Project methods

A team of subject matter experts at the Georgetown University Center for Global Health Science and Security identified key areas of infectious disease preparedness and response in which national regulations or other implementing legislation will govern outbreak prevention and response. The team tracked each country's status with regard to relevant treaties, and also identified key topics.

Treaties, topics, and country inclusion

Treaties

The team developed a list of twelve treaties that are most relevant to outbreak prevention and response:

1. Biological Weapons Convention
2. Convention on Biological Diversity
    a. Cartagena Protocol
    b. Nagoya Protocol
3. Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)
4. Geneva Protocol
5. International Health Regulations

6. Paris Agreement
7. World Health Organization Constitution
8. World Organization for Animal Health (formerly OIE)
9. World Trade Organization (Marrakesh Agreement)
    a. Agreement on Trade-Related Aspects of Intellectual Property Rights, including the Doha Declaration

The team reviewed official websites and/or the UN depository page to identify the most recent version of each treaty or international organization's constitution. We then uploaded the treaty document to a database and cataloged the relevant dates (e.g., date signed, date ratified/accessed, date entered into force) and any reservations, understandings, and declarations for each country.

Topics

The team, again in consultation with other subject matter experts, identified key topic areas in which national regulations or other implementing legislation govern outbreak prevention and response. The list will continue to grow as the project expands.

Topics completed so far:

1. Access and benefit sharing
2. Antimicrobial resistance and water, sanitation, and hygiene
3. Antimicrobial resistance in agriculture
4. Childhood vaccination
5. General vaccination policies
6. Trade and intellectual property

Topics in progress:

1. Biosafety
2. Biosecurity
3. Export controls
4. Military engagement
5. Quarantine and isolation

6. Risk communication and community engagement

Literature Review & Subtopic Selection

To begin, we conducted a literature review to identify key themes and important areas of legislation related to the overarching topic. Following this step, we pulled 4-6 key themes in order to create subtopics for each topic. We then coded these subtopics following a review of the relevant legislation, as outlined below.

Legislation

After selecting subtopics, our researchers review government websites and existing databases to identify relevant national legislation. Any legal documents with relevant provisions are uploaded to our Airtable database. Sections that address the subtopic (e.g., a clause outlining provisions for restricting vaccine exports during an outbreak) are highlighted to help users quickly find the relevant information.

Country Inclusion

Our team reviewed national legislation from each of the 193 UN member states for each topic. Additional countries and/or territories were reviewed if they were identified as having separate legislation during the initial topic literature review, or if they are members/observers of a treaty or international organization relevant to the topic (e.g., a WHO associate member). Legislation from subnational entities is outside the scope of this project.

Access and benefit-sharing methods

Access and benefit-sharing (ABS) occupy a legislative space at the nexus of environmental legislation, biotechnology, intellectual property, and for our purposes specifically, epidemiology. As a result, the research team performed a

literature and landscape review of these disparate fields to identify relevant legislation.

Identification of relevant policies

For each country, 5 search steps were conducted in sequence.

Firstly, the ABS Clearing House (ABSCH) was used. This is an online platform administered by the Convention of Biological Diversity Secretariat where providers may share documents and legislation relevant to ABS. Each country's profile was reviewed in turn, and the available legislation was downloaded.

Secondly, the World Intellectual Property Organization (WIPO) LEX database was searched. The WIPOLEX is centrally administered by the WIPO and contains legislation relevant to intellectual property in each country. Each country was searched, and laws were filtered for a "Genetic Resources" tag. If the legislation was available, it was downloaded.

Thirdly, the Food and Agriculture Organization legal database (FAOLEX) was used to widen the scope of capture, as one of the world's largest legal databases. The sections of "Environment" and "Wild Species and Ecosystem" were manually reviewed, and relevant legislation was extracted.

Where possible, the next step involved a manual search of the national government's legal database. The website was either referenced in one of the previous databases or was obtained from a manual Google search. If a legal database was available and open-access, it was perused for legislation relevant to ABS and genetic resources. Any legislation found was downloaded.

The final step in the search was a manual search on the Google search engine, with the first results page being reviewed using the following search terms:

- [Insert Country] "access benefit sharing"
- [Insert Country] "digital sequence information"
- [Insert Country] "genetic resource"

If the previous 5 steps failed to yield ABS-relevant legislation, the country was coded as “No ABS legislation available.”

Any relevant legislation not in English or French was then translated into English using Google Translate.

Country status and inclusion criteria

Policies included in the Analysis and Mapping of Policies for Emerging Infectious Disease database must be legally binding. As a result, documents encompassing strategies, reports, and draft laws were not included. The only exception was the inclusion of support documents designed to clarify the interpretation of associated active laws.

