

# Rapid Review

## Governance of COVID-19 Vaccine Data in Federations

Prepared for the Public Health Agency of Canada

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The views expressed herein do not necessarily represent the views of the Public Health Agency of Canada.



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## List of Abbreviations

AIR	Australian Immunisation Register
COVID-19	Coronavirus Disease 2019
DIM	Digitales Impfquotenmonitoring
FOPH	Federal Office of Public Health
IfSG	Protection Against Infection Act
MADIP	Multi-Agency Data Integration Project
PCEHR	Personally Controlled Electronic Health Record
RKI	Robert Koch Institute
SARS	Severe Acute Respiratory Syndrome
SHI	Social Health Insurance
UK	United Kingdom



### **Executive Summary**

The response to an emergency, such as the COVID-19 pandemic, can be particularly complex in federated systems as the federal and subnational governments often share responsibility for public health, and the level of coordination and collaboration required to protect and preserve public health is even more acute during such emergencies. For decades, information sharing across governments in Canada has been identified as a critical constraint in ensuring optimal decision-making and citizen outcomes. Other federations face similar challenges and have achieved various levels of success with implementing national public health surveillance drawing on subnational data.

This rapid review aims to draw lessons for Canada from other federations and quasi-federations (in the case of the United Kingdom [UK]) on the governance of COVID-19 vaccine data, with a view of compiling and standardizing subnational data at the national level. We conducted rapid comparative case studies of four jurisdictions (Germany, Australia, Switzerland, and the UK), which included an environmental scan of the literature with validation by local experts.

COVID-19 vaccine data governance approaches varied across the four jurisdictions. Australia has a centralized vaccine information system that is governed by immunization legislation, enabling a comprehensive national dataset for COVID-19 vaccines for surveillance, reporting, research, and data linkages. Germany operates a centralized vaccine information system that is governed by epidemic legislation and operationalized through a broad network of government and non-governmental stakeholders. Switzerland has decentralized COVID-19 vaccine information systems, where cantons report to the federal government in accordance with epidemics legislation. The UK does not have a specific legal basis for COVID-19 vaccine data sharing, but data is reported to the UK through collaborative efforts between statistical, public health, and/or government representatives in England, Wales, Scotland, and Northern Ireland. Each country in this review offers unique challenges to generating standardized COVID-19 vaccine data at a national level.

Based on this review, there are five key considerations for governance structures and mechanisms for facilitating and standardizing COVID-19 vaccine data, and health data more broadly, across governments:

- Immunization legislation or legislation related to the control of epidemics help set out expectations on the roles of subnational and national governments, and expectations concerning data sharing among governments. Such legislation could include stipulations related to establishing immunization registries (as in Australia), data reporting standards and data needs (as in Australia, Switzerland, and Germany), as well as data infrastructure needs.
- Data governance arrangements in place in each of these countries is shaped by their respective historically rooted health system context. Some key drivers of the current data governance mechanisms include public health emergencies, and system-wide health data strategies. The COVID-19 pandemic may similarly motivate legislative and health data governance changes in Canada.
- 3. Variation in **immunization management and reporting systems** across vaccination settings and providers can contribute to time lags and data quality problems that impede appropriate surveillance as well as the evidence needed for rapid and effective policy interventions by national and subnational governments. These were present for both centralized and decentralized immunization information systems. While details on mechanisms to overcome these issues were



not identified, ongoing financial and technical support may be important considerations for overcoming these challenges.

- 4. Legislation and guidelines around COVID-19 vaccine data collection and reporting tended to include minimum data sets and data variable descriptions at the national level for use within federal/national jurisdictions. Countries that did not have national frameworks, such as the UK, or where participation in the national data system was voluntary (as in Switzerland) tended to report discrepancies and inconsistencies in data across subnational jurisdictions. These discrepancies can have an impact on the accuracy of reporting vaccination rates at the national level.
- 5. The types of data to report and share may change over time due to epidemiological or health systems changes. While change cannot be anticipated, governance mechanisms should **build in capacity for change or adaptation to processes** around data collection, reporting, and use. For example, all countries appear to have adapted their vaccination reporting to include information on third dose/booster vaccinations. In Switzerland, this included updating instructions on minimum data requirements to regional-level governments.



## Introduction & Background

As of June 30, 2021, 3.9 million people had died of COVID-19 (1). As countries entered the recovery phase of the pandemic, an effective vaccine rollout became critical. Responding to an emergency, such as the COVID-19 pandemic, can be particularly complex in federated systems (2) as the federal and subnational governments often share responsibility for public health, and the level of coordination and collaboration required to protect and preserve public health is even more acute during such emergencies (3–5).

