Body___21_22_12_2016.pdf] Accessed September 2020

[2] Accredia. Website search. 2020. "Testing Laboratories (Laboratori di prova)".

[http://services.accredia.it/accredia_labsearch.jsp?ID_LINK=1734&area=310&dipartimento=L%2CS&submit1=Esegui] Accessed September 2020

[3] Accredia. 4 October 2018. "An Italian Health Agency obtained accreditation to ISO 15189 for all clinical laboratories".

[<https://www.accredia.it/en/2018/10/04/an-italian-health-agency-obtained-accreditation-to-iso-15189-for-all-clinical-laboratories/>] Accessed September 2020

[4] ASL T

[5] National Institute of Infectious Diseases (Istituto Nazionale per le Malattie Infettive "Lazzaro Spallanzani"). January 2017. "Clinical management protocol of Tuberculosis (Protocollo di gestione clinica della Tubercolosi)".

[http://www.inmi.it/linee_guida/Protocollo%20Tubercolosi%20Rev.%207_2017.pdf] Accessed September 2020

[5] Centre for Tropical Diseases (Centro Malattie Tropicali). Undated.

[<http://www.tropicalmed.eu/Page/WebObjects/PageTropE.woa/wa/displayPage?name=Malaria>] Accessed September 2020

2.1.2b

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

Yes = 1, No = 0

Current Year Score: 1

Italy's health care system has a regional structure, and some of its regional clinical laboratories have been subject to external quality assurance reviews. Among these are the Lazio region's Lazzaro Spallanzani institute, the ASL TO4 Amadeo di Savoia ASL of the Piedmont region, and the Centre for Tropical Diseases in Verona, key facilities in testing for WHO core infectious diseases. [1, 2]

A typical review process was the ECDC's external quality assessment (EQA) scheme for the typing of verocytotoxin-producing *Escherichia coli* (VTEC). The ECDC's third EQA scheme, begun in October 2010, was coordinated in Italy by the EU reference laboratory for VTEC (EU RL VTEC) at the National Institute of Health (Istituto Superiore di Sanità--ISS); the labs of 5 regional experimental zooprophyllactic institutes (IZSs) signed up to participate. [3]

[1] National Institute of Infectious Diseases (Istituto Nazionale per le Malattie Infettive "Lazzaro Spallanzani"). 2018. "Virology Laboratory (Laboratorio di Virologia)." [http://www.inmi.it/SITO_COLORE/sito%20blu/laboratorio_di_virologia.html] Accessed September 2020

[2] Centre for Tropical Diseases (Centro Malattie Tropicali). 2017.

[<http://www.tropicalmed.eu/name/CQ+interno+esterno.html>] Accessed September 2020

[3] European Centre for Disease Control and Prevention (ECDC). February 2014. "Third external quality assessment scheme for typing of verocytotoxin producing *E. coli*

(VTEC)." [<https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/3rd-external-quality-assessment-typing-of-verocytotoxin-producing-E.-coli-web.pdf>] Accessed September 2020

2.2 LABORATORY SUPPLY CHAINS

2.2.1 Specimen referral and transport system

2.2.1a

Is there a nationwide specimen transport system?

Yes = 1, No = 0

Current Year Score: 0

There is insufficient evidence of a nationwide specimen transport system in Italy. While there is some evidence of regional protocols for specimen transport, there is insufficient evidence of a system that covers the entire country.

Numerous private companies in Italy, such as the Turin-based Cernesoni Group, transport hazardous goods throughout Italy as well as to other countries. [1] As Italy's health care system is regional in structure, the Local Health Units (ASLs) in the regions create policy on the transport of specimens. For example, ASL AL, the ASL of the Piedmont Region, operates a protocol on the secure transport of biological samples which accounts for different scenarios and parameters, such as transport from a hospital ward to the laboratory via internal staff, or from a hospital to an external diagnostic center through commercial operators. Procedures and packaging are stipulated according to the substance to be transported, and Involved

personnel are assigned specific roles and responsibilities. This protocol does not, however, constitute a system for transporting such materials outside of the region itself. [2]

The Piedmont ASLs protocol, as well as those of all regional ASLs, is based on the Italian Ministry of Health's Circular No. 5 of May 8 2003, on the transport of infectious materials and diagnostic samples. This circular complies with the United Nations' and IATA's classifications for the transport of dangerous goods. It also imposes responsibilities on the sender, the courier and the recipient of such materials. [3]

Among other key Italian government agencies, neither the Ministry of Agriculture nor the National Institute of Health (ISS) provide evidence of administering nationwide specimen transport systems. [4, 5] The latter, does, however, from time to time issue procedural guidelines for public healthcare stakeholders, such as a guidebook on the transport of blood, blood components and related biological samples published in February 2020 by the ISS's National Blood Center. [5]

[1] Cernesoni Group. International Transport. 2020. "Hazardous goods transportation - A.D.R."

[<https://www.cermesongroup.com/international-transportation-by-land/trasporto-merce-pericolosa-adr/?lang=en>]

Accessed September 2020

[2] ASL Regione Piemonte (ASL AL). December 2010. "Procedure for Secure Transport of Biological Samples (Procedura per il Trasporto in sicurezza dei campioni biologici)". [http://www.asl.al.it/allegati/TRASPORTO_CAMPIONI_BIOLOGICI.pdf]

Accessed September 2020

[3] Republic of Italy. Ministry of Health. May 8 2003. "Recommendations for the safe transport of infectious materials and diagnostic samples (Raccomandazioni per la sicurezza del trasporto di materiali infettivi e di campioni diagnostici)". [http://www.salute.gov.it/imgs/C_17_normativa_394_allegato.pdf] Accessed September 2020

[4] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website.

[<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202>] Accessed September 2020

[5] Republic of Italy. National Institute of Health (ISS). National Blood Center. 2020. "Guidelines (Linee guida)".

[<https://www.centronazionalesangue.it/node/91>] Accessed September 2020 Other sources: United Nations Economic

Commission for Europe. Country information. "List of Competent Authorities for the application of ADR including Chapter 1.5 and notifications." [https://www.unece.org/trans/danger/publi/adr/country-info_e.html] Accessed September 2020 ADR

Book. 2017. "2.62 CLASS 6.2 INFECTIOUS SUBSTANCES." [<https://adrbook.com/en/2017/ADR/2.2.62>] Accessed September 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

Available evidence does not indicate that Italy has a national 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. Neither of the two key national plans addressing the public health system's response to pandemic outbreaks discuss the mechanics of how mandated disease-assessment interventions are to scale up during such crises.

These two plans are the Ministry of Health's National Plan for Preparedness and Response to an Influenza Pandemic (2006) and its National Plan for Epidemic Emergencies, known as the "Itavet Plan" (2014). Both plans accord a considerable role to

laboratories--particularly during the early phases of an outbreak--but are unspecific as regards mandating actual testing for novel pathogens and scaling such activity.

In defining its public health objectives during such a crisis, the 2006 influenza plan draws upon the World Health Organization (WHO)'s 2005 action framework of six pandemic phases. The plan thus mandates epidemiological and virological surveillance during Phase 3, such as to "insure the rapid characterisation and rapid identification of the new viral subtype," which implies a mandate for testing, but it does not describe a testing system with goals or means for scaling such testing. The plan does mandate that during the alert phases, virological surveillance be strengthened, by carrying out quality control at laboratories and preparing new methods for rapid and differential diagnoses by laboratories. [1]

Similarly, the 2014 Itavet Plan delineates five intervention phases (suspicion; investigation; confirmation; response; and containment and eradication), and thus at the earliest stages can be said to require field investigation and veterinary checks for suspected disease vectors. In suspect cases the local IZS (Experimental Prophylactic Institutes--veterinary health units) are to apply the relevant diagnostic tests and register results in the national veterinary reporting system (SIMAN). Many IZS serve as reference laboratories for specific veterinary diseases. Data thus collected, reported and recorded are the basis of the epidemiological outlook formed during the suspicion and outbreak periods. However, the plan does not describe a testing system with goals or means for scaling such testing. [2]

Finally, among relevant government entities neither the Ministry of Agriculture nor the National Institute of Health (ISS) provide evidence of administering a stand-alone plan for laboratories to ramp-up interventions during a pandemic outbreak. [3, 4]

[1] Republic of Italy. Ministry of Health. 2006. "NATIONAL PLAN FOR PREPAREDNESS AND RESPONSE TO AN INFLUENZA PANDEMIC." [http://www.salute.gov.it/imgs/C_17_pubblicazioni_501_ulterioriallegati_ulterioreallegato_0_alleg.pdf] Accessed September 2020

[2] Republic of Italy. Ministry of Health. Directorate of Animal Health and Veterinary Drugs. 2014. "National Plan for Epidemic Emergencies. (PIANO NAZIONALE PER LE EMERGENZE DI TIPO EPIDEMICO ITALIAN VETERINARY CONTINGENCY PLAN 'ITAVETPLAN')." [http://www.quadernidellasalute.it/imgs/C_17_pagineAree_1670_listaFile_itemName_0_file.pdf] Accessed September 2020

[3] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website.

[https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202] Accessed September 2020

[4] Republic of Italy. National Institute of Health (ISS). 2020. Website. [https://www.iss.it] Accessed September 2020

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: 0

Available evidence does not indicate that Italy conducts ongoing event-based surveillance with regard to public health concerns, whether or not on a daily basis.

The country's civil-protection structure operates at the municipal, provincial and regional levels; in large-scale incidents, responsibility may escalate from the municipal to the national level, where the Department of Civil Protection (Dipartimento della Protezione Civile), runs the National Service of Civil Protection (Servizio nazionale di protezione civile). The Department maintains the Italy Situation Room, a permanent control center operating 24 hours a day and running the so-called System (Sistema), which monitors incidents occurring nationwide, becoming "Crisis Unit - S3" during an emergency and coordinating with other authorities. [1, 2] However, the Department is focused on responding to natural disasters, and disease outbreaks are not normally the triggering factor for response.

Evidence does indicate that Italy's public health surveillance policy is based on a graduated response to the phases of disease outbreaks. Italy's two key policy plans on addressing public health emergencies are the Ministry of Health's National Plan for Preparedness and Response to an Influenza Pandemic (2006) and its National Plan for Epidemic Emergencies, known as the "Itavet Plan" (2014). Both plans structure their respective public health intervention policies around the phases of an outbreak; surveillance is activated at the first phase, when suspicion of the presence of an infectious disease vector arises. In line with the understanding that Italy's day-to-day healthcare system is operated at the regional/provincial level, both plans accord a considerable role to regional reference laboratories and their veterinary analogues (the IZSs)--particularly during the early phases of an outbreak. [3, 4]

In that regard, outbreaks of infectious disease are largely handled by regional reference centers such as the Lazzaro Spallanzani National Institute for Infectious Diseases in the capital Rome, and the Luigi Sacco Hospital in Milan, which continuously train to respond. [5] Reporting systems include InFluNet, the national influenza surveillance system which reports to the National Institute of Health (ISS) via its network of sentinel physicians. [3] Zoonotic outbreaks are coordinated by the Ministry of Health's Central Crisis Unit (Unità Centrale di Crisi) and other authorities such as the regional veterinary reference laboratories (IZSs). Data on zoonotic and epizootic outbreaks are processed via SIMAN, the veterinary disease reporting network. [2]

Finally, the Ministry of Agriculture, although at least tangentially associated with public policy on animal diseases and zoonoses, provides no evidence of having a policy to conduct event-based surveillance with regard to human health. [6]

[1] European Commission. October 16 2017. "Vademecum - Civil Protection Italy - Disaster management structure". [http://ec.europa.eu/echo/files/civil_protection/vademecum/it/2-it-1.html] Accessed September 2020

[2] Republic of Italy. Presidency of the Council of Ministers. Department of Civil Protection. 2020. "System at the Italy Situation Room (Sistema nella Sala Situazione Italia)". [http://www.protezionecivile.gov.it/attivita-rischi/schede-tecniche/dettaglio/-/asset_publisher/default/content/sistema-nella-sala-situazione-italia] Accessed September 2020

[3] Republic of Italy. Ministry of Health. 2006. "NATIONAL PLAN FOR PREPAREDNESS AND RESPONSE TO AN INFLUENZA PANDEMIC." [http://www.salute.gov.it/imgs/C_17_pubblicazioni_501_ulterioriallegati_ulterioreallegato_0_alleg.pdf] Accessed September 2020

[4] Republic of Italy. Ministry of Health. Directorate of Animal Health and Veterinary Drugs. 2014. "National Plan for Epidemic Emergencies. (PIANO NAZIONALE PER LE EMERGENZE DI TIPO EPIDEMICO ITALIAN VETERINARY CONTINGENCY PLAN 'ITAVETPLAN')." [http://www.quadernidellasalute.it/imgs/C_17_pagineAree_1670_listaFile_itemName_0_file.pdf] Accessed September 2020

[5] ANSA. 24 November 2014. "Ebola: two [are the] Italian reference centers for the emergency (Ebola: due i centri riferimento Italia contro l'emergenza)". [http://www.ansa.it/saluteebenessere/notizie/rubriche/medicina/2014/11/24/ebola-due-i-centri-riferimento-italia-contro-lemergenza_6e39bedd-ed0-4b8f-a8e5-d67701014cb2.html] Accessed September 2020

[6] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website.

[<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202>] Accessed September 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: 0

Available evidence does not indicate that Italy has reported a potential public health emergency of international concern (PHEIC) to the World Health Organization (WHO) within the last two years. [1] For example, there is no evidence that Italy reported to the WHO on suspected or confirmed cases of the COVID-19 coronavirus prior to the WHO's own declaration of the disease as a PHEIC in January 2020. [1, 3]

The last report of a disease outbreak in Italy was in early September 2017, when the authorities reported an outbreak of Chikungunya. According to the WHO, the date of onset of symptoms of the first case was June 26 2017; as of September 26, 183 cases had been notified to the Lazio Region of Italy, which includes the capital city of Rome. Of the notified cases, 109 were confirmed and 74 additional cases were being investigated. Three more confirmed cases were also notified from other areas. On September 28th of that year the Ministry of Health issued new recommendations to strengthen surveillance and control activities at the national level, including disinfection at ports and airports. [2]

[1] World Health Organization (WHO). Emergencies preparedness, response. Italy.

[<https://www.who.int/csr/don/archive/country/ita/en/>] Accessed September and October 2020 and April 2021

[2] World Health Organization (WHO). 29 September 2017. "Chikungunya - Italy". [<http://www.who.int/csr/don/29-september-2017-chikungunya-italy/en/>] Accessed September 2020

[3] World Health Organization (WHO). Italy country webpage. 2020. "The current COVID-19 situation."

[<https://www.who.int/countries/ita/>] Accessed October 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

Italy's has electronic reporting surveillance system and it collects ongoing and real-time laboratory data.

Italy has had since 1990 electronic systems of detection and reporting of infectious disease and threats to public health. They operate at the national, regional/provincial, and local/municipal levels, and information is increasingly shared in real time. [1, 3] The main national infectious disease information system for human health is the SIMI, which processes the initial reports made by treating physicians. The information in SIMI flows from the diagnosing doctor, hospital clinic or reference laboratory, to the relevant local health unit (ASL) for investigation, then to the regional public health agency and to the central authorities (the Ministries of Health and Labour and Social Policies, the ISTAT national statistics institute and the National Institute of Health (ISS)) and ultimately to international bodies such as the ECDC and WHO.

In addition to the SIMI, surveillance systems exist for other infectious diseases, including meningitis, legionellosis, influenza,

measles, rubella, Creutzfeld-Jacob disease and Campylobacter (Enternet) salmonellosis. [2] Overall, the SIMI is adopting new technologies such as web-based information systems, to enable the sharing of information at all levels in real time as well as the central collection of notifications at the national level. [1, 3]

A parallel system exists for zoonoses and other diseases of animal origin. The Ministry of Health is in charge of collecting such data via its dedicated animal disease information systems (the earlier SINzoo and the current SIMAN). [1] As concerns zoonoses found in livestock (in terms of national policy the main vector of concern), veterinarians report incidences of animal disease into the SIMAN system through the ministry's Vetinfo online portal of the national livestock registry (Banca Dati Nazionale dell'Anagrafe Zootecnica). Analogous to the role of the ASLs in analyzing human disease is that of the veterinary reference laboratories (IZSs) which through their analytical interventions are key players in the national veterinary surveillance and reporting system. Vetinfo has separate modules for the reporting of diseases in cows, sheep horses and swine. [4]

[1] Republic of Italy. Ministry of Health. 2020. "E-health initiatives in Italy (Le iniziative eHealth in Italia)."

[http://www.salute.gov.it/portale/temi/p2_5.jsp?lingua=italiano&area=eHealth&menu=iniziativa] September 2020

[2] National Institute of Health (Istituto superiore di sanità--ISS). EpiCentro. 2020. "Routine surveillance system for infectious diseases (Infectious Diseases Information System, Simi) (Il sistema di sorveglianza routinario per le malattie infettive (Sistema informativo malattie infettive, Simi))". [<https://www.epicentro.iss.it/infettive/sorveglianza>] Accessed September 2020

[3] Republic of Italy. Ministry of Health. Infectious Diseases. 2020. "Surveillance of communicable diseases (Sorveglianza delle malattie trasmissibili)."

[<http://www.salute.gov.it/portale/malattieInfettive/menuContenutoMalattieInfettive.jsp?lingua=italiano&area=Malattie%20infettive&menu=sorveglianza>] Accessed September 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

Italy's electronic reporting surveillance system collects ongoing and real-time laboratory data.

Italy has had since 1990 electronic systems of detection and reporting of infectious disease and threats to public health. They operate at the national, regional/provincial, and local/municipal levels, and information is increasingly shared in real time. [1, 3] The main national infectious disease information system for human health is the SIMI, which processes the initial reports made by treating physicians. The information in SIMI flows from the diagnosing doctor, hospital clinic or reference laboratory, to the relevant local health unit (ASL) for investigation, then to the regional public health agency and to the central authorities (the Ministries of Health and Labour and Social Policies, the ISTAT national statistics institute and the National Institute of Health (ISS)) and ultimately to international bodies such as the ECDC and WHO.

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disease into the SIMAN system through the ministry's Vetinfo online portal of the national livestock registry (Banca Dati Nazionale dell'Anagrafe Zootecnica). Analogous to the role of the ASLs in analyzing human disease is that of the veterinary reference laboratories (IZSs) which through their analytical interventions are key players in the national veterinary surveillance and reporting system. Vetinfo has separate modules for the reporting of diseases in cows, sheep horses and swine. [4]

[1] Republic of Italy. Ministry of Health. 2020. "E-health initiatives in Italy (Le iniziative eHealth in Italia)."

[http://www.salute.gov.it/portale/temi/p2_5.jsp?lingua=italiano&area=eHealth&menu=iniziativa] September 2020

[2] National Institute of Health (Istituto superiore di sanità--ISS). EpiCentro. 2020. "Routine surveillance system for infectious diseases (Infectious Diseases Information System, Simi) (Il sistema di sorveglianza routinario per le malattie infettive (Sistema informativo malattie infettive, Simi))". [<https://www.epicentro.iss.it/infettive/sorveglianza>] Accessed September 2020

[3] Republic of Italy. Ministry of Health. Infectious Diseases. 2020. "Surveillance of communicable diseases (Sorveglianza delle malattie trasmissibili)."

[<http://www.salute.gov.it/portale/malattieInfettive/menuContenutoMalattieInfettive.jsp?lingua=italiano&area=Malattie%20infettive&menu=sorveglianza>] Accessed September 2020

[4] Republic of Italy. Ministry of Health. 2020. Vetinfo. [<https://www.vetinfo.it/>] Accessed September 2020

2.4 SURVEILLANCE DATA ACCESSIBILITY AND TRANSPARENCY

2.4.1 Coverage and use of electronic health records

2.4.1a

Are electronic health records commonly in use?

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

Current Year Score: 2

Electronic health records (EHRs) are commonly used in Italy. According to the Annual European eHealth Survey for 2019, a white paper published by HIMSS Analytics, a European healthcare data consulting company, self-assessment respondents from Italian healthcare organisations indicated that 81% of data on patients is in digital format, and 88% of institutions use cross-organisational electronic patient records to exchange clinical data. On average, they rated their organisations' "digital maturity" level as 6.8 on a 1 to 10 scale. [1]

The Ministry of Health's national eHealth Information Strategy currently identifies five priority areas for development: Single Booking Centers (one-stop-shops for making medical appointments), Electronic Health Records, Telematic Certificates (used by employers to document paid leave), ePrescriptions and Telemedicine. [2]

[1] Himss Analytics. "Annual European eHealth Survey: 2019".

[https://europe.himssanalytics.org/sites/himssanalytics_europe/files/eHealth%20TREND%20BAROMETER%20-%20HIMSS%20Analytics%20Annual%20European%20eHealth%20Survey%202019.pdf] Accessed September 2020

[2] Republic of Italy. Ministry of Health. 2020. "E-health initiatives in Italy (Le iniziative eHealth in Italia)."

[http://www.salute.gov.it/portale/temi/p2_5.jsp?lingua=italiano&area=eHealth&menu=iniziativa] September 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

There is insufficient evidence that the national public health system in Italy has access to electronic health records of individuals in Italy. Although there is evidence that the national public health system is authorised to access patient EHRs without consent in the case of emergencies, there is insufficient evidence that it is able to access them generally, given the regionalised health care system in the country. [1,2,3]

In the Italian public health system, the national government sets general policy and funding, but the regional health care agencies control many specific functions, such as acting as the first link in the chain to process epidemiological data reported by local physicians. One such agency, that of the Emilia-Romagna region, states that patients have the right to choose who may access their personal health records, including even the healthcare staff who treat them. [1] This provision is in line with that of the European Union's General Data Protection Regulation (GDPR), which entered into force in 2018 in all Member States, including Italy. [2]

According to the national Ministry of Health, a National Register of Patients (ANA), established by law 27/12/2013 n. 147, will be interoperable with other national and regional databases and will operate in compliance with the legislation on the protection of personal data. [3] However, evidence indicates that the ANA, to be run by the Ministry of Economy and Finance, is not yet in service, and that the set-up of regional patient registries must come first.

Electronic health records (EHRs) have gained wide acceptance in Italy; as of 2019 81% of patient data are digitized, and 88% of healthcare institutions use cross-organisational electronic patient records to exchange clinical data. [4]

[1] Emilia-Romagna Regional Health Service. 2020. "My electronic health record (ESF) - questions and answers (Il mio Fascicolo sanitario elettronico (FSE) - domande e risposte)". [<https://www.fascicolo-sanitario.it/fse/faq>] Accessed September-October 2018

[2] European Patients Forum (EPF). Undated. "The new EU Regulation on the protection of personal data: what does it mean for patients?" [<https://www.eu-patient.eu/globalassets/policy/data-protection/data-protection-guide-for-patients-organisations.pdf>] Accessed September 2020

[3] Republic of Italy. Ministry of Health. 2020. "E-health initiatives in Italy (Le iniziative eHealth in Italia)." [http://www.salute.gov.it/portale/temi/p2_5.jsp?lingua=italiano&area=eHealth&menu=iniziativa] September 2020

[4] Himss Analytics. "Annual European eHealth Survey: 2019". [https://europe.himssanalytics.org/sites/himssanalytics_europe/files/eHealth%20TREND%20BAROMETER%20-%20HIMSS%20Analytics%20Annual%20European%20eHealth%20Survey%202019.pdf] Accessed September 2020 Other sources: Lidia Di Minco. 5 April 2017. "Electronic Health Record (EHR): implementation in Italy". Ministry of Health PowerPoint presentation. [https://www.consorzioarsenal.it/c/document_library/get_file?uuid=ac838533-9ec4-4546-95f3-2356170acc43&groupId=10157] Accessed September 2020

2.4.1c

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

Yes = 1 , No = 0

Current Year Score: 1

Italy legally mandates the application of data standards to ensure the compatibility of data used in electronic health records (EHRs). Over the last two decades, Italian legislation has systematised electronic record-keeping in the country's health care facilities, and the adoption of laws and guidelines on data governance has eased the acceptance of EHRs. The 2011 Ministry

of Health Guidelines on EHRs define technological standards and levels of data protection for the Italian EHR. [1]

More recent legislation has aimed to standardise data governance in processing EHRs. The Decree of the Presidency of the Council of Ministers No. 178/2015 defines the dataset of the EHR, the data collection process, the interconnection procedures for all national health datasets, the data encoding systems for the documents and the interoperability of the EHRs produced by the regional health systems. [2]

Due to other legislative actions, much of Italy's health care administration system already has been digitised, such as drug prescriptions, patients' personal health files, and epidemiological surveillance systems. [3, 4]

[1] Milieu, Ltd. "Overview of the national laws on electronic health records in the EU Member States: National Report for Italy". 28 February 2014. [https://ec.europa.eu/health/sites/health/files/ehealth/docs/laws_italy_en.pdf] Accessed September 2020

[2] Lidia Di Minco. 5 April 2017. "Electronic Health Record (EHR): implementation in Italy". Ministry of Health PowerPoint presentation. [https://www.consortioarsenal.it/c/document_library/get_file?uuid=ac838533-9ec4-4546-95f3-2356170acc43&groupId=10157] Accessed September 2020

[3] Republic of Italy. Ministry of Health. 2020. "E-health initiatives in Italy (Le iniziative eHealth in Italia)." [http://www.salute.gov.it/portale/temi/p2_5.jsp?lingua=italiano&area=eHealth&menu=iniziativa] Accessed September 2020

[4] Himss Analytics. "Annual European eHealth Survey: 2019". [https://europe.himssanalytics.org/sites/himssanalytics_europe/files/eHealth%20TREND%20BAROMETER%20-%20HIMSS%20Analytics%20Annual%20European%20eHealth%20Survey%202019.pdf] Accessed September 2020

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

2.4.2a

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

Yes = 1, No = 0

Current Year Score: 1

Italy's government has mechanisms for the sharing of human and animal epidemiological surveillance data. The country's epidemiological surveillance system is dual, with human and veterinary branches.