Scope of legislation Included documents were analyzed for the scope of their application. Many laws were drafted for different purposes, including biological conservation, biotechnology, and scientific research. Furthermore, some laws predated the widespread use of genetic technology. As a result, the wording of the law varied, and with it, its scope of application. Approaching laws from the perspective of pathogen-sharing, the research team found three broad interpretations of the scope described below.

The modern gold standard, as defined by the Nagoya Protocol, applied legislation to all genetic material and associated traditional knowledge. Another option was to establish the scope as genetic material alone, with no mention of traditional knowledge. A third option used a variety of specific scopes such as “flora and fauna”, “plants and animals”, or any other phrase which failed to capture micro-organisms such as bacteria and viruses. Any countries lacking any sort of legislation applicable to the access and/or benefit-sharing of genetic resources were coded as having no legislation. This included legislation that covered traditional knowledge without genetic material and legislation that was deemed too broad, such as covering “all natural resources.” Once potentially relevant policies that were legally enforceable and within scope were identified, the criteria described below were utilized to assess their applicability for inclusion in

the database. Legislation not relevant to any of the above subtopics was not uploaded into the database.

Digital sequence information Included documents were analyzed for their interpretation of digital sequence information (DSI). Where laws made their inclusion or exclusion of genetic sequence explicit, these were coded accordingly. Where laws used unclear terminology that could be interpreted to include DSI, these were coded as such. Where supporting documents existed that clarify a country's interpretation of its law, these were also uploaded and the country's DSI status was adjusted. Any countries lacking any sort of legislation applicable to the access and/or benefit-sharing of genetic resources were coded as having no legislation.

Access to resources Included documents were analyzed for the restrictions they imposed on access the genetic resources. If they made explicit that access to domestic resources was unrestricted, meaning that any foreign party could acquire and utilize genetic resources domestically free from fees or permits, they were coded as such. If any fees, permits, consent-seeking procedure, or benefit-sharing mechanism were incurred for access, this was coded as restricted. Any countries lacking any sort of legislation applicable to the access and/or benefit-sharing of genetic resources were coded as having no legislation.

Prior informed consent Included documents were analyzed for references to any prior informed consent mechanism (PIC) applicable. PIC refers to a process whereby local government entities or local communities need to consent to the acquisition and/or utilization of the genetic resources priorly. In the Nagoya protocol, this must also be fully informed, meaning that they must be provided with the full information on volume, purpose, and time of access. Countries with unrestricted access were excluded from this, as this was de facto not applicable. Countries with restricted access were differentiated into whether they had an outlined prior consent requirement of any kind, or not. Any countries lacking any sort of legislation applicable to the access and/or benefit sharing of genetic resources were coded as having no legislation.

Contractual terms Included documents were analyzed for references to any contract-setting process. Many countries require a formalized contract-setting process to access genetic resources, often with terms relating to the agreed-upon benefits to be shared. This can take various forms, including Mutually Agreed Terms, Material Transfer Agreements, ABS contracts, and more. Some countries furthermore provide model contracts, or strict guidance, to facilitate the process. Countries with unrestricted access were excluded from this, as this was de facto not applicable. Countries with access restrictions were divided according to contract requirements of any kind, or not. Any countries lacking any sort of legislation applicable to the access and/or benefit-sharing of genetic resources were coded as having no legislation.

Benefit-sharing Included documents were analyzed for references to benefit-sharing. Benefit-sharing refers to the process of sharing any incurred benefits from the accessed genetic resource. This can take a monetary form (such as royalties, access fees, and milestone payments), or a non-monetary form (such as scientific collaboration, capacity-building, or technology transfer). Countries with unrestricted access were excluded from this, as this was de facto not applicable. Countries with access restrictions were divided according to whether they had outlined benefit-sharing requirements, or not. Any countries lacking any sort of legislation applicable to the access and/or benefit-sharing of genetic resources were coded as having no legislation.

Compliance Included documents were analyzed for their establishing of compliance mechanisms. This was taken to mean any mechanism by which a country could ensure the legality of accessed resources was maintained, such as instituting enforcement agents or regular checkpoints. Here, countries without access restrictions were included, as many such countries still required compliance with foreign countries' legislation. Countries were coded as either having compliance mechanisms outlined or not. Any countries lacking any sort of legislation applicable to the access and/or benefit-sharing of genetic resources were coded as having no legislation.