Federalism entails benefits whereby subnational decision-making is responsive to local populations and contexts (6,7). However, federalism creates challenges such as with effective public health surveillance and the (6,8) availability and sharing of information between different levels of government. For decades, information sharing across governments in Canada has been identified as a critical constraint in ensuring optimal decision-making and citizen outcomes (9,10). The issue of data sharing hindering effective and efficient COVID-19 vaccine rollout across the country has been repeatedly discussed by scholars and in the media (11–13). Public health and healthcare data are collected in 13 different systems (13). Despite some legislative support such as the *Statistics Act (1985)* and *Public Health Agency of Canada Act (2006)*, any data sharing across governments is predominantly a product of informal collegiality and trust (10,14).

Other federations face similar challenges, and have achieved various levels of success with implementing national public health surveillance drawing on subnational data (6). Examining these jurisdictions may provide some lessons for Canada.

This rapid review aims to draw lessons for Canada from three federations—Australia, Germany, and Switzerland—and a quasi-federation, the UK, on the governance of COVID-19 vaccine data. Specifically, we are interested in learning about how these countries compile and standardize subnational data. In this review, we describe data governance according to Micheli and colleagues (2020) as the:

[P]ower relationship between all actors affected by, or having an effect on, the way data is accessed, controlled, shared and used, as well as the various socio-technical arrangements set in place to generate value from data, and how such value is redistributed between actors. (15)



## Methods

We conducted rapid comparative case studies of four jurisdictions, which included an environmental scan of government and non-governmental resources with review and validation by local experts.

#### **Data Collection**

*Environmental scan:* We performed targeted and iterative searches of academic and grey literature in bibliographic databases and search engines (e.g., MEDLINE, Google Scholar) and websites of key organizations (e.g., federal organizations). Search terms related to the COVID-19 vaccine or its equivalents in combination with concepts, including data governance, data stewardship, information management, data privacy, information sharing, data sharing, federalism, and intergovernmental relations. The search was limited to the selected countries from December 2019 to the present. Where necessary, we used online translation services to translate websites and texts from German to English language. We developed a standardized case report template to guide our search and facilitate data collection.

Local expert review and validation: Following the environmental scan, we contacted 1–2 local expert informants from each of the four selected jurisdictions to validate and supplement the identified information. Expert informants included mid-career and senior decision-makers, clinicians, and academic researchers. The completed case report narratives and template were shared with the key informants, along with targeted questions to fill gaps in data collection (e.g., clarifying ambiguities; providing relevant internal sources that are not publicly available, including planned next steps; providing more up-to-date information; confirming accuracy; and describing changes, if any). Experts were invited to connect at their convenience via email, phone, teleconference, or videoconference (i.e., Zoom, Microsoft Teams, or telephone).

#### Data Synthesis

We used a comparative approach to understand COVID-19 vaccine data sharing governance mechanisms and practices between the federal and subnational governments in each country in relation to their contextual similarities and differences. Our analysis was guided by the concepts described by the Strategic Advisory Group of Experts on Immunization (SAGE) working group on quality and use of immunization and surveillance data report (Table 1) (16).

Domain	Description/Role in governance
1. Leadership & Political Will	To establish processes for reporting and data quality improvement.
	Includes a transparent and closely monitored plan.
2. Coordination	Structures or mechanisms to facilitate efficient communication and work
	across units.
3. Accountability	For clearly defined terms of reference and deliverables, mechanisms for
	monitoring.
4. Resources	Allocated to support all aspects of data collection and management.
	Ensure adequate human and financial resources at all levels.
5. Standards & user-friendly	For tools and processes, including feedback.
guidance	
6. Sharing/access of data and	To those who need it for planning and decision-making.
information	May include linkage to health and social sector data.

Table 1	Analytical	framework for	comparing	COVID-19	vaccine o	data sharing	and governance <sup>1</sup>
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<sup>1</sup>Modified from SAGE working group on quality and use of immunization and surveillance data.



#### Scope and Limitations

Due to time constraints this review did not explore all possible aspects of data governance, such as the following: the quality and completeness of data at the subnational or national level; processes for reporting vaccine safety; composition, characteristics, or performance of data management and data sharing teams; or detailed information about adjustments/adaptation to data sharing due to COVID-19 third-dose boosters.



## Analytic Overview

A comparison of governance and mechanisms to support COVID-19 vaccine data sharing in Australia, Germany, Switzerland, and the UK is described in Table 2. Generally, there is a mix of centralized and decentralized COVID-19 immunization data reporting systems across jurisdictions. The most centralized approach to data governance and sharing is in Australia and Germany, where there are also central coordinating bodies tasked with standardizing and compiling COVID-19 vaccines data across each country. In contrast, a decentralized approach to data governance is taken in Switzerland and the UK, though there are important differences between these two countries. In Switzerland, there is national legislation providing a framework for voluntary data sharing and standardization at the subnational (canton) level, while in the highly decentralized nations comprising the UK there is no strategy or legislation, nor any explicit incentives, to support data sharing with the UK government. In the absence of a strategy or legislation in the UK, each country maintains its own immunization programs and data systems, with some voluntary sharing of aggregated or open-data following UK-level recommendations. Further details on COVID-19 vaccine data sharing governance and mechanisms in each jurisdiction are described in the remaining pages of this report.