Human epidemiology is addressed by entities such as the Ministry of Health and the National Institute of Health (ISS) conducting overarching policy and research, the regional health agencies forming context-specific policies, and the local health units (ASLs) acting in the field. [1, 2] For example, in the InFluNet system of influenza surveillance, data flows from the ASLs and ends with the ISS and the Ministry. [4]

Animal epidemiology is addressed in a parallel system, in which research facilities known as experimental zooprophyllactic institutes (IZSs) analyse data from the field and advise the authorities on policy, such as on preventing zoonoses. [3, 5] Data collection is governed by the national Animal Disease Information System (Sistema Informativo Malattie Animali--SIMAN), and consolidated on national veterinary data portals such as VetInfo, used by authorised public- and private-sector parties primarily to report diseases in livestock. [3, 5, 6]

At the national level, data from the two systems are consolidated to form policy and react to crises. An example of this

consolidation is EpiCentro, an online portal for non-confidential epidemiological information on infectious human and zoonotic diseases. [2] Other policy doctrines mandate such consolidation, such as Italy's national plans on influenza pandemics and veterinary epidemics, which reflect the integration of human and veterinary surveillance information. [5]

[1] Republic of Italy. Ministry of Health. Infectious Diseases. 2020. "Surveillance of communicable diseases (Sorveglianza delle malattie trasmissibili)."

[<http://www.salute.gov.it/portale/malattieInfettive/menuContenutoMalattieInfettive.jsp?lingua=italiano&area=Malattie%20infettive&menu=sorveglianza>] Accessed September 2020

[2] National Institute of Health (Istituto superiore di sanità--ISS). EpiCentro. 2020. "Routine surveillance system for infectious diseases (Infectious Diseases Information System, Simi) (Il sistema di sorveglianza routinario per le malattie infettive (Sistema informativo malattie infettive, Simi))." [<https://www.epicentro.iss.it/infettive/sorveglianza>] Accessed September 2020

[3] Republic of Italy. Ministry of Health. 2020. Animal Health (Sanità animale).

[http://www.salute.gov.it/portale/temi/p2_4.jsp?lingua=italiano&tema=Animali&area=sanitaAnimale] Accessed September 2020

[4] Republic of Italy. Ministry of Health. 2006. "NATIONAL PLAN FOR PREPAREDNESS AND RESPONSE TO AN INFLUENZA PANDEMIC." [http://www.salute.gov.it/imgs/C_17_pubblicazioni_501_ulterioriallegati_ulterioreallegato_0_alleg.pdf] Accessed September 2020

[5] Republic of Italy. Ministry of Health. Directorate of Animal Health and Veterinary Drugs. 2014. "National Plan for Epidemic Emergencies. (PIANO NAZIONALE PER LE EMERGENZE DI TIPO EPIDEMICO ITALIAN VETERINARY CONTINGENCY PLAN 'ITAVETPLAN')." [http://www.quadernidellasalute.it/imgs/C_17_pagineAree_1670_listaFile_itemName_0_file.pdf] Accessed September 2020

[6] Republic of Italy. Ministry of Health. Veterinary Information Systems (Sistemi Informativi Veterinari--Vetinfo). [<https://www.vetinfo.it/>] Accessed September 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: 0

Available evidence indicates that Italy does not make de-identified health surveillance data on disease outbreaks publicly available on a frequent and regular basis.

The country's key governmental agencies that could be expected to publish such data on disease incidence do so on an infrequent basis. The National Institute of Health (Istituto Superiore di Sanità--ISS) provides a one-stop-shop for non-confidential epidemiological public health information called EpiCentro, which is accessible online via a dedicated website, www.epicentro.iss.it. While EpiCentro's website provides a list of over fifty infectious diseases, with specific epidemiological and other information available on each disease, such information is presented in summary form and is inconsistent in terms of type and frequency of publication. [1] Similarly, the Ministry of Health has a number of databases and registries on its website, but these are inconsistent in terms of type and frequency of publication; a search for data on infective diseases yields only one epidemiological report dating from 1996. [2] Finally, the national statistics institute Istat has data on mortality from various diseases, including infectious diseases, but such data is published only annually, with the latest annual series being available from 2017. [3]

- [1] National Institute of Health (Istituto Superiore di Sanita--ISS). EpiCentro. 2020. "Data find (Trova dati)."
[<https://www.epicentro.iss.it/index/dati>] Accessed September 2020
- [2] Republic of Italy. Ministry of Health. 2020. "Databases and registries (Banche dati e anagrafi)." Filter "Infectious Diseases (Malattie infettive)."
[http://www.salute.gov.it/portale/documentazione/p6_2_8_1.jsp?lingua=italiano&area=Malattie+infettive&btnCerca=]
Accessed September 2020
- [3] Republic of Italy. Italian National Institute of Statistics (Istat). 2020. "Mortality by territory of event (Mortalità per territorio di evento)."[http://dati.istat.it/Index.aspx?DataSetCode=DCIS_CMORTE1_EV#] Accessed September 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

Italy makes de-identified surveillance data on COVID-19 (including details such as daily case count, mortality rate, etc) available via daily reports on the website of the Ministry of Health. The ministry provides a wealth of information on the outbreak in Italy, including infographics and interactive maps, and a bulletin with aggregate incidence data collected from the regional health agencies. This daily bulletin is updated and published daily and contains over ten data categories, including the total number of COVID-19 positive cases and their current condition (recovered with symptoms, remaining in intensive therapy, or isolated at home). Other data points include the total number of cases identified by screening activities, and the total number of swab samples made. [1]

The National Institute of Health's EpiCentro epidemiological information platform also provides updated aggregate data on COVID-19, in the form of a daily infographic dashboard, containing data points such as daily cases, aggregate fatalities and total number of cured patients. [2]

- [1] Republic of Italy. Ministry of Health. 2020. "Covid-19 - Situation in Italy (Covid-19 - Situazione in Italia)."
[<http://www.salute.gov.it/portale/nuovocoronavirus/dettaglioContenutiNuovoCoronavirus.jsp?area=nuovoCoronavirus&id=5351&lingua=italiano&menu=vuoto>] Accessed September 2020
- [2] National Institute of Health (ISS). EpiCentro. 2020. "Coronavirus." [<https://www.epicentro.iss.it/coronavirus/>] Accessed September 2020

2.4.4 Ethical considerations during surveillance

2.4.4a

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

Yes = 1 , No = 0

Current Year Score: 1

Italy has fairly strong laws that safeguard the confidentiality of identifiable health information for individuals, in particular private medical records.

A 2014 European Commission study of Italy's laws on electronic health records states as follows: "Furthermore, access to

data should be granted only in accordance with the confidentiality principle and measures of protection of the patient's privacy should be enforced. Electronic health records shall always be developed in accordance with the legislation on personal data protection. Therefore, the processing of the data dealt with in the electronic health records can only be carried out with the patient's consent. The lack of such a consent does not affect the patient's right to health. Anyone with access to electronic health records is bound by professional secrecy in accordance with the Italian Law on personal data protection."

[1] The legal basis for this policy is reflected in the Italian Data Protection Authority's Guidelines on the Electronic Health Record and the Health File, as published in Italy's Official Journal no. 178 dated 3 August 2009. [2]

Finally, the confidentiality of identifiable health information for individuals is safeguarded by the EU's General Data Protection Regulation (GDPR), which came into force in May 2018. [3]

[1] Milieu, Ltd. "Overview of the national laws on electronic health records in the EU Member States: National Report for Italy." February 28 2014. [https://ec.europa.eu/health/sites/health/files/ehealth/docs/laws_italy_en.pdf] Accessed September 2020

[2] Italian Data Protection Authority (Garante Privacy--Garante per la protezione dei dati personali). "Guidelines on the Electronic Health Record and the Health File - 16 July 2009" [1672821]. [<https://www.gpdp.it/web/guest/home/docweb/-/docweb-display/docweb/1672821>] Accessed September 2020

[3] Official Journal of the European Union. April 27 2016. "REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)." [<https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN>]. Accessed September 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

Italy's laws and regulations on protecting private electronic health records (EHRs) require the adoption of data security measures. While the rules do not specifically mention cyber attacks, they do address unauthorised access.

Italy's laws on EHRs are based on the confidentiality principle. Several laws and decrees address data security, especially Article 31 of Legislative Decree no. 196 of 30 June 2003, the "Personal Data Protection Code", as amended, which states that personal data must be hosted and protected in such a way as to reduce the risk of destruction, loss, unauthorised access or processing. [1] Both civil and criminal liability may arise in case of violation of any provision on security measures of this decree. Cabinet-level decrees dated April 1 2008 and December 3 2013 set out technical rules on the secure holding of digital documents; these rules also apply to EHRs. [1]

The Italian Data Protection Authority's Guidelines on the Electronic Health Record and the Health File, published in 2009, strongly mandate security measures in order to comply with the Personal data Protection Code. To protect data against unauthorised access, theft and/or loss, among other measures the Guidelines stipulate the use of authentication and authorization systems for persons in charge of data processing, as well as the use of criteria to separate disclosable data from other personal data. [1, 2]

In addition, the confidentiality of identifiable health information for individuals is safeguarded by the EU's General Data

Protection Regulation (GDPR), which came into force in May 2018. The GDPR contains stipulations around network and information security, including a requirement that data held by state authorities must be overseen by a dedicated data protection officer who is proficient in dealing with cyber attacks and a requirement to inform all affected individuals within 72 hours of discovering a data breach. [3]

[1] Milieu, Ltd. "Overview of the national laws on electronic health records in the EU Member States: National Report for Italy." February 28 2014. [https://ec.europa.eu/health/sites/health/files/ehealth/docs/laws_italy_en.pdf] Accessed September 2020

[2] Italian Data Protection Authority (Garante Privacy--Garante per la protezione dei dati personali). "Guidelines on the Electronic Health Record and the Health File - 16 July 2009" [1672821]. [<https://www.gdpd.it/web/guest/home/docweb/-/docweb-display/docweb/1672821>] Accessed September 2020

[3] Official Journal of the European Union. April 27 2016. "REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)." [<https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&from=EN>]. Accessed September 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, Yes, commitments have been made to share data only for one disease = 1, No = 0

Current Year Score: 2

There is evidence that the Government of Italy has made a commitment via public statements, legislation, and/or a cooperative agreement to share surveillance data specifically during a public health emergency with other countries in the region, for more than one disease.

As a member of the European Union, Italy shares surveillance data during a public health emergency with other countries in the region. All EU and EEA countries are part of the European Centre for Disease Prevention and Control (ECDC)'s Early Warning and Response System (EWRS). The EWRS is a platform used to exchange information related to disease outbreaks. Its use is restricted to staff of the ECDC, the Member States and the European Commission's Directorate General Health and Food Safety (SANTE). [1]

Article 9 of Chapter IV of the European Union (EU) Decision on Serious Cross-Border Threats to Health (No. 1082/2013/EU) notes that the European Commission "shall make available to the national competent authorities through the EWRS any information that may be useful for coordinating the response...including information related to serious crossborder threats to health and public health measures related to serious cross-border threats to health transmitted through rapid alert and information systems established under other provisions of Union law or the Euratom Treaty." [2]

[1] European Centre for Disease Prevention and Control. September 3 2018. "Early Warning and Response System (EWRS)." [<https://ecdc.europa.eu/en/early-warning-and-response-system-ewrs>]. Accessed September 2020

[2] Official Journal of the European Union. "Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on Serious Cross-Border Threats to Health and Repealing Decision No 2119/98/EC."

[https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/decision_serious_crossborder_threats_221020]

13_en.pdf]. Accessed September 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: 0

There is insufficient evidence that the national government in Italy supports sub-national systems to provide support at the sub-national level to conduct contact tracing in the event of a public health emergency.

Although Italy's healthcare system is devolved, with the Regions in charge of most day-to-day functions, [1] available evidence indicates that Italy traditionally has not had a national system in place to conduct contact tracing. The country's two key national-level administrative bodies for public health, the Ministry of Health and the National Institute of Health (ISS), provide no evidence that they have traditionally promoted a policy for using contact tracing as a method of data collection during such an emergency. Actual on-the-ground surveillance and data collection are undertaken by the regional health agencies and by their veterinary counterparts. [1, 2, 3]

In the wake of the COVID-19 coronavirus pandemic outbreak in early 2020, the national government has adopted overarching policies to conduct contact tracing as a monitoring and surveillance tool to contain the disease. Through Italy's ASLs (local health units) the Regional and Provincial authorities are obliged to conduct monitoring and surveillance of the disease using data obtained via methods such as the voluntary contact tracing efforts of individuals using government-approved digital "apps" on their mobile telephones to conduct reporting. [4, 5] Some Italian Regions have developed their own digital tools to track and contain infected residents, in most cases basing their efforts on analyses of movements and gatherings identified from anonymous data. [5] There is, however, no evidence of specific support/resources provided by the national government at the sub-national level to conduct this contact tracing.

[1] Roosa Tikkanen, Robin Osborn, Elias Mossialos, Ana Djordjevic, and George A. Wharton. June 5, 2020. International Healthcare System Profiles. "Italy." The Commonwealth Fund. [<https://www.commonwealthfund.org/international-health-policy-center/countries/italy>] Accessed September 2020

[2] Republic of Italy. Ministry of Health. Infectious Diseases. 2020. "Surveillance of communicable diseases (Sorveglianza delle malattie trasmissibili)."

[<http://www.salute.gov.it/portale/malattieInfettive/menuContenutoMalattieInfettive.jsp?lingua=italiano&area=Malattie%20infettive&menu=sorveglianza>] Accessed September 2020

[3] National Institute of Health (Istituto superiore di sanità--ISS). EpiCentro. 2020. "Routine surveillance system for infectious diseases (Infectious Diseases Information System, Simi) (Il sistema di sorveglianza routinario per le malattie infettive (Sistema informativo malattie infettive, Simi))." [<https://www.epicentro.iss.it/infettive/sorveglianza>] Accessed September 2020

[4] Republic of Italy. Ministry of Health. November 10 2020. "New coronavirus: Home / FAQ - Covid-19, questions and answers / What to know about testing, tracking, quarantine (Nuovo coronavirus: Home / FAQ - Covid-19, domande e risposte / Cosa sapere su test, tracciamento, quarantena)."

[<http://www.salute.gov.it/portale/nuovocoronavirus/dettaglioFaqNuovoCoronavirus.jsp?lingua=italiano&id=244>] Accessed April 2021

[5] Antonio Giulio de Belvis, Giovanni Fattore, Alisha Morsella, Gabriele Pastorino, Andrea Poscia, Walter Ricciardi, Andrea Silenzi. November 20 2020. "Policy Responses for Italy: 1.4 Monitoring and surveillance." WHO Regional Office for Europe and European Observatory on Health Systems and Policies. COVID-19 Health System Response Monitor.

[<https://www.covid19healthsystem.org/countries/italy/livinghit.aspx?Section=1.4%20Monitoring%20and%20surveillance&Type=Section>] Accessed April 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: 2

Italy provides "wraparound services" to infected people and their contacts to self-isolate or quarantine as recommended, including medical care and economic support. It can provide these services because of its social-welfare system.

A major part of this system is Italy's universal healthcare system, which provides a range of statutory benefits under the Essential Levels of Assistance (Livelli essenziali di assistenza--LEA) package. These benefits include home and hospice care. Patients requiring long-term care can receive two form of benefits: an accompanying allowance, awarded by the National Pension Institute to all Italian citizens who need continuous assistance; and care vouchers, awarded by some but not all municipalities according to the patient's level of income, need, and clinical severity. [1]

The second key part is Italy's unemployment benefits system, which typically provides benefits in two forms: INASPI, a cash benefit granted on request to employed workers in the event of involuntary redundancy; and DIS-COLL, a cash benefit awarded on request to workers with atypical employment contracts in the event of involuntary redundancy. [2]

[1] Roosa Tikkanen, Robin Osborn, Elias Mossialos, Ana Djordjevic, and George A. Wharton. June 5, 2020. International Healthcare System Profiles. "Italy." The Commonwealth Fund. [<https://www.commonwealthfund.org/international-health-policy-center/countries/italy>] Accessed September 2020

[2] European Commission. Employment, Social Affairs & Inclusion. 2020. "Italy - Unemployment benefits: NASpi and DIS-COLL." [<https://ec.europa.eu/social/main.jsp?catId=1116&langId=en&intPagId=4627>] Accessed September 2020

2.5.1c

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

Yes = 1, No = 0

Current Year Score: 0

Evidence indicates that Italy makes de-identified data on contact tracing efforts for COVID-19 available via weekly, rather than daily, reports from the Ministry of Health. Otherwise, the data on COVID-19 when published are not broken down into a category specific to this method. Without specifying the method of data collection, Italy makes de-identified surveillance data on COVID-19 (including details such as daily case count, mortality rate, etc) available via at least three sources:

First, the Ministry of Health provides a dedicated webpage, "Covid-19 - Situation in Italy," with wealth of information on the outbreak in Italy, including infographics and interactive maps, and a bulletin with aggregate incidence data collected from the regional health agencies. This daily bulletin is updated and published daily and contains over ten data categories, including the total number of COVID-19 positive cases and their current condition (recovered with symptoms, remaining in intensive therapy, or isolated at home).[1] Data on case counts are broken down into two data categories; "cases identified by diagnostic suspicion" and "cases identified by screening activities." The former category represents swab-positive cases that emerged from clinical activity; while the latter data points come from investigations and tests which diagnose positive cases by swab count. [2] On its dedicated COVID-19 webpage, the ministry now also provides a "Phase 2 weekly monitoring report" containing textual commentary on the epidemiological situation, with weekly updates on the percentage of new cases detected through contact tracing activities. For example, for the week of October 12-18, the ministry noted that only one in four new cases were detected through contact tracing activities, while 31.7% were detected through onset of symptoms. [1]

Second, case data on COVID-19 are also published daily by EpiCentro, the epidemiological information platform of the National Institute of Health (ISS). [3] EpiCentro states that the Prevention Departments of the regional health services are instrumental in surveilling new infections, "...to guarantee the necessary activities such as: contact tracing, epidemiological investigations, health surveillance for positive cases and their contacts, constant information to citizens through a dedicated telephone service, request of swabs, the management of the IT platform for data collection, communication with general practitioners (GPs) and local administrations, management of reports, home care for swabs." The published data are not broken down by method of collection. [4]

Third, Italy's Department of Civil Protection has a dedicated COVID-19 dashboard website with standard metrics on case data published data. It does not break down the data by method of collection. [5]

- [1] Republic of Italy. Ministry of Health. 2020. "Covid-19 - Situation in Italy (Covid-19 - Situazione in Italia)." [<http://www.salute.gov.it/portale/nuovocoronavirus/dettaglioContenutiNuovoCoronavirus.jsp?area=nuovoCoronavirus&id=5351&lingua=italiano&menu=vuoto>] Accessed September and October 2020
- [2] Republic of Italy. Ministry of Health. October 28 2020. "October 28, 2020 - Covid-19 cases update: Daily aggregate data Regions / PPAA [Autonomous Provinces] - Ministry of Health - National Institute of Health (28 ottobre 2020 - Aggiornamento casi Covid-19: Dati aggregati quotidiani Regioni/PPAA - Ministero della Salute - Istituto Superiore di Sanità)." [<http://www.salute.gov.it/portale/nuovocoronavirus/dettaglioContenutiNuovoCoronavirus.jsp?area=nuovoCoronavirus&id=5351&lingua=italiano&menu=vuoto>] Accessed October 2020
- [3] National Institute of Health (ISS). EpiCentro. 2020. "Integrated COVID-19 surveillance data in Italy (Dati della Sorveglianza integrata COVID-19 in Italia)." [<https://www.epicentro.iss.it/coronavirus/sars-cov-2-dashboard>] Accessed October 2020
- [4] National Institute of Health (ISS). EpiCentro. 2020. "The new challenges in the management of COVID-19: the experience of the prevention services (Le nuove sfide nella gestione del COVID-19: l'esperienza dei Servizi di prevenzione)." [<https://www.epicentro.iss.it/coronavirus/sars-cov-2-esperienza-servizi-prevenzione>] Accessed September 2020
- [5] Republic of Italy. Department of Civil Protection. 2020. COVID-19 Dashboard. [<http://opendatadpc.maps.arcgis.com/apps/opsdashboard/index.html#/b0c68bce2cce478eaac82fe38d4138b1>] Accessed October 2020

2.5.2 Point of entry management

2.5.2a

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

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

Current Year Score: 1

There is evidence that Italy has a joint plan or cooperative agreement between the public health system and border control authorities to identify suspected and potential cases in international travelers and trace and quarantine their contacts in the event of an active public health emergency, but only in response to an ongoing emergency.

Neither of Italy's two key public health bodies, the Ministry of Health and the National Institute of Health (ISS) has traditionally used such a policy in their surveillance of communicable diseases among travellers or locals. [1, 2, 3] Similarly, the Ministry of Foreign Affairs and International Cooperation, in charge of administering Italy's international borders, gives no indication of having made an agreement with the health authorities in this regard. [4]

Nevertheless, in the wake of the COVID-19 outbreak in early 2020, Italy adopted a policy of surveillance of international travelers, involving containment of individuals if necessary. A series of legislative measures adopted since the outbreak (most recently in early April 2021) limit and even prohibit the mobility of individuals within the country according to several different zones graded by the severity of restrictions. These domestic restrictions apply to international travellers who have already complied with the separate series of restrictions imposed as a precondition of their entry into the country. These restrictions differ according to the classification of the country from which the traveller is arriving; Italy currently has five different lists of countries (Lists A through E), List C containing countries of the European Union among others. For example, all travellers who have stayed or transited in the fourteen days prior to entering Italy in one or more of the States and territories listed in List C must undergo a swab (molecular or antigenic) test within 48 hours prior to entry into Italy and present a negative test result. In addition, such travellers must undergo health surveillance and self-isolation for a period of five days, regardless of the result of the test, and then undergo a further molecular or antigenic test at the end of the five-day isolation period. Moreover, All adults must fill out the digital Self Declaration Form before departure to Italy, or risk being denied entry. Within the Italy digital Self Declaration Form, passengers must provide their contact information along with travel history and flight details. [5,6]

[1] Republic of Italy. Ministry of Health. Infectious Diseases. 2020. "Surveillance of communicable diseases (Sorveglianza delle malattie trasmissibili)."

[<http://www.salute.gov.it/portale/malattieInfettive/menuContenutoMalattieInfettive.jsp?lingua=italiano&area=Malattie%20infettive&menu=sorveglianza>] Accessed September 2020

[2] Republic of Italy. Ministry of Health. Infectious Diseases. December 13 2019. Diseases of travellers (Malattie dei viaggiatori).

[<http://www.salute.gov.it/portale/malattieInfettive/menuContenutoMalattieInfettive.jsp?lingua=italiano&area=Malattie%20infettive&menu=viaggiatori>] Accessed September 2020 and April 2021

[3] National Institute of Health (Istituto superiore di sanità--ISS). EpiCentro. 2020. "Routine surveillance system for infectious diseases (Infectious Diseases Information System, Simi) (Il sistema di sorveglianza routinario per le malattie infettive (Sistema informativo malattie infettive, Simi))". [<https://www.epicentro.iss.it/infettive/sorveglianza>] Accessed September 2020

[4] Republic of Italy. Ministry of Foreign Affairs and International Cooperation. 2020. [<https://www.esteri.it/mae/en>] Accessed September 2020

[5] Republic of Italy. Ministry of Health. April 7 2021. "New coronavirus: Home / FAQ - Covid-19, questions and answers / Containment measures and travel (Nuovo coronavirus: Home / FAQ - Covid-19, domande e risposte / Misure di contenimento e viaggi."