Legal sanctions Included documents were analyzed for specific legal sanctions relating to non-compliance with ABS legislation. This was taken to mean laws specifically applicable to the unauthorized access, export, and/or utilization of genetic resources. Here too, countries without access restrictions were included, as many such countries still required compliance with foreign countries' legislation. This was divided according to type, such as fines and criminalization (including incarceration), access restrictions (confiscations, revocations, or bans), or both. Any countries lacking any sort of legislation applicable to the access and/or benefit-sharing of genetic resources were coded as having no legislation.

Antimicrobial resistance and water, sanitation, and hygiene methods

In order to facilitate multi-faceted research on the nexus of Water, Sanitation and Hygiene (WASH) and Antimicrobial Resistance (AMR), a literature and landscape review was conducted by the research team to identify relevant topics for inclusion in the database. After preliminary policy categories were identified, a subject matter expert (SME) was consulted to verify the relevance of the areas of study. The selected topics explored the policies that may have both direct and indirect effects on the prevalence of AMR microbes in the environment.

Identification of Relevant Policies

The AMR LEX database (https://amr-lex.fao.org/main/profile/en), powered by the Food and Agriculture Organization of the United Nations (FAO LEX) was consulted to find relevant national legislation. Once identified from AMR LEX, policies were located and downloaded from an online repository of national legislation from the country's domain, where possible.

Where the relevant legislation was not found on AMR LEX, a standardized series of queries was used to search the internet for appropriate policies. The list of query terms used for each subtopic was developed by conducting a review of the

legislation surfaced by various queries for 10 countries to establish which search terms surfaced the most relevant policies. The standardized series of query terms utilized by the research team is listed below. In the case that all queries failed to produce relevant policies, the country was coded as having no relevant policies within that subtopic.

- Water Quality Standards: 1) “Water Quality Standards Regulations [Insert Country]” 2) “Water Quality Laws [Insert Country]” 3) “[Insert Country] Water Quality Standards”
- Water Quality Monitoring: 1) “Water Quality Monitoring Policy [Insert Country]” 2) “[Insert Country] Environmental Impact Assessment Laws” 3) “[Insert Country] Environmental Monitoring legislation”
- Pollutant Disposal in Water Sources: 1) “Water Pollution Regulations [Insert Country]” 2) “Water Pollution Laws [Insert Country]’ 3) “Pollutant Disposal Laws [Insert Country]”
- Sewerage: 1) “Sewerage Regulations [Insert Country]” 2) “Sewerage Laws [Insert Country]” 3) “[Insert Country] Sanitation Policy”
- Effluent Wastewater Disposal: 1) “Effluent Wastewater regulations [Insert Country]” 2) “Wastewater disposal regulations [Insert Country]” 3) “[Insert Country] Discharge Standards”
- Medical Waste Disposal: 1) “Medical waste policy [Insert Country]’ 2) “Medical Waste Management regulations [Insert Country]” 3) “[Insert Country] hazardous waste laws”

In many cases, search terms surfaced peer-reviewed publications assessing WASH infrastructure and policy within a country. In these cases, the research team conducted a review of available publications to ascertain the existence of relevant national level policies in that country and identify their titles. Any potentially relevant policies were then searched for by title. When policy titles had been translated into English, Google Translate was used to allow the research team to search for the title in the original language.

Once a potentially-relevant policy had been identified, a thorough review of the policy language was conducted by the policy team. For policies written in languages other than English or Spanish, Google Translate was used when necessary for policy review. The policy was then assessed based on the Inclusion Criteria.

Inclusion Criteria

Policies included in the Analysis and Mapping of Policies for Emerging Infectious Disease database are required to be legally binding. Strategies, plans and other documents outlining future actions of the national government or suggesting criteria for the development of legally-binding policies were excluded from this research effort.

Water Quality Standards Water quality policies included in this database were legally-binding policies that either directly set standards for water quality or mandated that a governmental body do so, including for drinking-water quality, environmental water quality, and/or recreational water quality. Any policy that addressed one or all of these categories of water was captured and included in the database. As the type of water quality regulated varied across countries and policies, the category of water covered in the document was noted in the document description. Countries that had published national plans to set water quality standards in the future, or use World Health Organization water quality standards but have not codified this practice, were coded as having no policy establishing water quality standards. Countries that were found to regulate water quality standards at the subnational level were coded as having water quality regulations, and the status justification was utilized to note the level of government where the policy could be located.

Water Quality Monitoring Policies included in the subtopic for water quality monitoring mandate that a competent environmental authority within the government either has the power to conduct or regulate the monitoring of residues in water sources. Applicable policies fell into two categories. In one

category, included policies stated that, at regular intervals, an entity responsible for ensuring the quality of water was overseeing the testing of water sources to monitor for contamination with pollutants, which could include antimicrobial substances. In the second category, policies included in the database are those that mandate that environmental impact assessments be conducted at sites that were potentially harmful to the environment, such as construction sites, industrial facilities, or agricultural areas. The category for policies in this subtopic was noted in the document description. Countries that were found to conduct monitoring at the subnational level were coded as having a mandate to conduct water quality monitoring, and the status justification was utilized to note the level of government where the policy could be located.

Pollutant Disposal in Water Sources Policies included in this subtopic establish legally-binding regulations on point-source pollution. The subtopic was intentionally designed to be broad, allowing for any regulation on chemical discharges into freshwater to be captured. Regulations included in the database establish maximum residue limits, criminalize the unlawful discharge of chemicals in water sources or outline penalties for point-source polluters. Countries that were found to regulate pollutant disposal in water sources at the subnational level were coded as having pollutant disposal regulations, and the status justification was utilized to note the level of government where the policy could be located.

Sewerage Policies included in this subtopic are legally-binding regulations on sewerage systems, all of which must have included requirements for sewerage infrastructure. While not used as a standard for inclusion, where available, policies that mandated that sewerage infrastructure be monitored by a competent governmental authority or established procedures for treatment and discharge of domestic sewage were also included. Plans to establish or expand sanitation infrastructure and guidelines for sanitation service provision that were not legally-enforceable were not included in this database. Countries that were found to regulate sewerage at the subnational level were coded as having

sewerage regulations, and the status justification was utilized to note the level of government where the policy could be located.

Effluent Wastewater Disposal Effluent wastewater disposal policies included in this subtopic are legally-binding regulations on the treatment and disposal of wastewater into water sources. Included regulations were those establishing chemical standards and approving discharge locations for wastewater from domestic and industrial locations. Specific regulations on wastewater from agricultural facilities or regulating the use of wastewater in agricultural practices were not included, as they were deemed beyond the scope of the project by the research team. In cases where all categories of wastewater were regulated by a single national policy, that policy was captured and included in the database. Countries that were found to regulate effluent discharge at the subnational level were coded as having effluent discharge regulations, and the status justification was utilized to note the level of government where the policy could be located.

Medical Waste Disposal Medical waste disposal policies included in this subtopic establish legally-enforceable methods for the management and final disposal of medical and pharmaceutical waste from healthcare or manufacturing facilities. Often, these regulations exist within broader regulations on hazardous waste. In these instances, the research team conducted a rigorous review of the policy language. As countries utilize various terms to encompass medical waste management, hazardous waste policies were included if they contained provisions for the handling and disposal of infectious, hospital, healthcare, bio-medical or medical waste. Guidelines published to inform the development of healthcare waste disposal policies at individual healthcare facilities were not included, as these documents are not legally-enforceable at the national level. Countries that were found to regulate medical waste disposal at the subnational level were coded as having medical waste disposal regulations, and the status justification was utilized to note the level of government where the policy could be located.

Antimicrobial resistance in agriculture methods

The research team collected data on policies directly relevant to antimicrobial resistance, such as policy on the prescription and sale of veterinary antimicrobials, as well as policy which indirectly addresses antimicrobial resistance through the management of animal health, such as regulating animal movement to prevent and control the spread of communicable diseases in animals. Data on relevant feed policies, in particular relating to the prophylactic use of antimicrobials and medicated feed were also collected.

Identification of relevant policies

The AMR LEX database, powered by the Food and Agriculture Organization of the United Nations, was consulted to find relevant national legislation. This was then cross-checked with the country's own legislature online, where possible. Where the relevant legislation was not found on AMR LEX, the country's legislature website was consulted directly. For certain subtopics, the WHO Global Database for Tracking Antimicrobial Resistance Country Self-Assessment Survey (TrACSS) was also cross-referenced where available. These were accessed between January and May 2023.

Policies included in the Analysis and Mapping of Policies for Emerging Infectious Disease database are required to be legally binding. Strategies, plans and other documents outlining future actions of the national government or suggesting criteria for the development of legally-binding policies were excluded from this research effort. Policies enacted at the national-level were collated within the database. Countries in which categories of policies are found universally at the subnational level were coded as having the associated policy, but the documents themselves were not collected within the document repository. Instead, the status justification was used to note that the policy existed at the subnational level.

When no policy could be surfaced through identification methods, the status for that category of policy was marked as the country not having an applicable policy.

Inclusion criteria

Once potentially relevant policies were identified, the following criteria were utilized to assess their applicability for inclusion in the database:

Competent veterinary authority Policies included under this subtopic identify and empower a veterinary authority to oversee and regulate the practice of veterinary practitioners within their jurisdiction. Policies that did not identify a veterinary authority or grant the veterinary authority the power to regulate veterinarians or that planned future strategies to empower a regulatory body overseeing veterinary practitioners were not included.