[<http://www.salute.gov.it/portale/nuovocoronavirus/dettaglioFaqNuovoCoronavirus.jsp?lingua=italiano&id=237>]

[6] iVisa.com. Italy Self Declaration Form. [<https://www.ivisa.com/italy-health-declaration-form>]

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

Field epidemiology training programs are available in Italy, run by the Italian National Institute of Health (Istituto Superiore di Sanità-ISS). However, available evidence does not indicate that Italy's government provides resources to send its citizens to participate in EPIET training programs in other countries.

The ISS is the technical and scientific body of the Italian National Health Service and the main Italian research Institute in biomedical and public health. Its Department of Infectious Diseases (DMI) is an acknowledged training site for EPIET and EUPHEM. ISS-DMI trained ten EPIET fellows between 1995 and 2014. [1] While the ISS, a branch of the Italian government, does offer work-study grants to university graduates through advertised competitions, evidence suggests that these are applied in local rather than foreign facilities. [2]

Moreover, these grants are distinct from the field epidemiology training programmes (FETP) it sponsors in conjunction with the European Centre for Disease Prevention and Control (ECDC). These FETP fellowship programmes are of two types; European Union (EU)-track fellows are assigned to a Member State other than their own, in which case the ECDC funds their salaries, while Member State (MS)-track fellows train within their own Member State and receive a salary from their local training institutes. In the case of Italy, MS-track fellows would be funded by the ISS. [3]

[1] European Centre for Disease Prevention and Control (ECDC). August 31 2018. "Istituto Superiore di Sanita - EPIET."

[<https://www.ecdc.europa.eu/en/instituto-superiore-di-sanita-epiet>] Accessed September 2020

[2] National Institute of Health (Istituto Superiore di Sanità-ISS). 2020. "Competition Notices (Bandi di Concorso)."

[<https://amministrazionetrasparente.iss.it/?tipologie=bandi-di-concorso>] Accessed September 2020

[3] European Centre for Disease Prevention and Control (ECDC). 2020. EPIET/EUPHEM. "At a glance."

[<https://ecdc.europa.eu/en/epiet-euphem/about/intro>] Accessed September 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

The main field epidemiology training programs (FETP) in Italy are run by the Italian National Institute of Health (Istituto Superiore di Sanità--ISS), which is an acknowledged training site for EPIET and EUPHEM. Information from the ECDC demonstrates that the EPIET and EUPHEM programmes are open to animal health professionals. [1]

Nevertheless, Italy does have an extensive research system for veterinary epidemiology, and has several dedicated veterinary research institutes, known as Experimental Zootechnic Institutes (Istituti zooprofilattici sperimentali--IZS), located throughout the country. One IZS at the forefront of epidemiological research stands out: the "Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise "Giuseppe Caporale". Known as IZSAM, this IZS is an autonomous public health institute which operates as a technical and scientific arm of the Italian state and the Abruzzo and Molise Regions. It performs analytical work for the public veterinary services and has operated a training department since 1990. [2]

[1] European Centre for Disease Prevention and Control (ECDC). 2020. "Call for application for cohort 2021 ECDC Fellowship Programme EPIET and EUPHEM paths, EU-track." [https://www.ecdc.europa.eu/en/about-us/work-us/call-application-cohort-2021-ecdc-fellowship-programme-epiet-and-euphem-paths-eu] Accessed September 2020

[2] IZSAM (Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise "Giuseppe Caporale"). September 2019. "Training". [http://www.izs.it/IZS/Training] Accessed September 2020

2.6.2 Epidemiology workforce capacity

2.6.2a

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

Yes = 1 , No = 0

Current Year Score: 0

2020

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

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

3.1 EMERGENCY PREPAREDNESS AND RESPONSE PLANNING

3.1.1 National public health emergency preparedness and response plan

3.1.1a

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

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

Current Year Score: 1

Italy has disease-specific plans in place to address national public health emergencies, but there is no evidence of an overarching plan which addresses multiple communicable diseases with epidemic or pandemic potential. Instead, Italy has a body of laws and plans that form a national public health emergency response policy that addresses such events. In the case of an outbreak or related national crises, these laws grant the Minister of Health special authority for such tasks as the organisation of preventive and emergency-response measures against the further spread of disease--human, animal or zoonotic. [1]

Two relevant, targeted national plans are the plan on influenza pandemics (2006) and the veterinary epidemic emergency plan (2014), both of which mandate coordination between the State, the Regions, the Ministry of Health and other actors during such crises. [2, 3] Two other relevant plans are the National Prevention Plan (Piano Nazionale della Prevenzione---PNP) for the 2020-2025 period, which elucidates a national strategy and interventions on preventing infective diseases, [4] and the Integrated National Plan of Controls (Piano Nazionale Integrato---PNI) for 2015-2019, which focuses on ensuring the health of the food chain and preventing outbreaks of food-borne and other zoonoses. [5]

[1] U.S. Library of Congress. June 9 2015. "Italy: Legal Responses to Health Emergencies".

[<https://www.loc.gov/law/help/health-emergencies/italy.php>] Accessed September 2020

[2] Republic of Italy. Ministry of Health. 2006. "NATIONAL PLAN FOR PREPAREDNESS AND RESPONSE TO AN INFLUENZA PANDEMIC." http://www.salute.gov.it/imgs/C_17_pubblicazioni_511_allegato.pdf] Accessed September 2020

[3] Republic of Italy. Ministry of Health. Directorate of Animal Health and Veterinary Drugs. 2014. "National Plan for Epidemic Emergencies. (PIANO NAZIONALE PER LE EMERGENZE DI TIPO EPIDEMICO ITALIAN VETERINARY CONTINGENCY PLAN 'ITAVETPLAN')." [http://www.quadernidellasalute.it/imgs/C_17_pagineAree_1670_listaFile_itemName_0_file.pdf] Accessed September 2020

[4] Republic of Italy. Ministry of Health. 2020. National Prevention Plan 2020-2025 (Piano Nazionale della Prevenzione 2020-2025---PNP)." [http://www.salute.gov.it/imgs/C_17_notizie_5029_0_file.pdf] Accessed September 2020

[5] Republic of Italy. Ministry of Health. January 1 2015. "INTEGRATED NATIONAL PLAN 2015-2019: ANIMAL HEALTH - INFECTIOUS DISEASES (PIANO NAZIONALE INTEGRATO 2015-2019: SANITÀ ANIMALE - MALATTIE INFETTIVE)." [<http://www.salute.gov.it/pianoNazionaleIntegrato2015/sezionePianoNazionaleIntegrato2015.jsp?cap=capitolo3&sez=pni-cap3-sanitaanimale-malattieinfettive>] Accessed September 2020

3.1.1b

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

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

Current Year Score: 0

Italy does not have a single, stand-alone plan to address all disease emergencies. There is instead a consolidated body of laws on health issues, along with several national plans, with specific provisions on infectious diseases that stipulate how the national, regional and local health agencies should act in case of an emergency. [1]

Two relevant, targeted national plans are the plan on influenza pandemics (2006) and the veterinary epidemic emergency plan (2014), both of which mandate coordination between the State, the Regions, the Ministry of Health and other actors during such crises. [2, 3] Two other relevant plans are the National Prevention Plan (Piano Nazionale della Prevenzione---PNP) for the 2020-2025 period, which elucidates a national strategy and interventions on preventing infective diseases including during public health emergencies, [4] and the Integrated National Plan of Controls (Piano Nazionale Integrato---PNI) for 2015-2019, which focuses on ensuring the health of the food chain and preventing outbreaks of food-borne and other zoonoses. [5]

Italy's national-level Department of Civil Protection operates a permanent control center operating 24 hours a day which monitors incidents occurring nationwide. However, it is focused on responding to natural disasters, and disease outbreaks are not normally the triggering factor for response. [6]

[1] U.S. Library of Congress. June 9 2015. "Italy: Legal Responses to Health Emergencies".

[<https://www.loc.gov/law/help/health-emergencies/italy.php>] Accessed September 2020

[2] Republic of Italy. Ministry of Health. 2006. "NATIONAL PLAN FOR PREPAREDNESS AND RESPONSE TO AN INFLUENZA PANDEMIC." http://www.salute.gov.it/imgs/C_17_pubblicazioni_511_allegato.pdf] Accessed September 2020

[3] Republic of Italy. Ministry of Health. Directorate of Animal Health and Veterinary Drugs. 2014. "National Plan for Epidemic Emergencies. (PIANO NAZIONALE PER LE EMERGENZE DI TIPO EPIDEMICO ITALIAN VETERINARY CONTINGENCY PLAN 'ITAVETPLAN')." [http://www.quadernidellasalute.it/imgs/C_17_pagineAree_1670_listaFile_itemName_0_file.pdf] Accessed September 2020

[4] Republic of Italy. Ministry of Health. 2020. National Prevention Plan 2020-2025 (Piano Nazionale della Prevenzione 2020-2025---PNP)." [http://www.salute.gov.it/imgs/C_17_notizie_5029_0_file.pdf] Accessed September 2020

[5] Republic of Italy. Ministry of Health. January 1 2015. "INTEGRATED NATIONAL PLAN 2015-2019: ANIMAL HEALTH - INFECTIOUS DISEASES (PIANO NAZIONALE INTEGRATO 2015-2019: SANITÀ ANIMALE - MALATTIE INFETTIVE)." [<http://www.salute.gov.it/pianoNazionaleIntegrato2015/sezionePianoNazionaleIntegrato2015.jsp?cap=capitolo3&sez=pni-cap3-sanitaanimale-malattieinfettive>] Accessed September 2020

[6] Republic of Italy. Presidency of the Council of Ministers. Department of Civil Protection. Undated. "Sistema (System) at Italy Situation Room". [http://www.protezionecivile.gov.it/risk-activities/technical-files/-/asset_publisher/default/content/sistema-nella-sala-situazione-italia] Accessed September 2020

3.1.1c

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

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

Current Year Score: 0

Italy does not have a single, stand-alone plan to address all disease emergencies, nor do existing plans specifically prioritise pediatric and other vulnerable populations. There is instead a consolidated body of laws on health issues, along with several national plans, with specific provisions on infectious diseases that stipulate how the national, regional and local health agencies should act in case of an emergency. [1]

Two relevant, targeted national plans focusing on emergencies are the plan on influenza pandemics (2006) and the veterinary epidemic emergency plan (2014), both of which mandate coordination between the State, the Regions, the Ministry of Health and other actors during such crises; neither, however, discuss vulnerable groups. [2, 3]

A key plan on addressing disease outbreaks is the National Prevention Plan (Piano Nazionale della Prevenzione---PNP) for the 2020-2025 period, which elucidates a national strategy and interventions on preventing infective diseases. One of the plan's key objectives is addressing public health emergencies, but it discusses the need for equality of intervention policies with respect to "vulnerable" groups such as children only in an general context. [4]

Italy's national-level Department of Civil Protection operates a permanent control center operating 24 hours a day which monitors incidents occurring nationwide. However, it is focused on responding to natural disasters, and disease outbreaks are not normally the triggering factor for response. [5]

[1] U.S. Library of Congress. June 9 2015. "Italy: Legal Responses to Health Emergencies".

[<https://www.loc.gov/law/help/health-emergencies/italy.php>] Accessed September 2020

[2] Republic of Italy. Ministry of Health. 2006. "NATIONAL PLAN FOR PREPAREDNESS AND RESPONSE TO AN INFLUENZA PANDEMIC." [http://www.salute.gov.it/imgs/C_17_pubblicazioni_511_allegato.pdf] Accessed September 2020

[3] Republic of Italy. Ministry of Health. Directorate of Animal Health and Veterinary Drugs. 2014. "National Plan for Epidemic Emergencies. (PIANO NAZIONALE PER LE EMERGENZE DI TIPO EPIDEMICO ITALIAN VETERINARY CONTINGENCY PLAN 'ITAVETPLAN')." [http://www.quadernidellasalute.it/imgs/C_17_pagineAree_1670_listaFile_itemName_0_file.pdf] Accessed September 2020

[4] Republic of Italy. Ministry of Health. 2020. National Prevention Plan 2020-2025 (Piano Nazionale della Prevenzione 2020-2025---PNP)." [http://www.salute.gov.it/imgs/C_17_notizie_5029_0_file.pdf] Accessed September 2020

[5] Republic of Italy. Presidency of the Council of Ministers. Department of Civil Protection. Undated. "Sistema (System) at Italy Situation Room". [http://www.protezionecivile.gov.it/risk-activities/technical-files/-/asset_publisher/default/content/sistema-nella-sala-situazione-italia] Accessed September 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: 0

Italy does not have a specific mechanism(s) for engaging with the private sector to assist with outbreak emergency preparedness and response. The Italian national health care system is largely a public system, and the country's consolidated laws on health issues assign specific responsibilities to the national, regional and local health agencies in responding to an infectious disease emergency. Available evidence indicates that there is little specific provision in law for liaison with private entities in the field of public health crisis management.

For example, although preparation for infectious disease emergencies is a key prevention strategy of the macro objectives stipulated by the Ministry of Health's latest National Prevention Plan (Piano nazionale prevenzione) 2020-2025, there is no specific role accorded therein to private-sector actors. [1]

Similarly, although the national plan for response to an influenza pandemic briefly mentions the private sector, stating that on surveillance and control of infective diseases the National Centre for Disease Prevention and Control (CCM) works not only with the regions, but also "with other structures of assistance and research both public and private...", it does not specify the nature of this liaison. [2]

No additional evidence on public-private cooperation during public health emergencies is available from Italy's national-level Department of Civil Protection, which is focused on responding to natural disasters. Disease outbreaks are not normally the triggering factor for it to respond. [3]

[1] Republic of Italy. Ministry of Health. 2020. National Prevention Plan 2020-2025 (Piano Nazionale della Prevenzione 2020-2025---PNP). [http://www.salute.gov.it/imgs/C_17_notizie_5029_0_file.pdf] Accessed September 2020

[2] Republic of Italy. Ministry of Health. 2006. "NATIONAL PLAN FOR PREPAREDNESS AND RESPONSE TO AN INFLUENZA PANDEMIC." [http://www.salute.gov.it/imgs/C_17_pubblicazioni_511_allegato.pdf] Accessed September 2020

[3] Republic of Italy. Presidency of the Council of Ministers. Department of Civil Protection. Undated. "Sistema (System) at Italy Situation Room". [http://www.protezionecivile.gov.it/risk-activities/technical-files/-/asset_publisher/default/content/sistema-nella-sala-situazione-italia] Accessed September 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

Italy has a general policy in place to implement non-pharmaceutical interventions (NPIs) during an epidemic or pandemic for one disease. This policy has come about as a result of the COVID-19 pandemic in early 2020. Otherwise, only one of Italy's

three key current national-level policies on such public health emergencies--the new influenza plan of 2021--discusses the implementation of human-oriented NPIs during such crises.

Italy's response to the COVID-19 outbreak includes NPIs such as mandatory 14-day self-quarantine for positive cases, the closing of schools and public events, contact tracing and social distancing, which have been rigorously applied. [4, 5] It has led to the creation of a new policy plan, the National strategic-operational plan for preparation and response to a flu pandemic (PanFlu) 2021-2023. It was adopted in January 2021 and replaces the older influenza response plan of 2006, focusing on surveillance, prevention and control of infection (mainly through vaccinations) and communication with stakeholders such as the public and first responders. The plan stipulates the use of NPIs such as increased hygiene of hands, surfaces and objects, respiratory masks for symptomatic individuals, indoor air quality improvement, Isolation of suspected / diseased / infected individuals, travel restrictions and the closure of schools and workplaces. The use of these NPIs is graded according to the severity of the outbreak. However, nowhere does the plan indicate its applicability to other infectious diseases. [2]

Italy's National Prevention Plan (PNP) for 2020-2025 aims to refocus infectious disease prevention policy towards building systemic capacity and flexibility of response, creating intersectoral synergies, and recognizing individuals as conduits of information essential for developing an Evidence-Based-Prevention (EBP) strategy. However, none of the plan's 13 Lines of Action discuss non-pharmaceutical interventions as tools to be used. The plan's sixth Macro Objective, which focuses on priority infectious diseases, makes no mention of NPIs, instead stressing the need for disease surveillance and public awareness-raising. [1]

The National Plan for Epidemic Emergencies, adopted in 2014 and known as the Itavet Plan, focuses on veterinary diseases capable of "spillover" to humans. Its mandated interventions follow the principles of suspicion, identification, response, containment and eradication and to those ends it focuses on surveillance and medical prophylaxis (vaccinations). Some of its interventions may be considered to be NPIs, such as disinfection of contaminated areas and disposal of infected animals--but these are not oriented towards the human population. [3]

[1] Republic of Italy. Ministry of Health. 2020. National Prevention Plan 2020-2025 (Piano Nazionale della Prevenzione 2020-2025---PNP)." [http://www.salute.gov.it/imgs/C_17_notizie_5029_0_file.pdf] Accessed September 2020

[2] Republic of Italy. Ministry of Health. Directorate-General of Sanitary Prevention. January 25 2021. "National strategic-operational plan for preparation and response to a flu pandemic (PanFlu) 2021-2023 (Piano strategico-operativo nazionale di preparazione e risposta a una pandemia influenzale (PanFlu) 2021-2023)." [<https://www.quotidianosanita.it/allegati/allegato4004886.pdf>] Accessed April 2021

[3] Republic of Italy. Ministry of Health. Directorate of Animal Health and Veterinary Drugs. 2014. "National Plan for Epidemic Emergencies. (PIANO NAZIONALE PER LE EMERGENZE DI TIPO EPIDEMICO ITALIAN VETERINARY CONTINGENCY PLAN 'ITAVETPLAN')." [http://www.quadernidellasalute.it/imgs/C_17_pagineAree_1670_listaFile_itemName_0_file.pdf] Accessed September 2020

[4] Emanuele Torri, Luca Gino Sbrogiò, Enrico Di Rosa, Sandro Cinquetti, Fausto Francia, and Antonio Ferro. May 17 2020. "Italian Public Health Response to the COVID-19 Pandemic: Case Report from the Field, Insights and Challenges for the Department of Prevention." International Journal of Environmental Research and Public Health. 2020 May; 17

[10] : 3666. [<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7277676/>] Accessed September 2020

[5] Antonio Giulio de Belvis, Giovanni Fattore, Alisha Morsella, Gabriele Pastorino, Andrea Poscia, Walter Ricciardi, Andrea Silenzi. November 20 2020. "Policy Responses for Italy: 1.3 Isolation and quarantine." WHO Regional Office for Europe and European Observatory on Health Systems and Policies. COVID-19 Health System Response Monitor.

[<https://www.covid19healthsystem.org/countries/italy/livinghit.aspx?Section=1.3%20Isolation%20and%20quarantine&Type=Section>] Accessed April 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 recent evidence that in the past year Italy has activated a national emergency response plan for an infectious disease outbreak. Evidence does not indicate that it has engaged in a national-level biological threat-focused exercise within the past year.

As reported by the national newspaper Corriere della Sera, the government had drawn up a plan in February to combat the COVID-19 coronavirus outbreak, which it had kept confidential until the beginning of September to prevent any panic in the population that might compromise the continuity of care. The plan aimed to rationalize access to care and ensure the optimal use of resources such as medical supplies, but above all, beds in intensive care units. It had three outcome scenarios graded by the degree of transmission of the infection. It also anticipated problems arising between the State and Regions in coordinating a policy response to the crisis. The Minister of Health has denied that the plan constitutes a policy rather than a research study. [6]

By contrast, there is little evidence of Italy conducting health-threat-focused exercises in the past year. According to the World Organisation for Animal Health (OIE), a field simulation exercise on African swine fever (ASF) was to be conducted in November 2018 in the Friuli-Venezia Giulia region by the health ministry in conjunction with the local veterinary services and the National Reference Laboratory for ASF diseases. [1] There is insufficient evidence that the exercise was conducted. Moreover, the World Health Organization (WHO) does not count Italy as having conducted a disease-outbreak simulation exercise in recent years. [7]

Notably, Italy has no stand-alone policy plan to address all infectious disease outbreaks. Instead, it has a National Prevention Plan for 2020-2025 (which promotes a preventive rather than a reactive approach to public health emergencies), a National Plan for Preparedness and Response to an Influenza Pandemic (which deals with a specific type of disease) and the Itavet Plan (a veterinary contingency plan pertaining primarily to outbreaks of animal diseases). [2, 3, 4] In addition, Italy has a host of plans specific to different human animal diseases.

Nevertheless, the country has mounted an effective response to the COVID-19 outbreak. The response was led by the Ministry of Health on policy, the National Institute of Health (ISS) on research and surveillance, and by the regional health services on front-line response; action consisted of draconian measures including mandated quarantines and self-isolation, closings of schools and public events, physical distancing and extensive contact tracing. [5]

[1] World Organisation for Animal Health (OIE). 2019. "Simulation exercise: African swine fever in Italy."

[https://www.oie.int/en/animal-health-in-the-world/the-world-animal-health-information-system/simulation-

exercises/detail/article/simulation-exercise-african-swine-fever-in-italy/] Accessed September 2020

[2] Republic of Italy. Ministry of Health. 2020. National Prevention Plan 2020-2025 (Piano Nazionale della Prevenzione 2020-2025---PNP)." [http://www.salute.gov.it/imgs/C_17_notizie_5029_0_file.pdf] Accessed September and October 2020

[3] Republic of Italy. Ministry of Health. 2006. "NATIONAL PLAN FOR PREPAREDNESS AND RESPONSE TO AN INFLUENZA PANDEMIC." [http://www.salute.gov.it/imgs/C_17_pubblicazioni_511_allegato.pdf] Accessed September 2020

[4] Republic of Italy. Ministry of Health. Directorate of Animal Health and Veterinary Drugs. 2014. "National Plan for Epidemic Emergencies. (PIANO NAZIONALE PER LE EMERGENZE DI TIPO EPIDEMICO ITALIAN VETERINARY CONTINGENCY PLAN 'ITAVETPLAN')." [http://www.quadernidellasalute.it/imgs/C_17_pagineAree_1670_listaFile_itemName_0_file.pdf] Accessed September 2020

[5] Emanuele Torri, Luca Gino Sbrogiò, Enrico Di Rosa, Sandro Cinquetti, Fausto Francia, and Antonio Ferro. May 17 2020. "Italian Public Health Response to the COVID-19 Pandemic: Case Report from the Field, Insights and Challenges for the Department of Prevention." International Journal of Environmental Research and Public Health. 2020 May; 17

[10] : 3666. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7277676/] Accessed September 2020

[6] Monica Guerzoni and Fiorenza Sarzanini. September 8 2020. "Covid, here is the government's secret plan: the three scenarios outlined in February (Covid, ecco il piano segreto del governo: i tre scenari delineati a febbraio)." Corriere della Sera. [https://www.corriere.it/cronache/20_settembre_08/covid-ecco-piano-segreto-governo-tre-scenari-delineati-febbraio-c9b3ad06-f14b-11ea-9f2b-89b4229fc5bf.shtml] Accessed October 2020

[7] World Health Organization (WHO). Strategic Partnership for International Health Regulations (2005) and Health Security (SPH). 2020. "Simulation exercise activities." [https://extranet.who.int/sph/simulation-exercise] Accessed October 2020

3.2.1b

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

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

Current Year Score: 0

Available evidence does not indicate that in the past year Italy 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.