Qualifications for prescribing veterinary medical products Policies under this topic outline legally-enforceable standards for the qualifications of personnel prescribing veterinary medications. Included policies may address the academic and/or professional qualifications required for legal prescription of veterinary drugs, which may include antimicrobials. Guidelines for personnel prescribing veterinary medicines that were not legally enforceable or did not require that the personnel have acquired a standardized level of qualification were excluded from the database.

Prescription and sale of veterinary medical products Policies in this category create a legal framework for transactions involving veterinary medical products. Included policies must create a legally-enforceable mechanism for regulating the sale and prescription of veterinary drugs. These policies must not merely outline qualifications for those individuals approved to prescribe drugs, but must create a standardized framework for the conditions that warrant their prescription and sale. The majority of policies in this category outlined a list of ‘prescription only medicines’ (POMs), which included antimicrobials for veterinary use.

Prophylactic use of antimicrobials Policies under this topic must create a regulatory framework for the use of antimicrobial substances in animal agriculture. Policies that either banned or restricted the prophylactic use of antimicrobials in terrestrial and aquatic farmed animals were included in this database. Policies underwent a rigorous language review to be categorized as applying only to terrestrial animals, only to aquatic animals, to all farmed animals, or having no regulation on the use of antimicrobials in farming. Policies that outlined best practices for the use of AGPs, yet were not legally-enforceable, were excluded.

Medicated feed Policies in this category regulate the use of medicated feed in farmed animals within a jurisdiction. Included legally-enforceable frameworks must ban or limit the use of medicated feed in agricultural facilities.

Childhood vaccination methods

The research team conducted a literature and landscape review to identify policies directly relevant to childhood vaccination. After preliminary policy categories were identified, a subject matter expert (SME) was consulted to verify the relevance of the areas of study. Previous analyses of vaccination policies have focused on mandates within individual countries or geographical regions. This project represents the most comprehensive mapping of legally enforceable childhood and emergency immunization policy to date.

*Note: The childhood vaccination and general vaccination topics were led by the same member of the research team and were conducted simultaneously, as there is significant overlap in the topics. Thus, the methodology is largely the same for both topics, except for the inclusion criteria used for subtopic categories.

Country selection

The research team analyzed routine childhood and emergency vaccination policies for 192 of the United Nations (UN) Member States, as well as the Holy See (Vatican City) and Taiwan. The Democratic People's Republic of Korea (ROK) was excluded due to a lack of publicly available policy information.

Definitions

Only legally binding policies were included in the study. To capture the diversity of ways in which countries codify their rules and regulations, in this work, policy was used as a broad term to describe a legally binding document produced by a competent governing authority to control the conduct of individuals and entities within their jurisdiction. For this work, we categorized legally binding policies as those that included specific enforcement mechanisms in the document or associated with a penal code that could be used to require parties within the jurisdiction to comply with the document's contents. Strategies, plans, and other documents outlining future actions of the national government or suggesting criteria for the development of legally binding policies were excluded from this research effort. Similarly, documents codifying country participation in the World Health Organization's Expanded Programme on Immunizations (EPI) or other similar vaccination campaigns offering vaccinations to the population are not legally binding for citizens and were therefore excluded from this database.

Vaccination mandates vary significantly across nations and regions. However, this work necessitated a standardized definition for systematic application across all contexts included in this analysis. We therefore defined mandatory vaccination policy as a legally enforceable rule by which individuals are mandated to be vaccinated or to have their dependents vaccinated against one or more diseases.

A condition for inclusion in this research was that the policy had to be valid and capable of being enforced. Separately, we assessed enforcement mechanisms as specific language included in policies. Thus, legally enforceable policy and the existence of an enforcement mechanism are not synonymous, as provisions within a policy can lack a clear scheme for enforcement.

Routine childhood vaccination is the immunization of individuals legally categorized as children on a prescribed interval for a set of conditions, per internationally agreed best practices. Emergency vaccination, on the other hand, is used in this work to describe vaccinations that are prescribed as the result of an acute threat facing a population (e.g. war, natural disaster, disease outbreak), and may not limited to a particular demographic group within a population.

Policies created to mandate vaccination against COVID-19 have been previously described and were outside the scope of this work. These policies do not appear in our database. We do, however, include policies that address general emergency vaccination powers, many of which were utilized for COVID-19 vaccinations.

Identification of relevant policies

A standardized series of queries was used to search for appropriate policies. The standardized query terms used for each topic were developed through a literature review and then evaluated by reviewing the legislation surfaced by various queries for a 10-country pilot study to establish which search terms returned the most relevant policies. Throughout policy identification, all searches were first conducted in English. For countries where English is not utilized to conduct governmental affairs, Google Translate was used to translate the queries into the language used by the targeted country's government. If all queries failed to produce relevant policies, the country was coded as having no relevant policies identified within that subtopic. In each case, a literature review was conducted to verify that no vaccination mandates are currently enforceable within that country.

Once a potentially relevant, legally binding policy had been identified, a thorough review of the policy language was conducted by the research team. For policies written in languages other than those spoken by the research team, Google Translate was used for policy review and a fluent speaker was contacted to

confirm translation, where applicable. The policy was then assessed based on the inclusion criteria.

Country status and inclusion criteria

Any country found to mandate childhood or emergency vaccinations universally at the subnational level, such as the USA, was coded as having that category of regulation, and the status justification was utilized to note the level of government where the policy could be located. The regulation of a policy category in a country at the subnational level was verified by identifying national-level policy devolving power over the specified sector to a subnational governing body. Countries in which some provinces have enforceable vaccination mandates, while others do not, were coded as having no relevant policy. This was the case for Canada, which only had vaccine mandates for Ontario, New Brunswick, and Manitoba provinces. This also applied to Pakistan, which only had identifiable vaccination requirements in Sindh province.

Additionally, in many cases, the legally enforceable policy mandated that the relevant authority, often the Ministry of Health, set a calendar of diseases for which vaccinations must be routinely administered to children. In these cases, the research team surfaced the most recent version of this immunization calendar on the target country's domain and used that calendar in conjunction with the policy authorizing its creation for inclusion criteria assessment.

Inclusion criteria were used to perform a standardized, yet flexible review of the contents of policies across the diversity of socio-political contexts present in UN Member States. The inclusion criteria were used to assess which subcategories were contained within each policy. The inclusion criteria framework used in this study is described below.

Measles Policies included in this database were those legally binding policies that mandated that children residing in the country be vaccinated against measles with a measles-containing vaccine. To meet the criteria, this policy must have either directly stated that children were required to be vaccinated against

measles or empowered a competent authority to set a mandatory vaccination calendar that included vaccination against measles. Countries that were found to universally mandate vaccination at the subnational level were coded as having mandatory vaccination against measles and the status justification was used to note which level of government the applicable policy could be located.

Polio Policies included in this database are those legally binding policies that mandate that children residing in the country be vaccinated against polio. To meet the criteria, this policy must have either directly stated that children were required to be vaccinated against polio or empowered a competent authority to set a mandatory vaccination calendar that included a vaccination against polio. Countries that were found to universally mandate vaccination at the subnational level were coded as having mandatory vaccination against polio and the status justification was used to note which level of government the applicable policy could be located.

Diptheria Policies included in this database are those legally binding policies that mandate that children residing in the country be vaccinated against diphtheria. To meet the criteria, this policy must have either directly stated that children were required to be vaccinated against diphtheria or empowered a competent authority to set a mandatory vaccination calendar that included a vaccination against diphtheria. Countries that were found to universally mandate vaccination at the subnational level were coded as having mandatory vaccination against diphtheria and the status justification was used to note which level of government the applicable policy could be located.

Tuberculosis Policies included in this database are those legally binding policies that mandate that children residing in the country be vaccinated against tuberculosis. To meet the criteria, this policy must have either directly stated that children were required to be vaccinated against tuberculosis or empowered a competent authority to set a mandatory vaccination calendar that included a vaccination against tuberculosis. Countries that were found to universally mandate vaccination at the subnational level were coded as having mandatory

vaccination against tuberculosis and the status justification was used to note which level of government the applicable policy could be located.

Varicella Policies included in this database are those legally binding policies that mandate that children residing in the country be vaccinated against varicella. To meet the criteria, this policy must have either directly stated that children were required to be vaccinated against varicella or empowered a competent authority to set a mandatory vaccination calendar that included vaccination against varicella. Countries that were found to universally mandate vaccination at the subnational level were coded as having mandatory vaccination against varicella and the status justification was used to note which level of government the applicable policy could be located.

General vaccination policies methods

The research team conducted a literature and landscape review to identify general and emergency vaccination policies. After preliminary policy categories were identified, a subject matter expert (SME) was consulted to verify the relevance of the areas of study. Previous analyses of vaccination policies have focused on mandates within individual countries or geographical regions. This project represents the most comprehensive mapping of legally enforceable general and emergency immunization policy to date.