The World Health Organization (WHO) does not indicate recent cooperation with Italy on such exercises; it lists no activities for the country in the past year in terms of after action reviews (AAR) or simulation exercises (SimEx). [1, 6] Other sources indicate that After Action Reviews (AAR) were performed earlier in Slovenia, Italy, Serbia and Greece, following a severe West Nile virus (WNV) outbreak in 2018; [2] also in 2018 Italy was one of 12 countries that participated in a 2-day polio outbreak simulation exercise (POSE) that was organized by WHO/Europe and the European Centre for Disease Prevention and Control (ECDC). The simulation was based on a real event and allowed countries to review and update their national plans for responding to such an event in a poliovirus essential facility (PEF). [3]

Finally, neither the Ministry of Health nor the Department of Civil Protection indicate that they have developed plans or exercises regarding their public health response capabilities. [4, 5]

[1] World Health Organization (WHO). Strategic Partnership for International Health Regulations (2005) and Health Security (SPH). 2020. "After Action Review." [https://extranet.who.int/sph/after-action-review]. Accessed September and October 2020

- [2] Flavia Riccardo, Francesco Bolici, Mario Fafangel, Verica Jovanovic, Maja Socan, Petra Klepac, Dragana Plavska, Milena Vasic, Antonino Bella, Gabriele Diana, Luca Rosi, Patrizio Pezzotti, Xanthi D. Andrianou, Marco Di Luca, Giulietta Venturi, Francesco Maraglino, Danai Pervanidou, Orlando Cenciarelli, Agoritsa Baka, Johanna Young, Tamas Bakonyi, Giovanni Rezza & Jonathan E. Suk. May 18 2020. "West Nile virus in Europe: after action reviews of preparedness and response to the 2018 transmission season in Italy, Slovenia, Serbia and Greece." *Globalization and Health* volume 16, Article number: 47 (2020). [<https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-020-00568-1>] Accessed September 2020
- [3] World Health Organization. November 1 2018. "Simulated poliovirus containment breach helps countries increase biorisk safety and security". [<http://www.euro.who.int/en/countries/sweden/news/news/2018/11/simulated-poliovirus-containment-breach-helps-countries-increase-biorisk-safety-and-security>]. Accessed September 2020
- [4] Republic of Italy. Ministry of Health. 2020. Infectious Diseases Portal. [<http://www.salute.gov.it/portale/malattieInfettive/homeMalattieInfettive.jsp>] Accessed October 2020
- [5] Republic of Italy. Department of Civil Protection. "Activities on Risk (Attività sui rischi)." [<http://www.protezionecivile.gov.it/attivita-rischi>] Accessed October 2020
- [6] World Health Organization (WHO). Strategic Partnership for International Health Regulations (2005) and Health Security (SPH). 2020. "Simulation Exercise." [<https://extranet.who.int/sph/simulation-exercise>] Accessed October 2020

3.2.2 Private sector engagement in exercises

3.2.2a

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

Yes = 1 , No = 0

Current Year Score: 0

Available evidence does not indicate that in the past year Italy has undergone a national-level biological threat-focused exercise that has included private sector representatives.

The World Health Organization (WHO) does not indicate recent cooperation with Italy on such exercises; it lists no activities for the country in the past year in terms of after action reviews (AAR) or simulation exercises (SimEx). [1, 6] Other sources indicate that After Action Reviews (AAR) were performed earlier in Slovenia, Italy, Serbia and Greece, following a severe West Nile virus (WNV) outbreak in 2018. The Italian AAR was performed with the participation of public health experts from the National Institute of Health (ISS), which coordinated the exercise, together with ECDC/WHO experts and members of the Faculty of Economics of the University of Cassino and Southern Lazio, among others. There is no proof of participation by private-sector representatives. [2]

Also in 2018 Italy was one of 12 countries that participated in a 2-day polio outbreak simulation exercise (POSE) that was organized by WHO/Europe and the European Centre for Disease Prevention and Control (ECDC). The simulation was based on a real event and allowed countries to review and update their national plans for responding to such an event in a poliovirus essential facility (PEF). [3]

Finally, neither the Ministry of Health nor the Department of Civil Protection indicate that they have developed plans or exercises regarding their public health response capabilities. [4, 5]

[1] World Health Organization. Strategic Partnership for International Health Regulations (2005) and Health Security (SPH). 2020. "After Action Review." [<https://extranet.who.int/sph/after-action-review>]. Accessed September and October 2020

[2] Flavia Riccardo, Francesco Bolici, Mario Fafangel, Verica Jovanovic, Maja Socan, Petra Klepac, Dragana Plavska, Milena

Vasic, Antonino Bella, Gabriele Diana, Luca Rosi, Patrizio Pezzotti, Xanthi D. Andrianou, Marco Di Luca, Giulietta Venturi, Francesco Maraglino, Danai Pervanidou, Orlando Cenciarelli, Agoritsa Baka, Johanna Young, Tamas Bakonyi, Giovanni Rezza & Jonathan E. Suk. May 18 2020. "West Nile virus in Europe: after action reviews of preparedness and response to the 2018 transmission season in Italy, Slovenia, Serbia and Greece." *Globalization and Health* volume 16, Article number: 47 (2020). [<https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-020-00568-1>] Accessed September 2020

[3] World Health Organization. November 1 2018. "Simulated poliovirus containment breach helps countries increase biorisk safety and security". [<http://www.euro.who.int/en/countries/sweden/news/news/2018/11/simulated-poliovirus-containment-breach-helps-countries-increase-biorisk-safety-and-security>]. Accessed September 2020

[4] Republic of Italy. Ministry of Health. 2020. Infectious Diseases Portal. [<http://www.salute.gov.it/portale/malattieInfettive/homeMalattieInfettive.jsp>] Accessed October 2020

[5] Republic of Italy. Department of Civil Protection. "Activities on Risk (Attività sui rischi)". [<http://www.protezionecivile.gov.it/attivita-rischi>] Accessed October 2020

[6] World Health Organization (WHO). Strategic Partnership for International Health Regulations (2005) and Health Security (SPH). 2020. "Simulation Exercise." [<https://extranet.who.int/sph/simulation-exercise>] Accessed October 2020

3.3 EMERGENCY RESPONSE OPERATION

3.3.1 Emergency response operation

3.3.1a

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

Yes = 1 , No = 0

Current Year Score: 0

Italy's primary emergency operations center does not address pandemics.

Italy's general emergency operations center is the Italy Situation Room at the Department of Civil Protection, which runs the Sistema incident-monitoring unit.. However, as the Department is focused on responding to natural disasters, disease outbreaks are not normally the triggering factor for response, and an analogous single institution does not exist for human public health emergencies. [1, 2] Instead, public health emergencies in Italy, including epidemics and even incidents caused by terrorists, are addressed by the national, regional, and municipal health agencies. The national government intervenes in proportion to the magnitude of the emergency. [3]

In pandemics, for example, the National Centre for Disease Prevention and Control (CCM) sets up a committee to liaise with other relevant agencies at all levels. [4] In that regard, the first line of defense in outbreaks of disease are the regional reference centers, such as the Luigi Sacco Hospital in Milan, which coordinate with the Lazzaro Spallanzani National Institute for Infectious Diseases in Rome. [5] The Sacco hospital has a round-the-clock rapid intervention group (composed of medical and nursing staff) for the transfer of highly contagious patients from other regions of Northern Italy to the Spallanzani institute in clinical cases in the initial phase of epidemic events requiring special isolation procedures as well as in episodes attributable to bioterrorism. [6]

[1] European Commission. October 16 2017. "Vademecum - Civil Protection Italy - Disaster management structure".

[http://ec.europa.eu/echo/files/civil_protection/vademecum/it/2-it-1.html] Accessed September 2020

[2] Republic of Italy. Presidency of the Council of Ministers. Department of Civil Protection. 2020. "System at the Italy Situation Room (Sistema nella Sala Situazione Italia)". [http://www.protezionecivile.gov.it/attivita-rischi/schede-tecniche/dettaglio/-/asset_publisher/default/content/sistema-nella-sala-situazione-italia] Accessed September 2020

- [3] U.S. Library of Congress. 9 June 2015. "Italy: Legal Responses to Health Emergencies". [<https://www.loc.gov/law/help/health-emergencies/italy.php>] Accessed September 2020
- [4] Republic of Italy. Ministry of Health. National Center for Disease Prevention and Control (Centro nazionale per la prevenzione e il controllo delle malattie--Ccm). "The reaction to emergencies". <http://www.ccm-network.it/pagina.jsp?id=node/318&lingua=english>] Accessed September 2020
- [5] ANSA. 24 November 2014. "Ebola: due [are the] Italian reference centers for the emergency (Ebola: due i centri riferimento Italia contro l'emergenza)". [http://www.ansa.it/salutebenessere/notizie/rubriche/medicina/2014/11/24/ebola-due-i-centri-riferimento-italia-contro-lemergenza_6e39bedd-edd0-4b8f-a8e5-d67701014cb2.html] Accessed September 2020
- [6] Region of Lombardy. ASST Fatebenefratelli Sacco. 2020. "Infectious diseases and Bioterrorism (Emergenze infettivologiche e Bioterrorismo)". [<https://www.asst-fbf-sacco.it/reparti-e-servizi/info/emergenze-infettivologiche-e-bioterrorismo>] Accessed September 2020

3.3.1b

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

Yes = 1 , No = 0

Current Year Score: 0

There is no evidence that Italy has an emergency operations center which conducts drills for public health emergencies once a year, whether as a requirement or not.

Italy's general emergency operations center is the Italy Situation Room at the Department of Civil Protection, which is focused on responding to natural disasters. Disease outbreaks are not normally the triggering factor for response. Moreover, publicly available evidence does not indicate that the center is required to conduct a drill at least once per year. [1, 4, 5] An analogous single institution does not exist in Italy for human public health emergencies. [1, 2]

Instead, such emergencies, including epidemics and even incidents caused by terrorists, are addressed by the national, regional, and municipal health agencies, with the national government intervening as needed. [4] In pandemics, for example, the National Center for Disease Prevention and Control (CCM) sets up a committee to liaise with other relevant agencies at all levels. [6]

In that regard, the first line of defense in such outbreaks are the regional reference centers (such as the Luigi Sacco Hospital in Milan), which coordinate with the Lazzaro Spallanzani National Institute for Infectious Diseases in Rome. The Sacco hospital has a round-the-clock rapid intervention group (composed of medical and nursing staff) for the transfer of highly contagious patients to the Spallanzani institute in clinical cases in the initial phase of health emergencies requiring special isolation procedures. [7] There is no evidence from either the CCM, the Sacco or the Spallanzani that they conduct annual drills on emergency operations. [6, 7, 8]

- [1] European Commission. October 16 2017. "Vademecum - Civil Protection Italy - Disaster management structure". [http://ec.europa.eu/echo/files/civil_protection/vademecum/it/2-it-1.html] Accessed September 2020
- [2] Republic of Italy. Ministry of Health. 2014. "NATIONAL PLAN FOR EPIDEMIC EMERGENCIES (PIANO NAZIONALE PER LE EMERGENZE DI TIPO EPIDEMICO)". [http://www.salute.gov.it/imgs/C_17_pagineAree_1670_listaFile_itemName_0_file.pdf] Accessed September 2020
- [3] Republic of Italy. Ministry of Health. 2006. "NATIONAL PLAN FOR PREPAREDNESS AND RESPONSE TO AN INFLUENZA PANDEMIC (PIANO NAZIONALE DI PREPARAZIONE E RISPOSTA AD UNA PANDEMIA INFLUENZALE)".

[http://www.salute.gov.it/imgs/C_17_pubblicazioni_501_ulterioriallegati_ulterioreallegato_0_alleg.pdf] Accessed September 2020

[4] U.S. Library of Congress. June 9 2015. "Italy: Legal Responses to Health Emergencies".

[<https://www.loc.gov/law/help/health-emergencies/italy.php>] Accessed September 2020

[5] Republic of Italy. Presidency of the Council of Ministers. Department of Civil Protection. 2020. "System at the Italy Situation Room (Sistema nella Sala Situazione Italia)". [http://www.protezionecivile.gov.it/attivita-rischi/schede-tecniche/dettaglio/-/asset_publisher/default/content/sistema-nella-sala-situazione-italia] Accessed September 2020

[6] Republic of Italy. Ministry of Health. National Centre for Disease Prevention and Control (Centro nazionale per la prevenzione e il controllo delle malattie--Ccm). "The reaction to emergencies". <http://www.ccm-network.it/pagina.jsp?id=node/318&lingua=english>] Accessed September 2020

[7] Region of Lombardy. ASST Fatebenefratelli Sacco. 2020. "Infectious diseases and Bioterrorism (Emergenze infettivologiche e Bioterrorismo)". [<https://www.asst-fbf-sacco.it/reparti-e-servizi/info/emergenze-infettivologiche-e-bioterrorismo>] Accessed September 2020

[8] INMI "Lazzaro Spallanzani". 2020. Website. [<https://www.inmi.it/>] Accessed September 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 no readily available evidence that Italy's general emergency operations center has launched a response to either a drill or an emergency situation within 120 minutes of identification.

Evidence suggests that Italy's Emergency Operations Center, the Italy Situation Room at the Department of Civil Protection, is a key participating entity in the department's program of emergency response and drill activities. It operates 24 hours a day and in the case of an actual emergency becomes a dedicated crisis unit called Crisis Unit - S3. The department does not specify its time frame for response to either a drill or a real emergency situation. [1, 2] In any case, the department is focused on responding to natural disasters, not infectious disease outbreaks.

Instead, such emergencies are addressed by the national, regional, and municipal health agencies. In pandemics, for example, the National Center for Disease Prevention and Control (CCM) sets up a committee to liaise with other relevant agencies at all levels. [3] In that regard, regional reference centres such as the Luigi Sacco Hospital in Milan coordinate with the Lazzaro Spallanzani National Institute for Infectious Diseases in Rome. The Sacco hospital has a round-the-clock rapid intervention group to transfer highly contagious patients to Spallanzani in health emergencies requiring special isolation procedures. [4, 5] There is no evidence from either the CCM, the Sacco or the Spallanzani that they conduct drills or respond to emergencies within 120 minutes of the identification of the emergency or scenario. [3, 4, 5]

[1] Republic of Italy. Presidency of the Council of Ministers. Department of Civil Protection. 2020. "System at the Italy Situation Room (Sistema nella Sala Situazione Italia)". [http://www.protezionecivile.gov.it/attivita-rischi/schede-tecniche/dettaglio/-/asset_publisher/default/content/sistema-nella-sala-situazione-italia] Accessed September 2020

[2] Republic of Italy. Presidency of the Council of Ministers. Department of Civil Protection. 2020. "Exercises (Esercitazioni)". [<http://www.protezionecivile.gov.it/servizio-nazionale/attivita/prevenzione/esercitazioni>] Accessed September 2020

[3] Republic of Italy. Ministry of Health. National Centre for Disease Prevention and Control (Centro nazionale per la prevenzione e il controllo delle malattie--Ccm). "The reaction to emergencies". <http://www.ccm->

network.it/pagina.jsp?id=node/318&lingua=english] Accessed September 2020

[4] ASST Fatebenefratelli Sacco. 2020. "Infectious diseases and Bioterrorism (Emergenze infettivologiche e Bioterrorismo)".

[https://www.asst-fbf-sacco.it/reparti-e-servizi/info/emergenze-infettivologiche-e-bioterrorismo] Accessed September 2020

[5] INMI "Lazzaro Spallanzani". 2020. Website. [https://www.inmi.it/] Accessed September 2020

3.4 LINKING PUBLIC HEALTH AND SECURITY AUTHORITIES

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

3.4.1a

Does the country meet one of the following criteria?

- Is there public evidence that public health and national security authorities have carried out an exercise to respond to a potential deliberate biological event (i.e., bioterrorism attack)?

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

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

Current Year Score: 1

Public information is not readily available on whether official exercises have been carried out in Italy to defend against bioterrorist attacks. But evidence does indicate the existence of national defense plans and ministerial responsibilities with regard to addressing such attacks. According to an undated document published by the Military Corps of the Italian Red Cross, the country does have a so-called National Plan of Defense against chemical, biological and radiological (CBR) terrorist attacks (Piano Nazionale di Difesa da attacchi terroristici di tipo CBR). The plan aims at prevention, surveillance, rescue and treatment of affected persons. It is a joint agreement of the Ministry of the Interior, Ministry of Health, Department of Civil Protection and the Defense General Staff, and lays out the command responsibilities of these authorities. [1]

Another official document, published in 2011 by the Ministry of Health, stipulates the responsibilities of the Ministry in civil defense matters. Among these are: to maintain an inventory of the production, commercialisation and distribution of defense resources against bioterrorism; to create epidemiological networks to assess the impact of possible bioterrorist attacks; and to supply primary prophylaxis in the event of crisis to prioritised individuals such as government officials and certain professionals. [2] It is possible that more detailed plans internal to the government, but these have not been published publicly.

[1] Military Corps of the Italian Red Cross (Corpo Militare della Croce Rossa Italiana). Undated. "Measures of Defense and Combating the BCR/N threat (Misure di Difesa e Contrasto alla minaccia BCR/N)". PowerPoint Presentation.

[http://www.vigilfuoco.it/asp/download_file.aspx?id=11539] Accessed September 2020

[2] Dr. Virgilio COSTANZO. September 15 2011. "SKILLS OF THE MINISTRY OF HEALTH IN MATTERS OF CIVIL DEFENSE (COMPETENZE DEL MINISTERO DELLA SALUTE IN MATERIA DI DIFESA CIVILE)". Ministry of Health PowerPoint Presentation.

[http://www.salute.gov.it/resources/static/ministero/usmaf/corso_15_e_16_settembre_2011/COSTANZO_difesa_civile.pdf] Accessed September 2020

3.5 RISK COMMUNICATIONS

3.5.1 Public communication

3.5.1b

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

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence of a risk communication plan that addresses how to reach populations and sectors with different communications needs in Italy. [1]

In operational terms, Italy's health care system is mostly regional in structure, and most public health emergency response plans are executed by the regions. In such emergencies, the national authorities intervene according to the gravity of the crisis, with the Ministry of Health and National Institute of Health as the key bodies controlling risk communication between national, regional, and local health authorities. [1] These interagency relationships are described in key policy documents relating to public health issues. For example, the national plan on influenza pandemics (2006) requires responsible parties to optimise their risk-communication practices and mandates the news media to provide "...constant and clear communication of information available, even if uncertain..." [2] The latest National Prevention Plan (2020-2025) in elucidating a general framework for prevention puts heavy emphasis on the necessity of timely, efficient and accurate communication between public and private-sector stakeholders as well as the general public. However, it does not specifically mention groups with special communication needs. [3]

The regional health authorities have regional prevention plans (piani regionali di prevenzione--PRP) that address infectious disease outbreaks, mandating communication between professionals as well as with the citizenry. A 2016 Ministry of Health presentation recommends that the PRPs increase risk-communication for "hard to reach" populations. [4]

However, neither the Ministry of Health's National Centre for Disease Prevention and Control (CCM) nor the Department of Civil Protection provide evidence that they operate a general risk communication policy, or one for people with special communications needs.

[1] U.S. Library of Congress. 9 June 2015. "Italy: Legal Responses to Health Emergencies".

[<https://www.loc.gov/law/help/health-emergencies/italy.php>] Accessed September 2020

[2] Republic of Italy. Ministry of Health. 2006. "NATIONAL PLAN FOR PREPAREDNESS AND RESPONSE TO AN INFLUENZA PANDEMIC." [http://www.salute.gov.it/imgs/C_17_pubblicazioni_501_ulterioriallegati_ulterioreallegato_0_alleg.pdf] Accessed September 2020

[3] Republic of Italy. Ministry of Health. 2020. National Prevention Plan 2020-2025 (Piano Nazionale della Prevenzione 2020-2025---PNP). [http://www.salute.gov.it/imgs/C_17_notizie_5029_0_file.pdf] Accessed September 2020

[4] Stefania Iannazzo. 3 May 2016. " (REDUCING THE PREVENTABLE AND AVOIDABLE LOAD OF MORBOSITY, MORTALITY AND DISABILITY OF INFECTIOUS DISEASES (RIDURRE IL CARICO PREVENIBILE ED EVITABILE DI MORBOSITÀ, MORTALITÀ E DISABILITÀ DELLE MALATTIE INFETTIVE)". Ministry of Health. PowerPoint presentation.

[http://www.salute.gov.it/imgs/C_17_notizie_2559_listaFile_itemName_15_file.pdf] Accessed September 2020

[5] Republic of Italy. Ministry of Health. National Center for Disease Prevention and Control (Centro nazionale per la prevenzione e il controllo delle malattie--Ccm). "The reaction to emergencies". [<http://www.ccm->

network.it/pagina.jsp?id=node/318&lingua=english] Accessed September 2020

[6] Republic of Italy. Presidency of the Council of Ministers. Department of Civil Protection. 2020. "Risk activities (Attività sui rischi)." [http://www.protezionecivile.gov.it/attivita-rischi] Accessed September 2020 Other sources: National Institute of Health (ISS). EpiCentro. 2020. "Information networks and warning systems for infectious diseases and food toxins (Reti informative e sistemi di allerta per malattie infettive e tossinfezioni alimentari)". [https://www.epicentro.iss.it/tossinfezioni/toss_com] Accessed September 2020

3.5.1 Risk communication planning

3.5.1a

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

Yes = 1 , No = 0

Current Year Score: 0

There is insufficient evidence that Italy has a risk communication plan that is specifically intended for use during a public health emergency.

In operational terms, Italy's health care system is mostly regional in structure, and most public health emergency response plans are executed by the regions. In such emergencies, the national authorities intervene according to the gravity of the crisis, with the Ministry of Health and National Institute of Health as the key bodies controlling risk communication between national, regional, and local health authorities. [1] These interagency relationships are described in key policy documents relating to public health issues. For example, the national plan on influenza pandemics (2006) requires responsible parties to optimise their risk-communication practices and mandates the news media to provide "...constant and clear communication of information available, even if uncertain..." [2] The latest National Prevention Plan (2020-2025) in elucidating a general framework for prevention puts heavy emphasis on the necessity of timely, efficient and accurate communication between public and private-sector stakeholders as well as the general public. However, the plan aims at prevention and is not solely dedicated to be used in public health emergencies. [3]

The regional health authorities have regional prevention plans (piani regionali di prevenzione--PRP) that address infectious disease outbreaks, mandating communication between professionals as well as with the citizenry. A 2016 Ministry of Health presentation recommends that the PRPs increase risk-communication for "hard to reach" populations. [4]

In the event of a public health emergency such as a pandemic, the regional health authorities coordinate response actions with such national bodies as the keystone Lazzaro Spallanzani National Institute for Infectious Diseases in Rome and the Ministry of Health's National Center for Disease Prevention and Control (CCM), which liaises with other relevant agencies at all levels. [5, 6] In such instances, the Department of Civil Protection may play a cooperative role. [6] However, none of these three bodies provide evidence that they operate a general risk communication policy, or one for people with special communications needs. [5, 6, 7]

1] U.S. Library of Congress. 9 June 2015. "Italy: Legal Responses to Health Emergencies". [https://www.loc.gov/law/help/health-emergencies/italy.php] Accessed September 2020

[2] Republic of Italy. Ministry of Health. 2006. "NATIONAL PLAN FOR PREPAREDNESS AND RESPONSE TO AN INFLUENZA PANDEMIC." [http://www.salute.gov.it/imgs/C_17_pubblicazioni_501_ulterioriallegati_ulterioreallegato_0_alleg.pdf] Accessed September 2020

- [3] Republic of Italy. Ministry of Health. 2020. National Prevention Plan 2020-2025 (Piano Nazionale della Prevenzione 2020-2025---PNP)." [http://www.salute.gov.it/imgs/C_17_notizie_5029_0_file.pdf] Accessed September 2020
- [4] Stefania Iannazzo. 3 May 2016. " (REDUCING THE PREVENTABLE AND AVOIDABLE LOAD OF MORBOSITY, MORTALITY AND DISABILITY OF INFECTIOUS DISEASES (RIDURRE IL CARICO PREVENIBILE ED EVITABILE DI MORBOSITÀ, MORTALITÀ E DISABILITÀ DELLE MALATTIE INFETTIVE)". Ministry of Health. PowerPoint presentation. [http://www.salute.gov.it/imgs/C_17_notizie_2559_listaFile_itemName_15_file.pdf] Accessed September 2020
- [5] Republic of Italy. Ministry of Health. National Center for Disease Prevention and Control (Centro nazionale per la prevenzione e il controllo delle malattie--Ccm). "The reaction to emergencies". [<http://www.ccm-network.it/pagina.jsp?id=node/318&lingua=english>] Accessed September 2020
- [6] Republic of Italy. Presidency of the Council of Ministers. Department of Civil Protection. 2020. "Risk activities (Attività sui rischi)." [<http://www.protezionecivile.gov.it/attivita-rischi>] Accessed September 2020
- [7] INMI "Lazzaro Spallanzani". 2020. Website. [<https://www.inmi.it/>] Accessed September 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: 0

There is insufficient evidence that Italy's key policy documents outline a risk communication plan that is specifically intended for use during a public health emergency, or designate a specific position within the government to serve as the primary spokesperson to the public during such an emergency.

In operational terms, Italy's health care system is mostly regional in structure, and most public health emergency response plans are executed by the regions. In such emergencies, the national authorities intervene according to the gravity of the crisis, with the Ministry of Health and National Institute of Health (ISS) as the key bodies controlling risk communication between national, regional, and local health authorities. [1] These interagency relationships are described in key policy documents relating to public health issues. For example, the national plan on influenza pandemics (2006) requires responsible parties to optimise their risk-communication practices and mandates the news media to provide "...constant and clear communication of information available, even if uncertain..." [2] The latest National Prevention Plan (2020-2025) in elucidating a general framework for prevention puts heavy emphasis on the necessity of timely, efficient and accurate communication between public and private-sector stakeholders as well as the general public. However, the plan aims at prevention and is not solely dedicated to be used in public health emergencies. [3]

The regional health authorities have regional prevention plans (piani regionali di prevenzione--PRP) that address infectious disease outbreaks, mandating communication between professionals as well as with the citizenry. A 2016 Ministry of Health presentation on this subject recommends that the PRPs employ several communication strategies--such as between public agencies and with the public--during these crises. But it does not discuss designating specific individuals to execute these strategies. [4]

In the event of a public health emergency such as a pandemic, the regional health authorities coordinate response actions with such national bodies as the keystone Lazzaro Spallanzani National Institute for Infectious Diseases in Rome and the Ministry of Health's National Center for Disease Prevention and Control (CCM), which liaises with other relevant agencies at all levels. [5, 6] In such instances, the Department of Civil Protection may play a cooperative role. [6] However, none of these three bodies provide evidence that they operate a general risk communication policy, or one for people with special

communications needs. [5, 6, 7]

- [1] U.S. Library of Congress. 9 June 2015. "Italy: Legal Responses to Health Emergencies". [https://www.loc.gov/law/help/health-emergencies/italy.php] Accessed September 2020
- [2] Republic of Italy. Ministry of Health. 2006. "NATIONAL PLAN FOR PREPAREDNESS AND RESPONSE TO AN INFLUENZA PANDEMIC." [http://www.salute.gov.it/imgs/C_17_pubblicazioni_501_ulterioriallegati_ulterioreallegato_0_alleg.pdf] Accessed September 2020
- [3] Republic of Italy. Ministry of Health. 2020. National Prevention Plan 2020-2025 (Piano Nazionale della Prevenzione 2020-2025---PNP)." [http://www.salute.gov.it/imgs/C_17_notizie_5029_0_file.pdf] Accessed September 2020
- [4] Stefania Iannazzo. 3 May 2016. " (REDUCING THE PREVENTABLE AND AVOIDABLE LOAD OF MORBOSITY, MORTALITY AND DISABILITY OF INFECTIOUS DISEASES (RIDURRE IL CARICO PREVENIBILE ED EVITABILE DI MORBOSITÀ, MORTALITÀ E DISABILITÀ DELLE MALATTIE INFETTIVE)". Ministry of Health. PowerPoint presentation. [http://www.salute.gov.it/imgs/C_17_notizie_2559_listaFile_itemName_15_file.pdf] Accessed September 2020
- [5] Republic of Italy. Ministry of Health. National Center for Disease Prevention and Control (Centro nazionale per la prevenzione e il controllo delle malattie--Ccm). "The reaction to emergencies". [http://www.ccm-network.it/pagina.jsp?id=node/318&lingua=english] Accessed September 2020
- [6] Republic of Italy. Presidency of the Council of Ministers. Department of Civil Protection. 2020. "Risk activities (Attività sui rischi)." [http://www.protezionecivile.gov.it/attivita-rischi] Accessed September 2020
- [7] INMI "Lazzaro Spallanzani". 2020. Website. [https://www.inmi.it/] Accessed September 2020

3.5.2 Public communication

3.5.2a

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

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

Current Year Score: 2

There is evidence that in the past year Italy's public health system has actively shared messages via online media platforms to inform the public about ongoing public health concerns and/or dispel rumors, misinformation or disinformation.

Italy's key national public health agencies involved all use media platforms to inform the public about health emergencies. These entities include the Ministry of Health and the National Institute of Health (ISS), both of which have detailed websites with dedicated news and media sections. The ministry's site has hyperlinks to its accounts on popular social-media platforms such as Facebook, Twitter and LinkedIn. [1] The ISS has a dedicated website for public information on diseases, called EpiCentro, on which all manner of non-classified, up-to-date information on outbreaks can be found. [2] Both these entities have a sizeable presence on social media, with the ministry having 183,400 followers on Twitter alone. The ministry's Twitter feed posts not just promotional health messages, but also updates on public health emergencies; for instance, during the ongoing COVID-19 coronavirus pandemic it has provided daily updates on the disease, including statistics from the national COVID-19 online data dashboard, advisories on the proper use of prophylactic measures such as face masks and social distancing, and even recruitment notices from the regional health authorities, intended for persons interested in working as health personnel during the crisis. [3]

The all-important regional health authorities (Agenzie regionali di sanità--ARS) are the first line of defense in outbreaks; most if not all of them have detailed websites as well as a presence on social media. An example is the ARS of the Tuscany region, which has a detailed website with news feeds and a Facebook account with 7,750 followers. [4, 5]

[1] Republic of Italy. Ministry of Health. 2020. "News and media (News e media)."

[http://www.salute.gov.it/portale/news/p3_2.html] Accessed September 2020

[2] Republic of Italy. National Institute of Health (ISS). 2020. "Press office: news (Ufficio stampa: news)."

[<https://www.iss.it/news>] Accessed September 2020

[3] Twitter. 2020. Ministero della Salute. [<https://twitter.com/ministerosalute>] Accessed September and October 2020

[4] Region of Tuscany. ARS Toscana. 2020. Website. [<https://www.ars.toscana.it/>] Accessed September 2020

[5] Facebook. 2020. Agenzia regionale di sanità della Toscana. [<https://www.facebook.com/pagina.ARS.Toscana/>] Accessed September 2020

3.5.2b

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

No = 1, Yes = 0

Current Year Score: 1

Available evidence does not indicate that senior leaders in Italy (president or ministers) have shared misinformation or disinformation on infectious diseases in the past two years. However, some senior officials and/or entities have had to issue public statements to issue explanations in response to false information circulating in the national media or among the general public. A recent example is a statement issued by the Ministry of Health in April 2020 on refuting "bufale", or bits of journalistic misinformation, circulating among the public with regard to cures for the COVID-19 pandemic.[1]

It should be noted that articles in the Italian press have claimed that the government has had since February 2020 a formal plan to combat the COVID-19 coronavirus outbreak, which it kept confidential until September in order to prevent any panic in the population that might compromise the continuity of care. [2] The Minister of Health has denied that the plan constitutes a policy rather than a research study. [3]

Finally, a review of national and international news on Italy and public health published over the last two years otherwise does not point to any misstatements made by senior government officials concerning infectious diseases.

[1] Republic of Italy. Ministry of Health. April 24 2020. "Covid-19, the new fake news denied by the ministry (Covid-19, le nuove fake news smentite dal ministero)."

[http://www.salute.gov.it/portale/news/p3_2_1_1_1.jsp?lingua=italiano&menu=notizie&p=dalministero&id=4569] Accessed September 2020

[2] Monica Guerzoni and Fiorenza Sarzanini. September 8 2020. "Covid, here is the government's secret plan: the three scenarios outlined in February (Covid, ecco il piano segreto del governo: i tre scenari delineati a febbraio)." Corriere della Sera. [https://www.corriere.it/cronache/20_settembre_08/covid-ecco-piano-segreto-governo-tre-scenari-delineati-febbraio-c9b3ad06-f14b-11ea-9f2b-89b4229fc5bf.shtml] Accessed October 2020

[3] Pickline. September 8 2020. Did Italy have a secret plan for the coronavirus? (L'Italia aveva un piano segreto per il coronavirus?)" [<https://pickline.it/2020/09/08/litalia-aveva-un-piano-segreto-per-il-coronavirus/>]

3.6 ACCESS TO COMMUNICATIONS INFRASTRUCTURE

3.6.1 Internet users

3.6.1a

Percentage of households with Internet

Input number

Current Year Score: 74.39

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: 133.08

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: 2.0

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: 10.0

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, there is evidence that Italy has issued a restriction on the export/import of medical goods (e.g. medicines, oxygen, medical supplies, PPE) due to an infectious disease outbreak without international/bilateral support or in defiance of international trade rules. As reported by global law firm Baker McKenzie in March 2020, in relation to the COVID-19 coronavirus outbreak on March 15 the European Commission issued its Implementing Regulation (EU) 2020/402, applicable to Italy as a member state, which prohibits the export of certain personal protective equipment to destinations outside the EU, unless a license is first obtained from a Member State. The regulation remained in force for six weeks after that date. [1] No evidence of international/bilateral support for the ban was found via Italy's agriculture, health and foreign affairs ministries. [2, 3, 4]

[1] Anahita Thoms, Sunny Mann. March 18 2020. "New EU and National Export Controls on Face Masks and Medical Protective Equipment." Baker McKenzie. [<https://www.bakermckenzie.com/en/insight/publications/2020/03/new-eu-national-export-controls-medical-equipment>] Accessed September 2020

[2] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website.

[<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202>] Accessed October 2020

[3] Republic of Italy. Ministry of Health. 2020. Website. [www.salute.gov.it] Accessed October 2020

[4] Republic of Italy. Ministry of Foreign Affairs and International Cooperation. 2020. Website. [<https://www.esteri.it/mae/en>] Accessed October 2020

3.7.1b

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

Yes = 0, No = 1

Current Year Score: 1

Available evidence does not indicate that in the past year, Italy has issued a restriction, without international/bilateral support, on the export/import of non-medical goods (e.g. food, textiles, etc) due to an infectious disease outbreak.

In March 2020, the European Commission issued controls on exports of medical protective equipment; the regulation is binding for six months on all EU Member States, including Italy. Otherwise, no evidence of restrictions imposed by Italy on importing or exporting non-medical goods is available from the websites of the ministries of Health, Agriculture or Foreign Affairs. [2, 3, 4]

According to the World Health Organization (WHO), Italy last reported a domestic infectious disease outbreak in September

2017, when 183 cases of Chikungunya were reported to have occurred in the Lazio Region of Italy. In response, Italy implemented a series of public health measures such as strengthened surveillance and control activities at the national level, including disinfestation at ports and airports. [5] The evidence does not indicate that Italy stopped the movement of goods or people due to the disease.

[1] Anahita Thoms, Sunny Mann. March 18 2020. "New EU and National Export Controls on Face Masks and Medical Protective Equipment." Baker McKenzie. (<https://www.bakermckenzie.com/en/insight/publications/2020/03/new-eu-national-export-controls-medical-equipment>) Accessed September 2020

[2] Republic of Italy. Ministry of Health. 2020. Website [<http://www.salute.gov.it>] Accessed September 2020

[3] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website. [<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202>] Accessed September 2020

[4] Republic of Italy. Ministry of Foreign Affairs and International Cooperation. 2020. [<https://www.esteri.it/mae/en>] Accessed September 2020

[5] World Health Organization (WHO). 2020. "Emergencies preparedness, response: Italy". [<http://www.who.int/csr/don/archive/country/ita/en/>] Accessed September 2020

3.7.2 Travel restrictions

3.7.2a

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

Yes = 0 , No = 1

Current Year Score: 0

There is evidence that Italy has implemented a ban without international/bilateral support on travelers arriving from a specific country or countries due to an infectious disease outbreak. As an EU Member State and party to the Schengen system of border controls, it has complied with EU regulations in setting its own policy on the entry of international travelers, applied in response to the COVID-19 coronavirus pandemic.

During the COVID-19 crisis, the European Commission has adopted a number of actions to ensure that any measures taken by Member States to restrict free movement due to the COVID-19 pandemic are not in conflict with its own regulations on travel during the crisis. Member States and countries associated with the Schengen system have temporarily suspended all non-essential travel from a select group of third countries to the EU+ area. As of end-September 2020, Italy allows free travel between most EU and Schengen countries as well as San Marino and the Vatican City, the United Kingdom and Northern Ireland, Andorra and Monaco. [2]

No additional, separate evidence of a ban imposed by Italy on international travelers within the past year, prior to the COVID-19 outbreak, is available from the websites of the ministries of Health, Agriculture or Foreign Affairs. [3, 4, 5]

[1] Republic of Italy. Ministry of Foreign Affairs and International Cooperation. 2020. Travel Safely (Viaggiare sicuri). Website. [<http://www.viaggiaresicuri.it/approfondimenti-insights/saluteinviaggio>] Accessed September 2020

[2] European Commission. 2020. Coronavirus response. "Travel during the coronavirus pandemic." [https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/travel-during-coronavirus-pandemic_en] Accessed September 2020

[3] Republic of Italy. Ministry of Health. 2020. Website [<http://www.salute.gov.it>] Accessed September 2020

[4] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website.

[<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202>] Accessed September 2020

[5] [<https://www.esteri.it/mae/en>] Accessed September 2020

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

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

4.1.1 Available human resources for the broader healthcare system

4.1.1a

Doctors per 100,000 people

Input number

Current Year Score: 397.74

2018

WHO; national sources

4.1.1b

Nurses and midwives per 100,000 people

Input number

Current Year Score: 574.01

2018

WHO; national sources

4.1.1c

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

Yes = 1 , No = 0

Current Year Score: 0

Available evidence does not indicate that Italy has 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. Neither the Ministry of Health nor the Ministry of Labor and Social Policies indicate that they have such strategies. [1, 2] Major policy issues on labor force staffing are typically worked out between the national and regional governments and labor stakeholders

such as trade unions at representative bodies such as the Conference of the Regions and the Autonomous Provinces (Conferenza delle regioni e delle province autonome--CRPA). Currently, the major healthcare workers trade union Fials is in negotiation in this forum over the chronic shortage of nurses and other non-physician healthcare workers in the country. [3]

According to the European Commission, Italy's health workforce is growing but is characterized by a high ratio of physicians (4.0 per 1,000 population in 2017 compared with the EU average of 3.6), while the ratio of nurses (5.8 per 1 000 population compared with the EU average of 8.5) is among the lowest in the EU. [4] In general, across the country efforts are being made to train more nurses and strengthen their role, and the 2019-2021 national Pact for Health (Patto della Salute 2019-2021) requires regions to set "develop the professional skills" of non-physician healthcare workers such as nurses and rehabilitation specialists. [5]

The Jobs Act, a major workforce reform law, was adopted in 2015 in order to make Italy's labour market more dynamic by increasing flexibility in contractual employment and in pension and unemployment benefit arrangements, among other changes, but it does not specifically account for the healthcare workforce. [6, 7]

- [1] Republic of Italy. Ministry of Health. "Health planning (Programmazione sanitaria)". [http://www.salute.gov.it/portale/news/p3_2_0.jsp?lingua=italiano&id=957] Accessed September 2020
- [2] Republic of Italy. Ministry of Labour and Social Policies. 2020. Website. [<http://www.lavoro.gov.it/Pagine/default.aspx>] Accessed September 2020
- [3] Quotidiano Sanita. September 30, 2019 "Personnel shortage. Fials: "Health professions are absent from the document of the Regions" (Carenza personale. Fials: "Le professioni sanitarie sono assenti dal documento delle Regioni")." [http://www.quotidianosanita.it/lavoro-e-professioni/articolo.php?articolo_id=77315] Accessed September 2020
- [4] European Commission. 2020. "State of Health in the EU: Italy Country Health Profile 2019". [<https://www.oecd-ilibrary.org/docserver/cef1e5cb-en.pdf?expires=1601355320&id=id&accname=guest&checksum=C629EA11E90B02CBD89F334B63F8A4DD>] Accessed September 2020
- [5] Conference of the Regions and the Autonomous Provinces. 2020. "Pact for health 2019-2021: the text (Patto per la salute 2019-2021: il testo)." [<http://www.regioni.it/newsletter/n-3750/del-07-01-2020/patto-per-la-salute-2019-2021-il-testo-20616/>] Accessed September 2020
- [6] Andrea de Cillis. 28th April 2015. "Jobs Act, Health [care] problem (Jobs Act, problema Sanità)". Futuro Europa. [<http://www.futuro-europa.it/13398/politica/jobs-act-problema-sanita.html>] Accessed September 2020
- [7] Republic of Italy. Ministry of Labour and Social Policies. 2019. Jobs Act. Website. [<http://www.jobsact.lavoro.gov.it/Pagine/default.aspx>] Accessed September 2020

4.1.2 Facilities capacity

4.1.2a

Hospital beds per 100,000 people

Input number

Current Year Score: 314

2018

WHO/World Bank; national sources

4.1.2b

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

Yes = 1 , No = 0

Current Year Score: 1

Italy 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.

A scholarly study conducting research on European health care facilities over 2009-2010 found that Italy had a total of five isolation beds located in two facilities, both of which were high-level isolation units (HLIUs). [1] A more recent study, from 2015, identified three facilities with HLIUs; the Luigi Sacco University Hospital in Milan, the Lazzaro Spallanzani Hospital in Rome, and the Pratica di Mare air force base outside Rome. The units are mobile and may be transported by ground as well as by air, the latter route by Italy's specialised Aeromedical Isolation Team. Isolation principles used involve multi-layer protection, comprising a PVC envelope, negative pressure, HEPA filters and personal protective equipment (PPE). [2]

Other such units are used by the Italian Red Cross and military forces. A 2017 presentation by the Voluntary Military Corps of the Italian Red Cross described their bio-containment unit. It consists of a mobile isolation chamber and an enclosed stretcher for transporting highly infectious patients. [3] In May 2018, the Italian Air Force issued a statement that it had transported a patient suffering from Multi-drug resistant tuberculosis (MDR) in a biocontainment unit from Pratica di Mare to the Spallanzani centre for treatment. [4]

[1] Stefan Schilling , Francesco Maria Fusco, Giuseppina De Iaco, Barbara Bannister, Helena C. Maltezos, Gail Carson, Rene Gottschalk, Hans-Reinhard Brodt, Philippe Brouqui, Vincenzo Puro, Giuseppe Ippolito. 28 October 2014. "Isolation Facilities for Highly Infectious Diseases in Europe - A Cross-Sectional Analysis in 16 Countries". PLoS One. 2014; 9

[10] : e100401.[<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4211666/>] Accessed September 2020

[2] Giuseppe Paradiso Galatioto. 14 November 2015. "Biosafety containment solutions and medical care". PowerPoint presentation. CBRN Centres of Excellence. [http://www.aimcnet.it/data/xvi_congresso/GALATIOTO-AIMC2015BARI.pdf] Accessed September 2020

[3] Romano Tripodi. 2017. "The bio-containment unit of the Voluntary Military Corps of the Italian Red Cross (L' Unità di bio-contenimento del Corpo Militare Volontario della Croce Rossa Italiana)." Italian Red Cross PowerPoint presentation.[<http://www.siaarti.it/Materiale%20didattico/Anestesia%20e%20rianimazione%20in%20ambiente%20ostile/1%C2%B0%20Convegno%20anestesia%20e%20rianimazione%20in%20ambiente%20ostile%20Giu%202017%20%20TRIPODI%20Unita%CC%80%20Biocontenimento.ppt>.] Accessed September 2020

[4] Ministry of Defense of Italy (Ministero della Difesa). Air Force (AERONAUTICA MILITARE). 24 May 2018. "BIOCONTAINMENT: PATIENT AFFECTED BY TUBERCULOSIS TRANSPORTED BY MILITARY AIRCRAFT (BIOCONTENIMENTO: PAZIENTE AFFETTO DA TUBERCOLOSI TRASPORTATO DALL'AERONAUTICA MILITARE)".[http://www.aeronautica.difesa.it/comunicazione/notizie/Pagine/20180524_Paziente-affetto-da-tubercolosi-trasportato-in-Bio-Contenimento-dall-Aeronautica-Militare.aspx] Accessed September 2020

4.1.2c

Does the country meet one of the following criteria?

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

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

Yes = 1, No = 0

Current Year Score: 0

Available evidence does not indicate that Italy has demonstrated capacity or developed a plan to expand isolation capacity in response to an infectious disease outbreak in the past two years.

Its policies taken in response to the COVID-19 coronavirus pandemic outbreak in 2020 have aimed to avoid straining the capacity of the healthcare system. [1] A new policy plan issued in the wake of this disease aims to build national capacity to address flu pandemics but does not address isolation in this regard. In response to the COVID-19 outbreak in early 2020, Italy's government has focused on mandating 14-day "domiciliary" (home) isolation--in the form of self-quarantine--for individuals who have tested positive to COVID-19 but do not require hospitalization. The policy has aimed to avoid straining the capacity of the country's hospital system. To this end, it has promoted the extensive use of other tools such as rapid testing and contact tracing--including the voluntary use of mobile phone apps--to track the pathways of the disease. With the second wave of the pandemic later in 2020, the government shortened the term for mandatory isolation for positive but asymptomatic individuals from 14 to 10 days. [1]

Italy's new "National strategic-operational plan for preparation and response to a flu pandemic (PanFlu) 2021-2023", launched in January 2021 in the wake of the COVID-19 pandemic, aims to build national capacity in pandemic preparedness. The plan discusses isolation, but mostly in the context of supporting domiciliary self-isolation as a key non-pharmaceutical intervention tool to use in the early stages of a pandemic or epidemic. The new plan does not provide evidence that it aims to expand logistical and physical capacity of the healthcare system to facilitate isolation of individuals. In any case, actionable measures for this plan are still under development. [2]

The country's key documents setting public health policy during crises focus on such issues as increasing surveillance, staging responses providing prophylactic measures (chiefly vaccinations) and do not directly address the expansion of infrastructural capacity. Examples of such documents are the national plan on influenza pandemics (2006) and the latest National Prevention Plan (2020-2025). [3, 4]

[1] Antonio Giulio de Belvis, Giovanni Fattore, Alisha Morsella, Gabriele Pastorino, Andrea Poscia, Walter Ricciardi, Andrea Silenzi. November 20 2020. "Policy Responses for Italy: 1.3 Isolation and quarantine." WHO Regional Office for Europe and European Observatory on Health Systems and Policies. COVID-19 Health System Response Monitor. [<https://www.covid19healthsystem.org/countries/italy/livinghit.aspx?Section=1.3%20Isolation%20and%20quarantine&Type=Section>] Accessed April 2021

[2] Republic of Italy. Ministry of Health. Directorate-General of Sanitary Prevention. January 25 2021. "National strategic-operational plan for preparation and response to a flu pandemic (PanFlu) 2021-2023 (Piano strategico-operativo nazionale di preparazione e risposta a una pandemia influenzale (PanFlu) 2021-2023)." [<https://www.quotidianosanita.it/allegati/allegato4004886.pdf>] Accessed April 2021

[3] Republic of Italy. Ministry of Health. 2006. "NATIONAL PLAN FOR PREPAREDNESS AND RESPONSE TO AN INFLUENZA PANDEMIC." [http://www.salute.gov.it/imgs/C_17_pubblicazioni_501_ulterioriallegati_ulterioreallegato_0_alleg.pdf] Accessed September 2020

[4] Republic of Italy. Ministry of Health. 2020. National Prevention Plan 2020-2025 (Piano Nazionale della Prevenzione 2020-2025---PNP)." [http://www.salute.gov.it/imgs/C_17_notizie_5029_0_file.pdf] Accessed September 2020

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: 1

There is publicly available evidence suggesting that Italy has a national procurement protocol in place which can be utilized by the Ministry of Health but not the Ministry of Agriculture for the acquisition of laboratory supplies (e.g. equipment, reagents and media) and medical supplies (e.g. equipment, PPE) for routine needs.

The procurement system is regulated by the Directorate-General for Medical Devices and Pharmaceutical Service at the Ministry of Health. It develops overall policy on procurement, does cost-benefit analyses and engages in market surveillance, such as determining reference prices for medical devices to be purchased by the national health system. [1, 2]

This procurement system uses market-based mechanisms. At the top, the National system of verification and control on health care (Sistema nazionale di verifica e controllo sull'assistenza sanitaria--SiVeAS) oversees the efficiency of the National Health Service (Servizio Sanitario Nazionale), including with regard to procurement. Since the national health care system is regionally based, with the central government distributing funds to the regional health systems, [2] the SIVEAS closely monitors the spending of the regional systems through reimbursement contracts known as "piani di rientro." In this way, the SIVEAS measures the efficiency of the centralised procurement of goods and services conducted by each of the regions. [3]

In the field, government health care entities can use the system provided by Consip, Italy's Central Public Procurement Authority for the public administration. Consip is wholly owned by the Ministry of Economy and Finance. It concludes purchase agreements with third-party suppliers on behalf of the public administration and also works with the regional authorities to set up regional purchasing centers. [4] It makes available to purchasers an electronic, market-based system--the Electronic Market of the Public Administration (Mercato Elettronico della Pubblica Amministrazione-MEPA); its Aquistinretepa portal has a catalogue listing dozens of medical and laboratory product categories, ranging from vaccines and defibrillators to reagents and pipettes. [5]

[1] Republic of Italy. Ministry of Health. Directorate-General for Medical Devices and Pharmaceutical Service. April 17 2020. Webpage.