*Note: The childhood vaccination and general vaccination topics were led by the same member of the research team and were conducted simultaneously, as there is significant overlap in the topics. Thus, the methodology is largely the same for both topics, except for the inclusion criteria used for subtopic categories.

Country selection

The research team analyzed routine childhood and emergency vaccination policies for 192 of the United Nations (UN) Member States, as well as the Holy See (Vatican City) and Taiwan. The Democratic People's Republic of Korea (ROK) was excluded due to a lack of publicly available policy information.

Definitions

Only legally binding policies were included in the study. To capture the diversity of ways in which countries codify their rules and regulations, in this work, policy was used as a broad term to describe a legally binding document produced by a competent governing authority to control the conduct of individuals and entities within their jurisdiction. For this work, we categorized legally binding policies as those that included specific enforcement mechanisms in the document or associated with a penal code that could be used to require parties within the jurisdiction to comply with the document's contents. Strategies, plans, and other documents outlining future actions of the national government or suggesting criteria for the development of legally binding policies were excluded from this research effort. Similarly, documents codifying country participation in the World Health Organization's Expanded Programme on Immunizations (EPI) or other similar vaccination campaigns offering vaccinations to the population are not legally binding for citizens and were therefore excluded from this database.

Vaccination mandates vary significantly across nations and regions. However, this work necessitated a standardized definition for systematic application across all contexts included in this analysis. We therefore defined mandatory vaccination policy as a legally enforceable rule by which individuals are mandated to be vaccinated or to have their dependents vaccinated against one or more diseases.

A condition for inclusion in this research was that the policy had to be valid and capable of being enforced. Separately, we assessed enforcement mechanisms as specific language included in policies. Thus, legally enforceable policy and the existence of an enforcement mechanism are not synonymous, as provisions within a policy can lack a clear scheme for enforcement.

Routine childhood vaccination is the immunization of individuals legally categorized as children on a prescribed interval for a set of conditions, per internationally agreed best practices. Emergency vaccination, on the other hand, is used in this work to describe vaccinations that are prescribed as the result of an acute threat facing a population (e.g. war, natural disaster, disease outbreak), and may not limited to a particular demographic group within a population.

Policies created to mandate vaccination against COVID-19 have been previously described and were outside the scope of this work. These policies do not appear in our database. We do, however, include policies that address general emergency vaccination powers, many of which were utilized for COVID-19 vaccinations.

Identification of relevant policies

A standardized series of queries was used to search for appropriate policies. The standardized query terms used for each topic were developed through a literature review and then evaluated by reviewing the legislation surfaced by various queries for a 10-country pilot study to establish which search terms returned the most relevant policies. Throughout policy identification, all searches were first conducted in English. For countries where English is not utilized to conduct governmental affairs, Google Translate was used to translate the queries into the language used by the targeted country's government. If all queries failed to produce relevant policies, the country was coded as having no relevant policies identified within that subtopic. In each case, a literature review was conducted to verify that no vaccination mandates are currently enforceable within that country.

Once a potentially relevant, legally binding policy had been identified, a thorough review of the policy language was conducted by the research team. For policies written in languages other than those spoken by the research team, Google Translate was used for policy review and a fluent speaker was contacted to

confirm translation, where applicable. The policy was then assessed based on the inclusion criteria.

Country status and inclusion criteria

Any country found to mandate childhood or emergency vaccinations universally at the subnational level, such as the USA, was coded as having that category of regulation, and the status justification was utilized to note the level of government where the policy could be located. The regulation of a policy category in a country at the subnational level was verified by identifying national-level policy devolving power over the specified sector to a subnational governing body. Countries in which some provinces have enforceable vaccination mandates, while others do not, were coded as having no relevant policy. This was the case for Canada, which only had vaccine mandates for Ontario, New Brunswick, and Manitoba provinces. This also applied to Pakistan, which only had identifiable vaccination requirements in Sindh province.

Inclusion criteria were used to perform a standardized, yet flexible review of the contents of policies across the diversity of socio-political contexts present in UN Member States. The inclusion criteria were used to assess which subcategories were contained within each policy. The inclusion criteria framework used in this study is described below.

Childhood vaccination requirement Documents included in this subtopic were those legally binding policies that required parents or guardians of all children residing within the country of interest to be vaccinated against at least one disease. Policies that remained valid and required only vaccination against Smallpox for children are included in this database. Policies that meet the criteria for this category fall into two categories. Either, the policies directly mandated which diseases children were required to be vaccinated against, or the policy mandated that a competent authority set a calendar of mandatory vaccinations. Plans for mass vaccination campaigns or implementing legislation for the World Health Organization’s Expanded Programme on Immunizations (EPI) that did not

mandate vaccination were excluded from this database. Countries that were found to universally mandate vaccination at the subnational level were coded as having a childhood vaccination requirement and the status justification was used to note which level of government the applicable policy could be located.