[http://www.salute.gov.it/portale/ministro/p4_5_2_4_1.jsp?lingua=italiano&menu=uffCentrali&label=uffCentrali&id=1153] Accessed September 2020

[2] Roosa Tikkanen, Robin Osborn, Elias Mossialos, Ana Djordjevic, and George A. Wharton. June 5, 2020. International Healthcare System Profiles. "Italy." The Commonwealth Fund. [<https://www.commonwealthfund.org/international-health-policy-center/countries/italy>] Accessed September 2020

[3] Republic of Italy. Ministry of Health. National system of verification and control on health care (SiVeAS). November 30 2009. "What is SiVeAS? (Che cos'è il SiVeAS)."

[http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=1497&area=siveas&menu=vuoto] Accessed September 2020

[4] Republic of Italy. Ministry of Economy and Finance. Consip. 2020. Website. [<https://www.consip.it/>] Accessed September 2020

[5] Republic of Italy. Ministry of Economy and Finance. Consip. 2020. Aquistinretepa Procurement Portal. "Commodity area (Area merceologica)".

[<https://www.acquistinretepa.it/opencms/opencms/dettaglioCategoriaTile.html?idCategoria=4237c4f2514e82cb>] Accessed September 2020

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

Italy has a stockpile of medical supplies for national use during a public health emergency and there is evidence of what the stockpile contains. Specifically, evidence points to the existence of national stockpiles of MCMs (specified as chemical and pharmaceutical resources and antidotes), which are managed by the Ministry of Health's General Directorate of Sanitary Prevention. [1, 2] This resource is called the National Antidote Stockpile (Scorta Nazionale Antidoti--SNA); materials stored in the SNA's facilities are graded for use according to the urgency of the situation: priority 1 antidotes must be available for exposed persons within 30 minutes; priority 2 antidotes within 2 hours; and priority 3 antidotes within 6 hours. Some antidotes are classed Priority 4 due to scarcity. [1] A 2016 Ministry of Health PowerPoint presentation on the SNA lists a total of 34 regional and state deposit facilities across the nation. The presentation does not specify what types of medical supplies the SNAs hold other than chemical antidotes. [2] It should be noted that Italy is a signatory to the European Union's Joint Procurement Agreement to procure medical countermeasures, a directive that specifically addresses threats of a biological nature. [3]

The apparent absence in Italy of a national stockpile of medical supplies other than MCMs has been brought to national attention in the wake of the COVID-19 coronavirus outbreak; for example, in June 2020 an article in the Italian newspaper *Il Sole 24 Ore* criticized the apparent lack of a government policy on stocking medical supplies to cope with future crisis situations. [4] In that regard, in January 2021 the Italian government adopted a new response plan for future influenza pandemics, covering the 2021-2023 period. The plan recommends such procedures as routine pre-emptive purchasing and monitoring of stocks of a comprehensive range of medical supplies. [5]

[1] Virgilio Costanzo, MD. September 15 2011. "SKILLS OF THE MINISTRY OF HEALTH IN MATTERS OF CIVIL DEFENSE (COMPETENZE DEL MINISTERO DELLA SALUTE IN MATERIA DI DIFESA CIVILE)". PowerPoint Presentation. Ministry of Health. [http://www.salute.gov.it/resources/static/ministero/usmaf/corso_15_e_16_settembre_2011/COSTANZO_difesa_civile.pdf] Accessed September 2020

[2] Virgilio Costanzo, MD. June 9 2016. "The system for emergency management: The National Antidote Stocks (Il sistema per la gestione delle emergenze : La Scorta Nazionale Antidoti)". PowerPoint presentation. Ministry of Health, Directorate General for Health Prevention (Ministero della Salute, Direzione Generale della Prevenzione Sanitaria). [https://antidoti.ospfe.it/wp-content/uploads/2017/02/La-Scorta-Nazionale-Antidoti_Costanzo_9.6.16.pdf] Accessed September 2020

[3] European Commission. Crisis preparedness and response. 2020. "Signing ceremonies for Joint Procurement Agreement." [https://ec.europa.eu/health/preparedness_response/joint_procurement/jpa_signature_en] Accessed September 2020

[4] Veronica Vecchi, Giuditta Callea, Niccolò Cusumano. June 12 2020. "Towards a strategic health procurement in post

Covid. The case of stocks (Verso un procurement sanitario strategico nel post Covid. Il caso delle scorte)." Il Sole 24 Ore. [https://www.sanita24.ilsole24ore.com/art/imprese-e-mercato/2020-06-12/verso-procurement-sanitario-strategico-post-covid-caso-scorte-155712.php?uuid=ADmwZTX&refresh_ce=1] Accessed September 2020

[5] Republic of Italy. Ministry of Health. Directorate-General of Sanitary Prevention. January 25 2021. "National strategic-operational plan for preparation and response to a flu pandemic (PanFlu) 2021-2023 (Piano strategico-operativo nazionale di preparazione e risposta a una pandemia influenzale (PanFlu) 2021-2023)." [https://www.quotidianosanita.it/allegati/allegato4004886.pdf] Accessed April 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

Available evidence does not indicate that Italy has a stockpile of laboratory supplies (e.g. reagents, media) for national use during a public health emergency.

Italy does maintain a stockpile of medical countermeasures (MCM) (i.e. vaccines, therapeutics and diagnostics) for national use during a public health emergency, which includes essential medicines. This resource is the Ministry of Health's National Antidote Stockpile (Scorta Nazionale Antidoti --SNA); materials stored in the SNA's facilities are graded for use according to the urgency of the situation. It is unclear from the evidence if the SNAs hold any materials other than chemical antidotes. [2]

The apparent absence of a national stockpile of medical and laboratory supplies in Italy has been brought to national attention in the wake of the COVID-19 coronavirus outbreak; in June 2020 an article published in the Italian newspaper Il Sole 24 Ore criticised the apparent lack of a comprehensive government policy to ensure the existence of stocks of such supplies to cope with future crisis situations. It noted a lack of coordination between strategic health planning and procurement policies by government. [3]

Finally, no evidence of an official policy on maintaining stockpiles of medical supplies is provided by the defense, health, interior, civil protection or drug regulatory authorities. [4, 5, 6, 7, 8]

[1] Virgilio Costanzo, MD. September 15 2011. "SKILLS OF THE MINISTRY OF HEALTH IN MATTERS OF CIVIL DEFENSE (COMPETENZE DEL MINISTERO DELLA SALUTE IN MATERIA DI DIFESA CIVILE)". PowerPoint Presentation. Ministry of Health. [http://www.salute.gov.it/resources/static/ministero/usmaf/corso_15_e_16_settembre_2011/COSTANZO_difesa_civile.pdf] Accessed September 2020

[2] Virgilio Costanzo, MD. June 9 2016. "The system for emergency management: The National Antidote Stocks (Il sistema per la gestione delle emergenze : La Scorta Nazionale Antidoti)". PowerPoint presentation. Ministry of Health, Directorate General for Health Prevention (Ministero della Salute, Direzione Generale della Prevenzione Sanitaria). [https://antidoti.ospfe.it/wp-content/uploads/2017/02/La-Scorta-Nazionale-Antidoti_Costanzo_9.6.16.pdf] Accessed September 2020

[3] Veronica Vecchi, Giuditta Callea, Niccolò Cusumano. June 12 2020. "Towards a strategic health procurement in post Covid. The case of stocks (Verso un procurement sanitario strategico nel post Covid. Il caso delle scorte)." Il Sole 24 Ore. [https://www.sanita24.ilsole24ore.com/art/imprese-e-mercato/2020-06-12/verso-procurement-sanitario-strategico-post-covid-caso-scorte-155712.php?uuid=ADmwZTX&refresh_ce=1] Accessed September 2020

[4] Republic of Italy. Ministry of Defense. 2020. Website. [www.difesa.it] Accessed October 2020

[5] Republic of Italy. Ministry of Health. 2020. Website. [www.salute.gov.it] Accessed October 2020

[6] Republic of Italy. Department of Civil Protection. 2020. Website. [<http://www.protezionecivile.gov.it>] Accessed October 2020

[7] Republic of Italy. Ministry of the Interior. 2020. Website. [<https://www.interno.gov.it/it>] Accessed October 2020

[8] Republic of Italy. Italian Medicines Agency (AIFA). 2020. Website. [<http://www.agenziafarmaco.gov.it/>] Accessed October 2020

4.2.2c

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

Yes = 1, No = 0

Current Year Score: 0

Available evidence does not indicate that Italy conducts or requires an annual review of the national stockpile to ensure the supply is sufficient for a public health emergency.

Italy has a stockpile of medical supplies for national use during a public health emergency. Specifically, these supplies are MCMs (specified as chemical and pharmaceutical resources and antidotes), managed by the Ministry of Health's General Directorate of Sanitary Prevention. [1, 2] This resource is called the National Antidote Stockpile (Scorta Nazionale Antidoti--SNA); materials stored in the SNA's network of regional depository facilities are graded for use according to the urgency of the situation. Official documents from the Ministry of Health on the SNA list a total of 34 regional and state deposit facilities across the nation and indicate that stocks are held under security and maintenance protocols. However these documents do not specify that the facilities are subject to review procedures. [1, 2, 3]

The apparent absence in Italy of a national stockpile of medical supplies other than MCMs has been brought to national attention in the wake of the COVID-19 coronavirus outbreak, leading the Italian government to adopt in January 2021 a new response plan for future influenza pandemics, covering the 2021-2023 period. The plan mandates action in the routine pre-emptive purchasing and monitoring of stocks of a comprehensive range of medical supplies--in a scalable fashion and using the FIFO (First In First Out) inventory accounting method. It is not yet clear when such a monitoring and accounting system will be fully put into effect. [4]

[1] Virgilio Costanzo, MD. September 15 2011. "SKILLS OF THE MINISTRY OF HEALTH IN MATTERS OF CIVIL DEFENSE (COMPETENZE DEL MINISTERO DELLA SALUTE IN MATERIA DI DIFESA CIVILE)". PowerPoint Presentation. Ministry of Health. [http://www.salute.gov.it/resources/static/ministero/usmaf/corso_15_e_16_settembre_2011/COSTANZO_difesa_civile.pdf] Accessed September 2020 and April 2021

[2] Virgilio Costanzo, MD. June 9 2016. "The system for emergency management: The National Antidote Stocks (Il sistema per la gestione delle emergenze : La Scorta Nazionale Antidoti)". PowerPoint presentation. Ministry of Health, Directorate General for Health Prevention (Ministero della Salute, Direzione Generale della Prevenzione Sanitaria). [https://antidoti.ospfe.it/wp-content/uploads/2017/02/La-Scorta-Nazionale-Antidoti_Costanzo_9.6.16.pdf] Accessed September 2020 and April 2021

[3] Republic of Italy. Ministry of Health. General Directorate of Health Prevention Office 03. 2015. "NATIONAL STOCK OF ANTIDOTES (SCORTA NAZIONALE ANTIDOTI)."

[[https://www.sanita.puglia.it/documents/55154/441461/Scorta+Nazionale+Antidoti+-+Procedura+2015+\(PROCEDURA+SNA+AGO+2015.pdf\)/04d642a7-7919-467a-9267-009af8d65598](https://www.sanita.puglia.it/documents/55154/441461/Scorta+Nazionale+Antidoti+-+Procedura+2015+(PROCEDURA+SNA+AGO+2015.pdf)/04d642a7-7919-467a-9267-009af8d65598)] Accessed April 2021

[4] Republic of Italy. Ministry of Health. Directorate-General of Sanitary Prevention. January 25 2021. "National strategic-operational plan for preparation and response to a flu pandemic (PanFlu) 2021-2023 (Piano strategico-operativo nazionale di preparazione e risposta a una pandemia influenzale (PanFlu) 2021-2023)."

[<https://www.quotidianosanita.it/allegati/allegato4004886.pdf>] Accessed April 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 no direct evidence of a plan/agreement in Italy to leverage domestic manufacturing capacity to produce medical supplies (e.g. MCMs, medicines, vaccines, equipment, PPE) for national use during a public health emergency. However, it is clear that the country has a flexible plan/mechanism to procure such supplies during a crisis of this kind.

Italy's healthcare system is run largely by the national and regional/local governments; [1] the country's key documents setting public health policy during crises make very little mention of interaction with the private sector stakeholders. Examples of such documents are the national plan on influenza pandemics (2006) and the latest National Prevention Plan (2020-2025); as with others of their kind, these documents reflect the assumption that government will make agreements with such stakeholders as needed, on an ad hoc basis. [2, 3]

That said, Italy has an elaborate and advanced procurement system for medical supplies, geared for the use of the public administration. The system is regulated by the Directorate-General for Medical Devices and Pharmaceutical Service at the Ministry of Health. It develops overall policy on procurement, does cost-benefit analyses and engages in market surveillance, such as determining reference prices for medical devices to be purchased by the national health system. [1, 4] This procurement system uses market-based mechanisms. At the top, the National system of verification and control on health care (Sistema nazionale di verifica e controllo sull'assistenza sanitaria--SiVeAS) oversees the efficiency of the National Health Service (Servizio Sanitario Nazionale), including with regard to procurement. Since the national health care system is regionally based, with the central government distributing funds to the regional health systems, [4] the SiVeAS closely monitors the spending of the regional systems through reimbursement contracts known as "piani di rientro." In this way, the SiVeAS measures the efficiency of the centralised procurement of goods and services conducted by each of the regions, and can adjust accordingly to a change in needs. [5]

In the field, government health care entities can use the system provided by Consip, Italy's Central Public Procurement Authority for the public administration. Consip is wholly owned by the Ministry of Economy and Finance. It concludes purchase agreements with third-party suppliers on behalf of the public administration and also works with the regional authorities to set up regional purchasing centers. [6] It makes available to purchasers an electronic, market-based system--the Electronic Market of the Public Administration (Mercato Elettronico della Pubblica Amministrazione-MEPA); its "Aquistinretepa" portal has a catalogue listing dozens of medical and laboratory product categories, ranging from vaccines and defibrillators to reagents and pipettes. [7]

Evidence indicates that the Italian authorities expect the existing procurement system to be adaptable to emergencies. In the wake of the COVID-19 coronavirus pandemic outbreak, the Italian government has designed a new response plan with regard to future influenza pandemics. The new plan was adopted in January 2021 and covers the 2021-2023 period. The

plan recommends such procedures as pre-emptive purchasing and monitoring of stocks of medical equipment and drugs in normal times, as well as accelerated procurement procedures for obtaining vaccines during pandemic events; it also contemplates the activation of a joint procurement system by EU Member States. The plan does not discuss leveraging domestic manufacturing capacity to produce any such supplies including MCMs. [8]

[1] Roosa Tikkanen, Robin Osborn, Elias Mossialos, Ana Djordjevic, and George A. Wharton. June 5, 2020. International Healthcare System Profiles. "Italy." The Commonwealth Fund. [<https://www.commonwealthfund.org/international-health-policy-center/countries/italy>] Accessed September 2020

[2] Republic of Italy. Ministry of Health. 2006. "NATIONAL PLAN FOR PREPAREDNESS AND RESPONSE TO AN INFLUENZA PANDEMIC." [http://www.salute.gov.it/imgs/C_17_pubblicazioni_501_ulterioriallegati_ulterioreallegato_0_alleg.pdf] Accessed September 2020

[3] Republic of Italy. Ministry of Health. 2020. National Prevention Plan 2020-2025 (Piano Nazionale della Prevenzione 2020-2025---PNP)." [http://www.salute.gov.it/imgs/C_17_notizie_5029_0_file.pdf] Accessed September 2020

[4] Republic of Italy. Ministry of Health. Directorate-General for Medical Devices and Pharmaceutical Service. April 17 2020. Webpage.

[http://www.salute.gov.it/portale/ministro/p4_5_2_4_1.jsp?lingua=italiano&menu=uffCentrali&label=uffCentrali&id=1153] Accessed September 2020

[5] Republic of Italy. Ministry of Health. National system of verification and control on health care (SiVeAS). November 30 2009. "What is SiVeAS? (Che cos'è il SiVeAS)."

[http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=1497&area=siveas&menu=vuoto] Accessed September and October 2020

[6] Republic of Italy. Ministry of Economy and Finance. Consip. 2020. Website. [<https://www.consip.it/>] Accessed September 2020

[7] Republic of Italy. Ministry of Economy and Finance. Consip. 2020. Acquistinretepa Procurement Portal. "Commodity area (Area merceologica)".

[<https://www.acquistinretepa.it/opencms/opencms/dettaglioCategoriaTile.html?idCategoria=4237c4f2514e82cb>] Accessed September 2020

[8] Republic of Italy. Ministry of Health. Directorate-General of Sanitary Prevention. January 25 2021. "National strategic-operational plan for preparation and response to a flu pandemic (PanFlu) 2021-2023 (Piano strategico-operativo nazionale di preparazione e risposta a una pandemia influenzale (PanFlu) 2021-2023)."

[<https://www.quotidianosanita.it/allegati/allegato4004886.pdf>] Accessed April 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 insufficeint evidence that Italy has a mechanism to produce or procure laboratory supplies (e.g. reagents, media) for national use during a public health emergency.

Italy's healthcare system is run largely by the national and regional/local governments; [1] the country's key documents setting public health policy during crises make very little mention of interaction with the private sector stakeholders.

Examples of such documents are the national plan on influenza pandemics (2006) and the latest National Prevention Plan (2020-2025); as with others of their kind, these documents reflect the assumption that government will make agreements with such stakeholders as needed, on an ad hoc basis. [2, 3]

That said, Italy has an elaborate and advanced procurement system for medical and laboratory supplies, geared for the routine use of the public administration. The system is regulated by the Directorate-General for Medical Devices and Pharmaceutical Service at the Ministry of Health. It develops overall policy on procurement, does cost-benefit analyses and engages in market surveillance, such as determining reference prices for medical devices to be purchased by the national health system. [1, 4] This procurement system uses market-based mechanisms. At the top, the National system of verification and control on health care (Sistema nazionale di verifica e controllo sull'assistenza sanitaria--SiVeAS) oversees the efficiency of the National Health Service (Servizio Sanitario Nazionale), including with regard to procurement. Since the national health care system is regionally based, with the central government distributing funds to the regional health systems, [4] the SiVeAS closely monitors the spending of the regional systems through reimbursement contracts known as "piani di rientro." In this way, the SiVeAS measures the efficiency of the centralised procurement of goods and services conducted by each of the regions, and can adjust accordingly to a change in needs. [5]

In the field, government health care entities can use the system provided by Consip, Italy's Central Public Procurement Authority for the public administration. Consip is wholly owned by the Ministry of Economy and Finance. It concludes purchase agreements with third-party suppliers on behalf of the public administration and also works with the regional authorities to set up regional purchasing centers. [6] It makes available to purchasers an electronic, market-based system--the Electronic Market of the Public Administration (Mercato Elettronico della Pubblica Amministrazione-MEPA); its Aquistinretepa portal has a catalogue listing dozens of medical and laboratory product categories, ranging from vaccines and defibrillators to reagents and pipettes. [7]

Evidence indicates that the Italian authorities expect the existing procurement system to be adaptable to emergencies. In the wake of the COVID-19 coronavirus pandemic outbreak, the Italian government has designed a new response plan with regard to future influenza pandemics. The new plan was adopted in January 2021 and covers the 2021-2023 period. The plan recommends such procedures as pre-emptive purchasing and monitoring of stocks of medical and laboratory equipment and drugs in normal times, as well as accelerated procurement procedures for obtaining vaccines during pandemic events. The plan does not discuss leveraging domestic manufacturing capacity to produce any such supplies including laboratory supplies [8]

[1] Roosa Tikkanen, Robin Osborn, Elias Mossialos, Ana Djordjevic, and George A. Wharton. June 5, 2020. International Healthcare System Profiles. "Italy." The Commonwealth Fund. [<https://www.commonwealthfund.org/international-health-policy-center/countries/italy>] Accessed September 2020

[2] Republic of Italy. Ministry of Health. 2006."NATIONAL PLAN FOR PREPAREDNESS AND RESPONSE TO AN INFLUENZA PANDEMIC." [http://www.salute.gov.it/imgs/C_17_pubblicazioni_501_ulterioriallegati_ulterioreallegato_0_alleg.pdf] Accessed September 2020

[3] Republic of Italy. Ministry of Health. 2020. National Prevention Plan 2020-2025 (Piano Nazionale della Prevenzione 2020-2025---PNP)." [http://www.salute.gov.it/imgs/C_17_notizie_5029_0_file.pdf] Accessed September 2020

[4] Republic of Italy. Ministry of Health. Directorate-General for Medical Devices and Pharmaceutical Service. April 17 2020. Webpage.

[http://www.salute.gov.it/portale/ministro/p4_5_2_4_1.jsp?lingua=italiano&menu=uffCentrali&label=uffCentrali&id=1153] Accessed September 2020

[5] Republic of Italy. Ministry of Health. National system of verification and control on health care (SiVeAS). November 30 2009. "What is SiVeAS? (Che cos'è il SiVeAS)."

[http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=1497&area=siveas&menu=vuoto] Accessed September

and October 2020

[6] Republic of Italy. Ministry of Economy and Finance. Consip. 2020. Website. [<https://www.consip.it/>] Accessed September 2020

[7] Republic of Italy. Ministry of Economy and Finance. Consip. 2020. Acquistinretepa Procurement Portal. "Commodity area (Area merceologica)".

[<https://www.acquistinretepa.it/opencms/opencms/dettaglioCategoriaTile.html?idCategoria=4237c4f2514e82cb>] Accessed September 2020

[8] Republic of Italy. Ministry of Health. Directorate-General of Sanitary Prevention. January 25 2021. "National strategic-operational plan for preparation and response to a flu pandemic (PanFlu) 2021-2023 (Piano strategico-operativo nazionale di preparazione e risposta a una pandemia influenzale (PanFlu) 2021-2023)."

[<https://www.quotidianosanita.it/allegati/allegato4004886.pdf>] Accessed April 2021

4.3 MEDICAL COUNTERMEASURES AND PERSONNEL DEPLOYMENT

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

4.3.1a

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

Yes = 1 , No = 0

Current Year Score: 0

Available evidence does not indicate that Italy has 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).

Italy's Ministry of Health maintains a stockpile of medical countermeasures (specified as chemical and pharmaceutical resources and antidotes) for national use during a public health emergency. Its Directorate of Sanitary Prevention maintains the stockpile, called the National Antidote Stockpile (Scorta Nazionale Antidoti--SNA); the materials contained in its facilities are graded for use according to the urgency of the situation: priority 1 antidotes must be available for exposed persons within 30 minutes; priority 2 antidotes within 2 hours; and priority 3 antidotes within 6 hours. Some antidotes are classed Priority 4 due to scarcity. [4] A 2016 Ministry of Health presentation on the SNA lists a total of 34 depositories across Italy, but does not specify what countermeasures they hold other than antidotes. [1, 2] The protocol for activating the SNA starts with the local Prefect of the affected area contacting the General Directorate of Sanitary Prevention or the Department of Civil Protection's Italy Situation Room. The Ministry of Health then decides whether to activate the SNA and coordinate with the local authorities on delivery of the antidote(s). [1, 2, 4]

However, there is no readily available evidence of a national plan for dispensing such supplies. For example, the Ministry of Health's national influenza plan (2006) states that a distribution plan for antiviral drugs will be agreed between the national government and the regions; however, the plan makes no mention of other medical supplies in this regard and does not discuss dispensing. Moreover, the plan does not indicate that it may be used during outbreaks of other infectious diseases. [3]

Finally, the Ministry of Defense gives no indication of having a policy to dispense MCMs for national use during a public

health emergency. [4]

- [1] Virgilio Costanzo, MD. September 15 2011. "SKILLS OF THE MINISTRY OF HEALTH IN MATTERS OF CIVIL DEFENSE (COMPETENZE DEL MINISTERO DELLA SALUTE IN MATERIA DI DIFESA CIVILE)". PowerPoint Presentation. Ministry of Health. [http://www.salute.gov.it/resources/static/ministero/usmaf/corso_15_e_16_settembre_2011/COSTANZO_difesa_civile.pdf] Accessed September 2020
- [2] Virgilio Costanzo, MD. June 9 2016. "The system for emergency management: The National Antidote Stocks (Il sistema per la gestione delle emergenze : La Scorta Nazionale Antidoti)". PowerPoint presentation. Ministry of Health, Directorate General for Health Prevention (Ministero della Salute, Direzione Generale della Prevenzione Sanitaria). [https://antidoti.ospfe.it/wp-content/uploads/2017/02/La-Scorta-Nazionale-Antidoti_Costanzo_9.6.16.pdf] Accessed September 2020
- [3] Republic of Italy. Ministry of Health. 2006. "NATIONAL PLAN FOR PREPAREDNESS AND RESPONSE TO AN INFLUENZA PANDEMIC." [http://www.salute.gov.it/imgs/C_17_pubblicazioni_501_ulterioriallegati_ulterioreallegato_0_alleg.pdf] Accessed September 2020
- [4] Pavia Poison Control Centre. "Antidotes 2016-2017 (Antidoti 2016-2017)". <http://www.aslal.it/allegati/GUIDA%20ANTIDOTI%202016-17%20CAV%20PAVIA.pdf> Accessed September 2020
- [4] Republic of Italy. Ministry of Defense (Ministero della Difesa) 2020. Website. [<https://www.difesa.it/Pagine/default.aspx>] Accessed September 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 no readily available evidence from the defence or health ministries, Italian Red Cross, or national disease prevention and control centre indicating that Italy has a public plan in place that enables it to receive health personnel from other countries to respond to a public health emergency. [2, 3, 4, 5] According to a 2015 study on the topic by the Italian Red Cross, Italy has an "advanced and flexible" disaster response system which is enhanced by its participation in international cooperation agreements such as the European Union's Civil Protection Mechanism. [1, 2] However, the report also found that a "multiplicity of instruments" and rules governing disaster response "...may prevent the provision of assistance or may discourage it by imposing onerous procedures and financial obligations." [2]

Italy is party to numerous multilateral treaties on subjects related to disaster response, such as the Agreement on the Temporary Importation, Free of Duty, of Medical, Surgical and Laboratory Equipment for Use on Free Loan in Hospitals and Other Medical Institutions for Purposes of Diagnosis Or Treatment (1960). But Italian law generally has no specific rules for international civil-protection personnel, and those from another Schengen country may enter without a visa. While the Italian authorities require proof of the qualifications of foreign professionals such as physicians, the process generally is easy for EU citizens because of the transposition of EU qualification standards into Italian law. [2]

- [1] European Commission. Crisis Preparedness and Response. 2020. "Crisis Management". [https://ec.europa.eu/health/preparedness_response/crisis_management_en] Accessed September 2020
- [2] Italian Red Cross. 2015. "IDRL IN ITALY A Study on Strengthening Legal Preparedness for International Disaster Response". [<http://www.ifrc.org/PageFiles/202607/Italian%20IDRL%20Report%20ENG.pdf>] Accessed November 2018

- [3] Ministry of Health (Ministero della Salute). 15 September 2011. "SKILLS OF THE MINISTRY OF THE HEALTH IN MATTER OF CIVIL DEFENSE (COMPETENZE DEL MINISTERO DELLA SALUTE IN MATERIA DI DIFESA CIVILE)". PowerPoint Presentation. http://www.salute.gov.it/resources/static/ministero/usmaf/corso_15_e_16_settembre_2011/COSTANZO_difesa_civile.pdf Accessed September 2020
- [4] Ministry of Defense (Ministero della Difesa) 2020. Website. [<https://www.difesa.it/Pagine/default.aspx>] Accessed September 2020
- [5] National Centre for Disease Prevention and Control (CCM). 3 May 2011. "What is the CCM? (Che cos'è il Ccm)". [<http://www.ccm-network.it/pagina.jsp?id=node/7>] Accessed September 2020

4.4 HEALTHCARE ACCESS

4.4.1 Access to healthcare

4.4.1a

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

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

Current Year Score: 1

2020

World Policy Analysis Center

4.4.1b

Access to skilled birth attendants (% of population)

Input number

Current Year Score: 99.9

2014

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: 850.12

2017

WHO Global Health Expenditure database

4.4.2 Paid medical leave

4.4.2a

Are workers guaranteed paid sick leave?

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

Current Year Score: 2

2020

World Policy Analysis Center

4.4.3 Healthcare worker access to healthcare

4.4.3a

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

Yes = 1, No = 0

Current Year Score: 0

Evidence from the Ministry of Health, its national disease prevention and control center, and its key plans referring to health emergencies does not indicate that Italy has a policy to provide prioritized healthcare services to healthcare workers who become sick as a result of responding to a public health emergency. It does have a plan to prioritize healthcare workers for vaccinations during the alert phases of such crises. [1, 2, 3, 4]

For example, the Ministry's 2006 national plan for dealing with an influenza pandemic stipulates six priority categories for administering vaccinations during Phase 3 to 5, the alert phases of a pandemic. In summary, the plan's categories, listed according to highest priority, are as follows: 1. Health care personnel and other workers in hospitals, family practices, long-term health care facilities, public health services, clinical laboratories and pharmacies; 2. Security and emergency-service personnel such as public police forces, fire brigades and key emergency-service decision-makers; 3. Personnel in public-utility services such as armed forces and other police forces not included in priority Group 2, essential public transport, school and postal workers, and persons delivering raw materials; 4. Persons with a high risk of severe or fatal complications due to influenza; 5. Healthy children and adolescents aged between 2-18 years; 6. Healthy adults. For priority Groups 4-6, the scale can be subject to revision during pandemic alert phase 5, depending on the epidemiological characteristics of the virus in circulation. [1]

It should be noted that the 2006 influenza plan does not state that it may be used for other public health crises.

[1] Republic of Italy. Ministry of Health. 2006. "NATIONAL PLAN FOR PREPAREDNESS AND RESPONSE TO AN INFLUENZA PANDEMIC". [http://www.salute.gov.it/imgs/C_17_pubblicazioni_511_allegato.pdf] Accessed September 2020

[2] Republic of Italy. Ministry of Health. National Centre for Disease Prevention and Control (Centro nazionale per la prevenzione e il controllo delle malattie--Ccm). "What is Ccm". [<http://www.ccm-network.it/pagina.jsp?id=node/282&lingua=english>] Accessed September 2020

[3] Republic of Italy. Ministry of Health. 2014. National Prevention Plan 2014-2018 (Piano Nazionale della Prevenzione 2014-2018---PNP)". [http://www.salute.gov.it/imgs/C_17_pubblicazioni_2285_allegato.pdf] Accessed September 2020

[4] Republic of Italy. Ministry of Health. January 1 2015. "INTEGRATED NATIONAL PLAN 2015-2019: ANIMAL HEALTH - INFECTIOUS DISEASES (PIANO NAZIONALE INTEGRATO 2015-2019: SANITÀ ANIMALE - MALATTIE INFETTIVE)."

[<http://www.salute.gov.it/pianoNazionaleIntegrato2015/sezionePianoNazionaleIntegrato2015.jsp?cap=capitolo3&sez=pni-cap3-sanitaanimale-malattieinfettive>] Accessed September 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: 0

Available evidence does not indicate that Italy has a specific system or protocol for public health officials and healthcare workers to communicate during a public health emergency.

Instead, Italy has long had official protocols for communication between official parties involved in responding to a public health emergency, and it began to reorganize its national emergency relief capabilities after the powerful earthquakes that occurred in Italy's Abruzzo Region in 2009. A decree of the Presidency of the Council of Ministers (dPCM), in force as of 20 August 2016, concluded the reorganization by creating an entity called the Remote Medical Operations Emergency Unit (Centrale Remota Operazioni Soccorso Sanitario- -CROSS) to better coordinate urgent medical assistance in a national emergency such as an infectious disease outbreak. [1] CROSS builds upon an earlier dPCM adopted in 2011 that created advanced rapid-response medical units in the regions called Health Modules (Moduli Sanitari), equipped with advanced medical capabilities and specialised personnel, able to intervene and act autonomously for up to 72 hours. [2] Thus the Department can use CROSS to communicate with the regional civil-protection and health authorities and direct the mobile health modules in emergencies. [1, 2] However, It is unclear if there is a set system by which CROSS interacts with healthcare workers.

No further evidence is found via the Ministry of Health's Center for Disease Prevention and Control or via the Department of Civil Protection's emergency response facilities. [3, 4]

The outbreak of the COVID-19 coronavirus pandemic in early 2020 has led the Italian government to design a new response plan with regard to future influenza pandemics. The new plan was adopted in January 2021 and covers the 2021-2023 period. Although it emphasizes the importance of structured communication in the inter-pandemic phase (such as between central government bodies and the regional ASLs, or healthcare authorities), it does not specifically address communication between public health officials and healthcare workers. [5]

[1] Official Gazette of the Italian Republic. June 24 2016. "DIRECTIVE OF THE PRESIDENT OF THE COUNCIL OF MINISTERS June 24, 2016 Identification of the Remote Central Emergency Medical Operations for the coordination of emergency medical assistance as well as Regional Health Referents in the event of a national emergency. (16A06112) (GU General Series n.194 of 20-08-2016) ("DIRETTIVA DEL PRESIDENTE DEL CONSIGLIO DEI MINISTRI 24 giugno 2016) Individuazione della Centrale Remota Operazioni Soccorso Sanitario per il coordinamento dei soccorsi sanitari urgenti nonche' dei Referenti Sanitari Regionali in caso di emergenza nazionale. (16A06112) (GU Serie Generale n.194 del 20-08-2016))".

[<http://www.gazzettaufficiale.it/eli/id/2016/08/20/16A06112/sg>] Accessed September 2020

[2] Official Gazette of the Italian Republic. June 28 2011. "DIRECTIVE OF THE PRESIDENT OF THE COUNCIL OF MINISTERS June

28, 2011 Operative guides for the activation and management of health modules in the event of a catastrophe. (11A14018) (GU General Series n.250 of 26-10-2011) (DIRETTIVA DEL PRESIDENTE DEL CONSIGLIO DEI MINISTRI 28 giugno 2011 Indirizzi operativi per l'attivazione e la gestione di moduli sanitari in caso di catastrofe. (11A14018) (GU Serie Generale n.250 del 26-10-2011)".

[http://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=2011-10-26&atto.codiceRedazionale=11A14018&elenco30giorni=false] Accessed September 2020

[3] Republic of Italy. Ministry of Health. National Centre for Disease Prevention and Control (Centro nazionale per la prevenzione e il controllo delle malattie--Ccm). "The reaction to emergencies". <http://www.ccm-network.it/pagina.jsp?id=node/318&lingua=english>] Accessed September 2020

[4] Republic of Italy. Presidency of the Council of Ministers. Department of Civil Protection. 2020. "System at the Italy Situation Room (Sistema nella Sala Situazione Italia)". [http://www.protezionecivile.gov.it/attivita-rischi/schede-tecniche/dettaglio/-/asset_publisher/default/content/sistema-nella-sala-situazione-italia] Accessed September 2020

[5] Republic of Italy. Ministry of Health. Directorate-General of Sanitary Prevention. January 25 2021. "National strategic-operational plan for preparation and response to a flu pandemic (PanFlu) 2021-2023 (Piano strategico-operativo nazionale di preparazione e risposta a una pandemia influenzale (PanFlu) 2021-2023)."

[<https://www.quotidianosanita.it/allegati/allegato4004886.pdf>] Accessed April 2021 Other sources: Dott. Giuseppe Diegoli, Dott.ssa Eleonora Bertolani. 14 June 2017. "Emergency Plan for the Collective Prevention and Public Health Service (Piano emergenze del Servizio Prevenzione Collettiva e Sanità Pubblica)." PowerPoint presentation. Region of Emilia-Romagna. [http://salute.regione.emilia-romagna.it/prp/doc/atti-di-convegni/diegoli/at_download/file/Diegoli%2014%20giugno%202017.pdf]

4.5.1b

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

Yes = 1 , No = 0

Current Year Score: 0

Italy's system for communication during a public health emergency makes no particular provision for interaction with the private sector. No additional evidence is available from the Department of Civil Protection, Cabinet decrees on response to health emergencies, or the Ministry of Health's National Center for Disease Prevention and Control. [1, 4, 5]

A decree of the Presidency of the Council of Ministers ("dPCM"), in force as of 20 August 2016, concluded the reorganisation of the national medical emergency relief capabilities by setting up an entity called the Remote Medical Operations Emergency Unit (Centrale Remota Operazioni Soccorso Sanitario- -CROSS) to better coordinate urgent medical assistance in a national emergency such as an infectious disease outbreak. [1] CROSS builds upon an earlier dPCM, adopted on 28 June 2011, which created advanced rapid-response medical units in the regions called Health Modules (Moduli Sanitari), equipped with advanced medical capabilities and specialised personnel, able to intervene and act autonomously for up to 72 hours. This dPCM led to the signing of agreements between the Department of Civil Protection, the Armed Forces and volunteer organizations, creating a "mobile health assistance force" in Italy's regions. [1] Thus the Department can use CROSS to communicate with the regional civil-protection and health authorities and direct the mobile health modules in emergencies. Neither of these two dPCMs which created the current system make any particular provision for interaction of the responsible public authorities with private sector individuals or entities. [2,3]

The outbreak of the COVID-19 coronavirus pandemic in early 2020 has led the Italian government to design a new response plan with regard to future influenza pandemics. The new plan was adopted in January 2021 and covers the 2021-2023 period. Although it emphasizes the importance of structured communication in the inter-pandemic phase (such as between

central government bodies and the regional ASLs, or healthcare authorities), it does not specifically address communication between public health officials and the private sector. [6]

[1] Department of Civil Protection (Dipartimento della Protezione Civile). 23 August 2016. Directive on urgent health assistance for major emergencies published in the Official Gazette (Pubblicata in Gazzetta Ufficiale la Direttiva sui Soccorsi sanitari urgenti per grandi emergenze)". [http://www.protezionecivile.gov.it/jcms/it/view_new.wp?contentId=NEW58656] Accessed September 2020

[2] Official Gazette of the Italian Republic. June 24 2016. "DIRECTIVE OF THE PRESIDENT OF THE COUNCIL OF MINISTERS June 24, 2016 Identification of the Remote Central Emergency Medical Operations for the coordination of emergency medical assistance as well as Regional Health Referents in the event of a national emergency. (16A06112) (GU General Series n.194 of 20-08-2016) ("DIRETTIVA DEL PRESIDENTE DEL CONSIGLIO DEI MINISTRI 24 giugno 2016) Individuazione della Centrale Remota Operazioni Soccorso Sanitario per il coordinamento dei soccorsi sanitari urgenti nonche' dei Referenti Sanitari Regionali in caso di emergenza nazionale. (16A06112) (GU Serie Generale n.194 del 20-08-2016))".

[<http://www.gazzettaufficiale.it/eli/id/2016/08/20/16A06112/sg>] Accessed September 2020

[3] Official Gazette of the Italian Republic. June 28 2011. "DIRECTIVE OF THE PRESIDENT OF THE COUNCIL OF MINISTERS June 28, 2011 Operative guides for the activation and management of health modules in the event of a catastrophe. (11A14018) (GU General Series n.250 of 26-10-2011) (DIRETTIVA DEL PRESIDENTE DEL CONSIGLIO DEI MINISTRI 28 giugno 2011 Indirizzi operativi per l'attivazione e la gestione di moduli sanitari in caso di catastrofe. (11A14018) (GU Serie Generale n.250 del 26-10-2011))".

[http://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario?atto.dataPubblicazioneGazzetta=2011-10-26&atto.codiceRedazionale=11A14018&elenco30giorni=false] Accessed September 2020

[4] Republic of Italy. Ministry of Health. National Centre for Disease Prevention and Control (Centro nazionale per la prevenzione e il controllo delle malattie--Ccm). "The reaction to emergencies". [<http://www.ccm-network.it/pagina.jsp?id=node/318&lingua=english>] Accessed September 2020 and April 2021

[5] Republic of Italy. Presidency of the Council of Ministers. Department of Civil Protection. 2020. "System at the Italy Situation Room (Sistema nella Sala Situazione Italia)". [http://www.protezionecivile.gov.it/attivita-rischi/schede-tecniche/dettaglio/-/asset_publisher/default/content/sistema-nella-sala-situazione-italia] Accessed September 2020 and April 2021

[6] Republic of Italy. Ministry of Health. Directorate-General of Sanitary Prevention. January 25 2021. "National strategic-operational plan for preparation and response to a flu pandemic (PanFlu) 2021-2023 (Piano strategico-operativo nazionale di preparazione e risposta a una pandemia influenzale (PanFlu) 2021-2023)."

[<https://www.quotidianosanita.it/allegati/allegato4004886.pdf>] Accessed April 2021

4.6 INFECTION CONTROL PRACTICES AND AVAILABILITY OF EQUIPMENT

4.6.1 Healthcare associated infection (HCAI) prevention and control programs

4.6.1a

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

Yes = 1 , No = 0

Current Year Score: 1

There is evidence that Italy's public health system monitors and tracks the number of healthcare associated infections (HCAI) that take place in healthcare facilities.

The surveillance program is in line with the provisions of the European Center for Disease Prevention and Control (ECDC) and is made up of four components: 1. the National Surveillance System of Surgical Site Infections (SNiCh), which receives data from Health Agencies of nine regions; 2 the National Surveillance System for Infections in Intensive Care (SITIN), which aggregates data from different collaborative networks on intensive care; 3. Participation in ECDC prevalence studies of care-associated infections in acute care hospitals; and 4. Participation in ECDC prevalence studies of infections related to care in residential facilities for the elderly. [1]

[1] Republic of Italy. Ministry of Health. December 13 2019. "Surveillance of healthcare-related infections (Sorveglianza delle infezioni correlate all'assistenza)".

[<http://www.salute.gov.it/portale/malattieInfettive/dettaglioContenutiMalattieInfettive.jsp?lingua=italiano&id=1039&area=Malattie%20infettive&menu=ica>] Accessed September 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

Italy has several medical Ethics Committees at national and regional-local levels. Clinical trials in particular are governed by rules on good clinical practice. According to the Italian Medicines Agency (Agenzia Italiana del Farmaco--AIFA), clinical trials are regulated by Legislative Decree no 211 of 24 June 2003, which entered into force in January 2004 and transposed European Directive 2001/20/EC on implementing good clinical practice during the conduct of clinical trials on medicinal products for human use. The 2003 transposing decree further regulates the role of the Ethics Committees and the information to be submitted through the database of the National Monitoring Centre of Clinical Trials (Osservatorio Nazionale della Sperimentazione Clinica--OsSC). [1]

According to Legislative Decree 8 February 2013, Art. 1, with regard to clinical trials on medicinal products, ethics committees should: verify the applicability of the proposed trials, evaluating their rationale; verify the appropriateness of protocols (objectives, design, operation, result evaluation); verify the competence of researchers; and assess all the ethical aspects, with particular reference to informed consent, protection of confidentiality, and the use of biological samples. [2]

[1] Italian Medicines Agency (Agenzia Italiana del Farmaco--AIFA). August 2017. "Clinical Trials".

[<http://www.agenziafarmaco.gov.it/en/content/clinical-trials>] Accessed September 2020

[2] European Network of Ethics Research Committees (EUREC). "National Information: Italy".

[<http://www.eurecnet.org/information/italy.html>] Accessed September 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: 0

Available evidence does not indicate that Italy applies an expedited process for approving clinical trials for unregistered medical countermeasures (MCM) to treat ongoing epidemics. Its existing fast-track rules apply to rare diseases with low rates of incidence.

There is no readily available evidence from Ministry of Health decrees, from AIFA or from EUREC that Italy has such an expedited process. [1, 2, 3] Expanded access does not yet apply to the use of non-authorised products to treat pandemics. In November 2017, Italy's Ministry of Health enacted new fast-track rules on expanded access to a limited number of medicinal products subject to an ongoing authorization procedure. [3] The results of Phase I clinical trials may now under certain conditions "...be sufficient for requesting approval of an expanded access program intended to treat orphan diseases or rare cancers." This relatively new program is an example of a "compassionate use" program authorized by Article 83 of Regulation (EC) No 726/2004, on centrally approved medicinal products. Specific regulation of these is left to the Member States.

Italy's new rules on fast-track approval of clinical trials for MCMs applies specifically to rare diseases with low rates of incidence. There is no indication that this or any other of Italy's regulations allowing such expanded access apply to epidemics. [4, 5]

[1] Italian Medicines Agency (Agenzia Italiana del Farmaco--AIFA). Website. [<http://www.agenziafarmaco.gov.it/>] Accessed September 2020 and April 2021

[2] European Network of Ethics Research Committees (EUREC). "National Information: Italy". [<http://www.eurecnet.org/information/italy.html>] Accessed September 2020

[3] Official Gazzette of the Italian Republic. November 2 2017. "MINISTRY OF HEALTH DECREE September 7, 2017 Discipline of the therapeutic use of a medicine subjected to clinical trials. (17A07305) (GU General Series n.256 of 02-11-2017) (MINISTERO DELLA SALUTE DECRETO 7 settembre 2017 Disciplina dell'uso terapeutico di medicinale sottoposto a sperimentazione clinica. (17A07305) (GU Serie Generale n.256 del 02-11-2017)". [<http://www.gazzettaufficiale.it/eli/id/2017/11/02/17A07305/SG>] Accessed September 2020 and April 2021

[4] Riccardo Fruscalzo. November 15 2017. "New rules for expanded access in Italy". Hogan Lovells. [<https://www.hlregulation.com/2017/11/15/new-rules-for-expanded-access-in-italy/>] Accessed September 2020 and April 2021

[5] Italian Medicines Agency (Agenzia Italiana del Farmaco--AIFA). "Clinical Trials of Medicines in Italy 19th National Report - Year 2020 (La Sperimentazione Clinica dei Medicinali in Italia 19° Rapporto Nazionale - Anno 2020)". [https://www.aifa.gov.it/documents/20142/1284191/19-Rapporto-OsSC_2020.pdf/ed29d6ae-8efa-7c84-088c-0eddd1853ee5] Accessed April 2021

4.7.2 Regulatory process for approving medical countermeasures

4.7.2a

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

Yes = 1 , No = 0

Current Year Score: 1

Italy has a government agency responsible for approving new medical countermeasures (MCM) for humans. The Italian Medicines Agency (AIFA) approves and regulates medicinal products intended for human use--in a public health emergency or otherwise. Its Inspection and Certification Department works to ensure compliance with EU Good Manufacturing Practice and related guidelines. All facilities on the national territory that manufacture such products are regularly inspected. However, AIFA does not mention "medical countermeasures" specifically. [1]

Additionally, the Ministry of Health's Directorate-General for Medical Devices and Pharmaceutical Service (Direzione generale dei dispositivi medici e del servizio farmaceutico--DGFD) regulates medical devices--in a public health emergency or otherwise. [2]

In October 2014 Italy signed the European Union's Joint Procurement Agreement to procure medical countermeasures, a directive that specifically addresses threats of a biological nature. [3]

[1] Italian Medicines Agency (Agenzia Italiana del Farmaco--AIFA). 2020. Website. [<http://www.aifa.gov.it/en>] Accessed September 2020

[2] Republic of Italy. Ministry of Health. Directorate-General for Medical Devices and Pharmaceutical Service. April 17 2020. Webpage.

[http://www.salute.gov.it/portale/ministro/p4_5_2_4_1.jsp?lingua=italiano&menu=uffCentrali&label=uffCentrali&id=1153] Accessed September 2020

[3] European Commission. Crisis preparedness and response. 2020. "Signing ceremonies for Joint Procurement Agreement." [https://ec.europa.eu/health/preparedness_response/joint_procurement/jpa_signature_en] Accessed September 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: 0

There is little evidence of an expedited process for approving medical countermeasures during public health emergencies in Italy. The Italian Medicines Agency (AIFA) and the Ministry of Health's Directorate-General for Medical Devices and Pharmaceutical Service (DGFD) regulate medicinal products and medical devices respectively. Evidence is not readily available from them that they expedite such approval--in a public health emergency or otherwise. [1, 2]

In late 2017, Italy's Ministry of Health enacted new fast-track rules on expanded access to some medicinal products undergoing authorization procedures. [3, 4] But there is no readily available evidence that this pertains to the use of medical countermeasures during public health emergencies. Expanded access may now be sought for advanced-therapy medicinal products (ATMPs) and for products such as pharmaceuticals authorized in Italy or abroad for a different therapeutic use. [3, 4] The text of the decree creating these new rules lists the products and serious or life-threatening medical conditions that may justify expanded access to them, such as orphan diseases or rare cancers. But it does not mention countermeasures to treat pandemics and the like. [3, 4]

AIFA has expedited the approval of some therapies for life-threatening conditions, but there is little evidence that it expedites the approval of medical countermeasures for use in a public health emergency. Nor is there evidence that the two bodies in charge of the Italian National Antidote Stock--the Ministry of Health and the Pavia Poison Control Centre--have such

responsibility. [1, 2, 6]

[1] Italian Medicines Agency (Agenzia Italiana del Farmaco--AIFA). 2020. Website. [<http://www.aifa.gov.it/en>] Accessed September 2020

[2] Republic of Italy. Ministry of Health. Directorate-General for Medical Devices and Pharmaceutical Service. April 17 2020. Webpage.