Enforcement of childhood vaccination Policies included in this subtopic defined the mechanisms employed to enforce routine childhood vaccination mandates. These documents contained specific language indicating the sanctions or penalties that would be applied to individuals who failed to comply with mandatory vaccinations. To capture the diverse ways in which countries attempted to increase the fulfillment of childhood vaccination mandates, the research team defined an enforcement mechanism as a consequence specifically designed to punish noncompliance with vaccine mandates.

Exemption from childhood vaccination requirement This subtopic included policies that created a legal mandate for individuals to be exempt from routine vaccination mandates. These exemptions may fall into two categories, namely medical and non-medical exemptions. Medical exemptions were defined as those that were granted to an individual who was determined by a healthcare professional to be ineligible for a vaccination due to a physical health condition. By contrast, a non-medical exemption was any exemption granted due to religious, philosophical, or ideological principles that precluded an individual from receiving a vaccination. It is widely understood that medical exemptions are recognized in every country in the world; however, these exemptions are not always codified in the legally enforceable policy. Only those legally enforceable policies that included provisions for exemptions from routine vaccination were included.

Emergency vaccination Policies included in this subtopic were those that grant a competent authority the power to implement compulsory vaccination upon some or all of the individuals living under their jurisdiction during an emergency. While some policies broadly granted governments the right to take any action that is reasonable and necessary in the event of an emergency, only those

policies that explicitly stated that governments have the right to implement compulsory vaccination were included in the database.

Enforcement of emergency vaccination This subtopic included only policies that define the mechanisms employed to enforce compulsory emergency vaccinations. These documents contained specific language indicating the sanctions or penalties that would be applied to individuals who failed to comply with mandatory vaccination requirements. To capture the diverse ways in which countries attempted to increase compulsory vaccination acceptance, the research team defined an enforcement mechanism as a consequence specifically designed to punish noncompliance with emergency vaccine mandates

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Trade and intellectual property methods

In order to build a more complete picture of the patent legislation and compulsory licensing landscape, we collected data not only on patent legislation, but also on a country's WTO Member status, whether they are classified as an LDC by the UN, and their import and export status under TRIPS Article 31bis.

Sources

Sources included the World Intellectual Property Organization (WIPO) LEX database, an online database of IP laws and regulations from around the world. For countries whose patent legislation was not available on the WIPO LEX website, the websites of their national patent offices were consulted. In situations where the patent legislation was not available in English, it was translated using Google Translate. The WTO website was consulted for a list of WTO Members and Observers. The United Nations Conference on Trade and Development (UNCTAD) website was consulted to determine which countries are designated by the United Nations as the least developed countries.

Country status and policy inclusion criteria

Countries were assigned a status for each of the following five categories. WTO member status, LDC exemption status, and import/export status under TRIPS, country status could be pulled directly from WTO documentation. For compulsory licensing provision and pharmaceutical export provision, we identified the relevant country patent legislation in order to assign a status. For these two topics the inclusion criteria is described below.

World Trade Organization member status WTO member status was determined by looking at the latest edition of the Status of WTO Legal Instruments publication, published in 2021.

Least developed country (LDC) exemption under TRIPS LDC status was determined by consulting the list of least developed countries published by the UN on their website. There are currently 46 countries designated as LDCs by the UN. LDCs are automatically eligible importing Members under TRIPS Article 31bis.

Import and/or export status under Article 31bis Footnote 3 of the Annex to the TRIPS Agreement lists a number of countries that, for the purpose of Article 31bis, will not use the system as an importer. Other countries have stated that they will only use the system as importers in situations of national emergency or extreme urgency. Eligible importing Members are all LDCs (automatically), and those who have made notification to the TRIPS Council of their intent to use the system as an importing Member. Countries that are not LDCs and have not stated their intention either way were coded as 'Import/Export status not defined'.

Compulsory licensing provision We analyzed patent legislation for provisions on compulsory licensing. We searched patent legislation documents for key words relating to compulsory licensing, i.e. 'compulsory license', 'non-voluntary license', and 'use without authorization'.

Pharmaceutical export provision We analyzed patent legislation for provisions on compulsory licenses specifically for the import or export of pharmaceutical

products under the system defined in Article 31bis of the TRIPS Agreement. We searched for key words relating to this provision, i.e. 'pharmaceutical', 'medicine', 'drug', 'Doha', and 'August 30, 2003'.