[http://www.salute.gov.it/portale/ministro/p4_5_2_4_1.jsp?lingua=italiano&menu=uffCentrali&label=uffCentrali&id=1153] Accessed September 2020

[3] Official Gazette of the Italian Republic. November 2 2017. "MINISTRY OF HEALTH DECREE September 7, 2017 Discipline of the therapeutic use of a medicine subjected to clinical trials. (17A07305) (GU General Series n.256 of 02-11-2017) (MINISTERO DELLA SALUTE DECRETO 7 settembre 2017 Disciplina dell'uso terapeutico di medicinale sottoposto a sperimentazione clinica. (17A07305) (GU Serie Generale n.256 del 02-11-2017)".

[<http://www.gazzettaufficiale.it/eli/id/2017/11/02/17A07305/SG>] Accessed September 2020

[4] Riccardo Fruscalzo. November 15 2017. "New rules for expanded access in Italy". Hogan Lovells.

[<https://www.hlregulation.com/2017/11/15/new-rules-for-expanded-access-in-italy/>] Accessed September 2020

[5] Virgilio Costanzo, MD. June 9 2016. "The system for emergency management: The National Antidote Stock (Il sistema per la gestione delle emergenze : La Scorta Nazionale Antidoti)". PowerPoint presentation. Ministry of Health Directorate General for Health Prevention (Ministero della Salute Direzione Generale della Prevenzione Sanitaria). [https://antidoti.ospfe.it/wp-content/uploads/2017/02/La-Scorta-Nazionale-Antidoti_Costanzo_9.6.16.pdf] Accessed September 2020

[6] Pavia Poison Control Centre (Centro Antiveneni di Pavia--CAV). Website. [<http://www-3.unipv.it/reumatologia-tossicologia/cav/CAV/index.php>] Accessed September 2020

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

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

5.1.1 Official IHR reporting

5.1.1a

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

Yes = 1 , No = 0

Current Year Score: 1

2020

World Health Organization

5.1.2 Integration of health into disaster risk reduction

5.1.2a

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

Yes = 1, No = 0

Current Year Score: 0

Available evidence indicates that in Italy epidemics and pandemics are not specifically integrated into the national risk reduction strategy. Moreover there is no standalone national disaster risk reduction strategy for epidemics and pandemics.

Italy's national risk-reduction strategy is run by the Cabinet-level Department of Civil Protection and mainly concerns civil protection. It does not specifically integrate pandemics. [1] Although there is no evidence of a stand-alone risk-reduction strategy for pandemics, the Ministry of Health's National Center for Disease Prevention and Control (CCM) is tasked with pandemics risk reduction. As envisaged by the Ministerial Decree of 18 September 2008, the CCM is charged with analysing the risks from health emergencies and supporting the front-line regional health agencies with surveillance and prevention plans. In the event of pandemics, the CCM forms a Pandemics Committee to coordinate with regional and other bodies. [2]

An example of a plan integrating such risk reduction is the Ministry of Health's 2006 National Plan for addressing influenza pandemics, which adopted the WHO's classification for the six phases of pandemic, with risk management strategies embedded in each phase. [3]

[1] Republic of Italy. Presidency of the Council of Ministers. Department of Civil Protection. March 9 2011. "THE ITALIAN NATIONAL PLATFORM FOR DISASTER RISK REDUCTION".
[http://www.protezionecivile.gov.it/resources/cms/documents/Italian_national_platform_disaster_risk_pdf.pdf] Accessed September 2020

[2] Republic of Italy. Ministry of Health. National Centre for Disease Prevention and Control (Ccm). "The reaction to emergencies". [<http://www.ccm-network.it/pagina.jsp?id=node/318&lingua=english>] Accessed September 2020

[3] Republic of Italy. Ministry of Health. 2006. "NATIONAL PLAN FOR PREPAREDNESS AND RESPONSE TO AN INFLUENZA PANDEMIC." [http://www.salute.gov.it/imgs/C_17_pubblicazioni_501_ulterioriallegati_ulterioreallegato_0_alleg.pdf] Accessed September 2020

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

Italy has cross-border agreements as part of a regional group with regards to public health emergencies. As a Member State of the European Union (EU), Italy is party to the EU's policy on the cross-border preparedness for and response to health threats and emergencies.

The EU's Decision 1082/2013/EU on serious cross-border threats to health set the framework for preparedness and response to health emergencies. It works to ensure the inter-operability of national health emergency plans through coordination mechanisms. [1] EU Member States are thus required to notify the European Commission within 24 hours after the discovery of a serious cross-border threats to health. This is done confidentially, through the EU's Early Warning and Response system (EWRS). If the threat is caused by communicable diseases or antimicrobial resistance and healthcare-associated infections; or is of unknown origin, a risk assessment is carried out by the European Centre for Disease Prevention and Control (ECDC), [1] If an EU Member State intends to mount a public health response to a serious cross-border threat, it must first consult with all other EU countries unless immediate adoption is essential. In the event such a threat overwhelms national response capacities, an affected EU country may ask for assistance from other EU countries through the Community Civil Protection Mechanism. [1]

[1] European Commission. Crisis Preparedness and Response. "Crisis Management". 2020.

[https://ec.europa.eu/health/preparedness_response/crisis_management_en] Accessed September 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

Italy has cross-border agreements with the European Union (EU) with regards to animal health emergencies. As a Member State of the EU, Italy is party to the EU's Decision 1082/2013/EU on cross-border preparedness for and response to health threats and emergencies. This Decision states that diseases can arise from contact with animals, and also mandates close cooperation between health and veterinary sectors on preparedness and response planning in the event of a serious cross-border threat to health originating from a zoonotic infection. [1]

EU Regulation 2016/429A, otherwise known as the Animal Health Law, more specifically addresses emergencies arising from transmissible animal diseases. It addresses cross-border issues in several areas. Part VII of the Regulation deals with Emergency Measures, Article 257 mandating the Competent Authority of a Member State to execute specified control measures for listed diseases and impose restrictions on animals and products in the case of emerging diseases and hazards. In Article 258, the Regulation mandates authorities of Member States other than the Member State where the outbreak occurred, to take emergency measures specified in that Article. [2]

[1] European Commission. Crisis Preparedness and Response. "Crisis Management". 2020.

[https://ec.europa.eu/health/preparedness_response/crisis_management_en] Accessed September 2020

[2] Official Journal of the European Union. Volume 59, March 31 2016. "Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health (Animal Health Law)". [<https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=OJ:L:2016:084:FULL&from=EN>] Accessed September 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: 0

2021

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

5.4.1b

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

Yes = 1 , No = 0

Current Year Score: 0

2021

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

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

5.4.2a

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

Yes = 1 , No = 0

Current Year Score: 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

Available evidence does not indicate that Italy has allocated national funds to improve capacity specifically to address epidemic threats within the past three years. Italy has a Fund for National Emergencies (Fondo per le emergenze nazionali-- FEN), funded from the national budget, although evidence indicates that it has not generally been used to address public health emergencies. [1, 2] The FEN is part of the civil protection system, which is distinct from the health care system, and prior to 2020 there is no direct evidence from the legislature or from the Department of Civil Protection that the FEN has been applied toward health emergencies such as pandemics. [2, 3] In recent years, the FEN has focused on capital projects for the reconstruction of areas affected by natural disasters. [2]

Similarly, neither the health nor agriculture ministries provide evidence of having dedicated funds specifically to address epidemic threats within the past three years. [3, 4] A review of the official State budget for the Ministry of Health over the three years of the 2019-2021 period does not show specific allocations made for addressing such threats. [5]

[1] Chamber of Deputies (Camera dei Deputati). May 24 2017. "Themes of parliamentary activity THE FINANCING OF CIVIL PROTECTION INTERVENTIONS (Temi dell'attività parlamentare IL FINANZIAMENTO DEGLI INTERVENTI DI PROTEZIONE

CIVILE)". [http://www.camera.it/leg17/561?appro=le_misure_finanziarie_] Accessed September 2020

[2] Republic of Italy. Presidency of the Council of Ministers. Department of Civil Protection. "Civil Protection Legal Measures: Legge n. 225 del 24 febbraio 1992: istituzione del Servizio Nazionale della Protezione Civile".

[http://www.protezionecivile.gov.it/amministrazione-trasparente/provvedimenti/dettaglio/-/asset_publisher/default/content/legge-n-225-del-24-febbraio-1992-istituzione-del-servizio-nazionale-della-protezione-civile] Accessed September 2020

[3] Republic of Italy. Ministry of Health. 2020. Website [<http://www.salute.gov.it>] Accessed September 2020

[4] Republic of Italy. Ministry of Agricultural, Food and Forestry Policies. 2020. Website.

[<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/202>] Accessed September 2020

[5] Republic of Italy. Ministry of Economy and Finance. December 2018. "STATE BUDGET FOR THE THREE YEARS 2019 - 2021 MINISTRY OF HEALTH (BUDGET DELLO STATO PER IL TRIENNIO 2019 - 2021 MINISTERO DELLA SALUTE)."

[http://www.rgs.mef.gov.it/_Documenti/VERSIONE-l/attivita_istituzionali/formazione_e_gestione_del_bilancio/bilancio_di_previsione/budget_economico/2019-2021/DLB/150-DLB-2019-2021.pdf] Accessed September 2020

5.5.2 Financing under Joint External Evaluation (JEE) and Performance of Veterinary Services (PVS) reports and gap analyses

5.5.2a

Does the Joint External Evaluation (JEE) report, National Action Plan for Health Security (NAPHS), and/or national GHSA roadmap allocate or describe specific funding from the national budget (covering a time-period either in the future or within the past five years) to address the identified gaps?

Yes = 1 , No/country has not conducted a JEE = 0

Current Year Score: 0

2021

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

5.5.2b

Does the Performance of Veterinary Services (PVS) gap analysis and/or PVS assessment allocate or describe specific funding from the national budget (covering a time-period either in the future or within the past five years) to address the identified gaps?

Yes = 1 , No/country has not conducted a PVS = 0

Current Year Score: 0

2021

OIE PVS assessments

5.5.3 Financing for emergency response

5.5.3a

Is there a publicly identified special emergency public financing mechanism and funds which the country can access in the face of a public health emergency (such as through a dedicated national reserve fund, an established agreement with the

World Bank pandemic financing facility/other multilateral emergency funding mechanism, or other pathway identified through a public health or state of emergency act)?

Yes = 1, No = 0

Current Year Score: 1

Available evidence indicates that Italy has a publicly identified special emergency public financing mechanism and funds which the country can access in the face of a public health emergency.

Italy has a Fund for National Emergencies (Fondo per le emergenze nazionali--FEN), funded from the national budget, although evidence indicates that it has not been directly used to address public health emergencies. [1, 2] The FEN is part of the civil protection system, which is distinct from the health care system, and prior to 2020 there is no direct evidence from the legislature or from the Department of Civil Protection that the FEN has been applied toward health emergencies such as pandemics. [2, 3] In recent years, the FEN has focused on capital projects for the reconstruction of areas affected by natural disasters. [2]

Nevertheless, in the wake of the COVID-19 coronavirus outbreak, on April 20 2020 the Council of Ministers approved a new allocation of funds totaling € 900,000,000 from the FEN in favor of the extraordinary Commissioner appointed to address the Covid-19 emergency. The Council made clear that its decision was made "...in consideration of the evolution of the emergency context and in order to allow the continuation of the planned interventions (purchase of personal protective equipment, medical equipment and all kinds of instrumental goods useful for countering the emergency, as well as the expansion of both temporary and permanent hospital structures intended for the treatment of coronavirus patients." [3]

[1] Chamber of Deputies (Camera dei Deputati). May 24 2017. "Themes of parliamentary activity THE FINANCING OF CIVIL PROTECTION INTERVENTIONS (Temi dell'attività parlamentare IL FINANZIAMENTO DEGLI INTERVENTI DI PROTEZIONE CIVILE)". [http://www.camera.it/leg17/561?appro=le_misure_finanziarie_] Accessed September 2020

[2] Republic of Italy. Presidency of the Council of Ministers. Department of Civil Protection. "Civil Protection Legal Measures: Legge n. 225 del 24 febbraio 1992: istituzione del Servizio Nazionale della Protezione Civile". [http://www.protezionecivile.gov.it/amministrazione-trasparente/provvedimenti/dettaglio/-/asset_publisher/default/content/legge-n-225-del-24-febbraio-1992-istituzione-del-servizio-nazionale-della-protezione-civile] Accessed September 2020

[3] Republic of Italy. Presidency of the Council of Ministers. Undated. "Coronavirus: the measures taken by the government (Coronavirus, le misure adottate dal Governo)". [<http://www.governo.it/it/coronavirus-misure-del-governo>] Accessed September 2020

5.5.4 Accountability for commitments made at the international stage for addressing epidemic threats

5.5.4a

Is there evidence that senior leaders (president or ministers), in the past three years, have made a public commitment either to:

- Support other countries to improve capacity to address epidemic threats by providing financing or support?
- Improve the country's domestic capacity to address epidemic threats by expanding financing or requesting support to improve capacity?

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

Current Year Score: 0

There is insufficient evidence that Italy's senior leaders have made a public commitment over the past three years to support other countries to improve capacity to address epidemic threats by providing financing or support. There is also insufficient evidence that they have made a commitment to improve the country's own domestic capacity to address epidemic threats by expanding financing or requesting support.

Although there is evidence of support for international infectious diseases, it does not address infectious disease with pandemic potential. In August 2019, the Government of Italy announced a pledge of €161m over the next three years to the Global Fund to Fight AIDS, Tuberculosis and Malaria. The pledge was announced by Prime Minister Giuseppe Conte during the G7 Summit in Biarritz, France. The funds represent a 15% increase from Italy's previous contribution to the Fund to fight epidemics of these diseases. [1]

No evidence of a commitment to improve Italy's domestic capacity to fight epidemics is found via the websites of the Ministry of Health, the Ministry of Foreign Affairs and the United Nations in Italy. [2, 3, 4] the Ministry of Health's budget for the 2019-2021 period shows no specific allocation in this regard. [5]

[1] The Global Fund. August 25 2019. "Global Fund Welcomes Italy's Increased Contribution."

[<https://www.theglobalfund.org/en/news/2019-08-25-global-fund-welcomes-italy-increased-contribution/>] Accessed September 2020

[2] Republic of Italy. Ministry of Health. 2020. Website. [<http://www.salute.gov.it/>] Accessed September 2020

[3] Republic of Italy. Ministry of Foreign Affairs and International Cooperation. Official website. [<https://www.esteri.it/mae/en>] Accessed September 2020

[4] United Nations Italy. Official website. [<https://www.un.org/sg/en/countries/italy>] Accessed September 2020

[5] Republic of Italy. Ministry of Economy and Finance. December 2018. "STATE BUDGET FOR THE THREE YEARS 2019 - 2021 MINISTRY OF HEALTH (BUDGET DELLO STATO PER IL TRIENNIO 2019 - 2021 MINISTERO DELLA SALUTE)."

[http://www.rgs.mef.gov.it/_Documenti/VERSIONE-I/attivita_istituzionali/formazione_e_gestione_del_bilancio/bilancio_di_previsione/budget_economico/2019-2021/DLB/150-DLB-2019-2021.pdf] Accessed September 2020

5.5.4b

Is there evidence that the country has, in the past three years, either:

- **Provided other countries with financing or technical support to improve capacity to address epidemic threats?**
- **Requested financing or technical support from donors to improve the country's domestic capacity to address epidemic threats?**

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

Current Year Score: 1

There is evidence that in the past three years Italy has provided financing to support other countries to improve their capacity to address epidemic threats. It has received negligible amounts of financing from donors to improve its own domestic capacity to this end.

Globally, Italy commits funds to various countries to aid in efforts against epidemic diseases. According to the Georgetown Infectious Disease Atlas (GIDA) Global Health Security Tracker, over the years 2014 to 2020 Italy as a donor nation has disbursed US\$84.87m for domestic capacity improvement and has to-date committed US\$198.97m for this purpose. [1] By contrast, GIDA indicates next to no financing disbursed and committed (US\$43,570 and an unreported amount, respectively) to Italy over this time period as a recipient for domestic capacity improvement. [2]

[1] Global Health Security Agenda (GHSA). GHS Tracking Dashboard. 2020. "Funder Profile:Italy."
[<https://tracking.ghscosting.org/details/113/funder>] Accessed September 2020
[2] Global Health Security Agenda (GHSA). GHS Tracking Dashboard. 2020. "Recipient Profile:Italy."
[<https://tracking.ghscosting.org/details/113/funder>] Accessed September and October 2020

5.5.4c

Is there evidence that the country has fulfilled its full contribution to the WHO within the past two years?

Yes = 1 , No = 0

Current Year Score: 1

2021

Economist Impact analyst qualitative assessment based on official national sources, which vary by country

5.6 COMMITMENT TO SHARING OF GENETIC AND BIOLOGICAL DATA AND SPECIMENS

5.6.1 Commitment to sharing genetic data, clinical specimens, and/or isolated specimens (biological materials) in both emergency and nonemergency research

5.6.1a

Is there a publicly available plan or policy for sharing genetic data, clinical specimens, and/or isolated specimens (biological materials) along with the associated epidemiological data with international organizations and/or other countries that goes beyond influenza?

Yes = 1 , No = 0

Current Year Score: 1

There is evidence that Italy has a public policy for sharing genetic samples and clinical specimens with international organisations and/or other countries on infectious diseases that go beyond influenza.

Italy is a member of the Global Health Security Initiative, which has supported voluntary agreements among members to facilitate the rapid sharing of non-influenza biological materials during a potential or actual public health emergency. [1,2]

Beyond this, Italy has an advanced network of biobanks holding biological material, but the evidence from BBMRI, the Italian National Node of the European Biobanks and BioMolecular Resources Research Infrastructure (BBMRI-ERIC), does not suggest that there is a national or comprehensive policy for them to share samples with international agencies as opposed to local partners. [3]

As a Member State of the European Union, Italy cooperates closely on data sharing with the European Centre for Disease Prevention and Control (ECDC), but does not have information on sharing of specimens. [4]

[1] Global Health Security Initiative. 2020. "GHSI Members." [<http://ghsi.ca/ghsi-members/>]. Accessed September 2020
[2] Global Health Security Initiative. 2017. "Ministerial Statements: Brussels, Belgium - February 24, 2017."
[<http://www.ghsi.ca/english/statementBrussels2017.asp>]. Accessed September 2020

[3] BBMRI. 2020. "Biobanks (Biobanche)." [<https://www.bbmri.it/nodo-nazionale/biobanche/>] Accessed September 2020

[4] European Centre for Disease Prevention and Control (ECDC). 2020. "Disease and laboratory networks."

[<https://www.ecdc.europa.eu/en/about-us/who-we-work/disease-and-laboratory-networks>] September 2020

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 from news media or from the (World Health Organization) WHO that Italy has not shared samples in accordance with the PIP framework in the past two years.

According to the WHO's PIP Framework Annual Progress Report for 2018, during that year 75% of countries (3 of 4) that reported zoonotic influenza cases to WHO, shared Influenza Viruses with Human Pandemic Potential (IVPP) with the GISRS system; 132 countries shared influenza viruses/clinical specimens with WHO CCs at least once. [1]

[1] World Health Organization (WHO). Pandemic Influenza Preparedness Framework ("PIP Framework"). 2018. "Pandemic Influenza Preparedness Framework 1 January - 31 December 2018 ANNUAL PROGRESS REPORT."

[https://www.who.int/influenza/pip/benefit_sharing/pip_annualreport_31dec2018.pdf?ua=1] Accessed September 2020

5.6.1c

Is there public evidence that the country has not shared pandemic pathogen samples during an outbreak in the past two years?

Yes = 0 , No = 1

Current Year Score: 1

There is no public evidence either from news media or from international agencies such as the World Organisation for Animal Health (OIE), the World Health Organization (WHO) and the European Centre for Disease Prevention and Control (ECDC) that indicate that Italy has not shared pandemic pathogen samples other than influenza during an outbreak in the past two years.

[1, 2, 3] Lastly, there is no public evidence that Italy has not shared samples of the COVID-19 coronavirus; on the contrary, the Ministry of Health and the National Institute of Health (ISS) have collaborated to adapt the InFluNet national surveillance and reporting system, normally used to collect influenza samples, for the novel coronavirus. The National Influenza Center now collects COVID-19 samples under a revised protocol, known as CovidNet. On a weekly basis, the ISS and the NIC submit both epidemiological data to the ECDC and virological data to the WHO and ECDC. [4]

[1] World Organisation for Animal Health (OIE). 2020. WAHIS Interface. "Italy: exceptional epidemiological events: 2020."

[https://www.oie.int/wahis_2/public/wahid.php/Countryinformation/Countryreports] Accessed September 2020

[2] World Health Organization (WHO). "Emergencies preparedness, response: Italy."

[<http://www.who.int/csr/don/archive/country/ita/en/>] Accessed September 2020

[3] European Centre for Disease Prevention and Control (ECDC) "Tools." [<https://ecdc.europa.eu/en/tools>] Accessed September 2020

[4] Republic of Italy. Ministry of Health. Novel coronavirus (nuovo coronavirus). 2020. "Flu season 2020-2021, InFluNet & CovidNet operating protocol (Stagione influenzale 2020-2021, protocollo operativo InFluNet & CovidNet)."

[<http://www.salute.gov.it/portale/nuovocoronavirus/dettaglioNotizieNuovoCoronavirus.jsp?lingua=italiano&menu=notizie&>

p=dalministero&id=5122] Accessed October 2020

Category 6: Overall risk environment and vulnerability to biological threats

6.1 POLITICAL AND SECURITY RISK

6.1.1 Government effectiveness

6.1.1a

Policy formation (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 2

2020

Economist Intelligence

6.1.1b

Quality of bureaucracy (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 2

2020

Economist Intelligence

6.1.1c

Excessive bureaucracy/red tape (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 2

2020

Economist Intelligence

6.1.1d

Vested interests/cronyism (Economist Intelligence score; 0-4, where 4=best)

Input number

Current Year Score: 1

2020

Economist Intelligence

6.1.1e

Country score on Corruption Perception Index (0-100, where 100=best)

Input number

Current Year Score: 53

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: 2

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: 1

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: 1

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: 3

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: 99.16

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: 0.93

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: 1.1

2017

World Bank; Economist Impact

6.2.3b

Share of employment in the informal sector

Greater than 50% = 2, Between 25-50% = 1, Less than 25% = 0

Current Year Score: 0

According to a study published by the World Bank in 2012, informal self-employed workers accounted for around 20% of Italy's labor force. [1]

[1] Truman Packard, Johannes Koettl, and Claudio E. Montenegro. 2012. "In From the Shadow: Integrating Europe's Informal Labor." The World Bank.

[<http://documents1.worldbank.org/curated/en/458701468035954123/pdf/706020PUB0EPI0067902B09780821395493.pdf>]
Accessed September 2020

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: 1

2021

Economist Intelligence Democracy Index

6.2.6 Inequality

6.2.6a

Gini coefficient

Scored 0-1, where 0=best

Current Year Score: 0.36

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: 2

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: 2

2021

Economist Intelligence

6.4 ENVIRONMENTAL RISKS

6.4.1 Urbanization

6.4.1a

Urban population (% of total population)

Input number

Current Year Score: 70.74

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: 1.52

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: 83.35

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: 289.1

2019

WHO

6.5.1c

Population ages 65 and above (% of total population)

Input number

Current Year Score: 23.01

2019

World Bank

6.5.1d

Prevalence of current tobacco use (% of adults)

Input number

Current Year Score: 23.4

2018

World Bank

6.5.1e

Prevalence of obesity among adults

Input number

Current Year Score: 19.9

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: 98.77

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: 2677.77

2018

WHO Global Health Expenditure database

6.5.4 Trust in medical and health advice

6.5.4a

Trust medical and health advice from the government

Share of population that trust medical and health advice from the government , More than 80% = 2, Between 60-80%, or no data available = 1, Less than 60% = 0

Current Year Score: 1

2018

Wellcome Trust Global Monitor 2018

6.5.4b

Trust medical and health advice from medical workers

Share of population that trust medical and health advice from health professionals , More than 80% = 2, Between 60-80%, or no data available = 1, Less than 60% = 0

Current Year Score: 2

2018

Wellcome Trust Global Monitor 2018