	Australia	Germany	Switzerland	United Kingdom
COVID-19 vaccine data coordinating bodies	National Immunisation Program	Robert Koch Institute (RKI)	Not specified	Ad hoc <sup>1</sup>
Nature of immunization data reporting systems	Centralized (Australian Immunisation Register)	Centralized (RKI) and decentralized <sup>2</sup>	Decentralized (cantons)	Decentralized (devolved governments)
Frequency of reporting	Daily	Daily	Daily	Daily <sup>1,2</sup>
Level of data	Record	Record & aggregate <sup>3</sup>	Record	Aggregate
Linkage of national-level COVID-19 vaccine data	Yes	No	No	No
Mention of data sharing in vaccine strategy	Yes	Yes	Yes	No
Legislation on vaccine data sharing/reporting	Yes	Yes	Yes	No
Documented description of data flow from subnational to national level	Not applicable <sup>4</sup>	Yes	Yes	Yes
Identified incentives to subnational-national data sharing	Human Technical	Human Technical Financial	Technical Financial	None

Table 2. COVID-19 vaccine data sharing characteristics, governance, and mechanisms in select countries

<sup>1</sup> In the UK, the constituent countries maintain their own national immunisation programs, and while there is some policy coordination, there is no obligation to share data with the UK government.

<sup>2</sup> In the UK, the Coronavirus Dashboard contains vaccination data for all countries, and depends on publicly reported data from Scotland, Wales, and Northern Ireland, which may or may not be updated daily.

<sup>3</sup> In Germany, depending on the vaccination provider, data are either reported directly to the RKI (federal and *Länder* [states] vaccination centres), or aggregate data is submitted to the RKI (Social Health Insurance-accredited and private medical practices).

<sup>4</sup> In Australia, due to the centralized reporting system, data flows from vaccine providers to a national register and therefore does not flow from subnational to national governments.



## **Country Profiles**

#### Australia

Australia comprises a federal government (formally known as the Commonwealth), six states, and two self-governing territories (17). The federal government oversees national policies and programs, including the Medicare Benefits Scheme (MBS) and the Pharmaceutical Benefits Scheme (PBS), and provides funding and indirect support for its programs. Subnational governments own and are responsible for delivery of public health services, including public hospitals and community health centres (18).

The COVID-19 vaccine immunization program is coordinated through the Commonwealth, state, and territory governments. States and territories are responsible for developing vaccination implementation plans in their respective jurisdictions, and work jointly with the Commonwealth government to develop plans that are inclusive to specific populations including some aged care facilities and disability group residents, and Indigenous communities (19). COVID-19 vaccines providers include general practices, Commonwealth vaccination clinics, state-run mass vaccination clinics, Aboriginal and Torres Strait Islander Community Controlled Health Centres, and Community Pharmacies (19,20).

#### COVID-19 vaccine data, reporting, and linkage

Vaccinations are recorded in the national Australian Immunisation Register (AIR) by vaccine providers. The Australian government established the AIR in 2016, which records vaccinations for all ages in Australia and is administered by Services Australia (21). Since the AIR is a national register, the Commonwealth government can review the uptake of vaccine data without the need to request data from state or territorial governments. Data that is reported from the AIR is de-identified before being disclosed to state or territorial governments, or when publicly reported (22).

COVID-19 vaccination data in the AIR has been linked to other de-identified Commonwealth databases through the Multi-Agency Data Integration Project (MADIP) to address specific policy questions (23). For example, de-identified AIR data has been linked to other sociodemographic datasets to help identify priority groups to target for vaccination (23). In general, the MADIP allows for linkages between various health and social datasets (e.g., MBS data, Census data) and is governed by the *Census and Statistics Act* (1905), the *Privacy Act* (1998), and legislation relevant to agencies that share information with MADIP (24). In addition, prescribed research organizations, such as universities, have access to AIR data to carry out government contracted projects.

#### Related policies and legislation

Reporting of vaccination data, including COVID-19 vaccination, is governed by the *Australia Immunization Register (AIR) Act (2015)* and in accordance with the *Privacy Act (1998;* (22). The *AIR Act* commenced in January 2016 with the aim to consolidate legislation related to Australian immunisation registers and to generate a register that would capture immunisation data for all ages (birth-to-death) (21,25). In the early 2000s, the Australian Government undertook a review to consider the option of creating a whole-of-life register that would address concerns with existing immunisation registers, namely, the Australian Child Immunisation Register (ACIR) and National Human Papillomavirus Vaccination Register (HPV register). For example, the HPV register did not collect data on other adolescent vaccinations. At the time, there were also no national registers for adults, which was a concern raised by the Australian Technical Advisory Group on Immunisation (ATAGI) and recommended by the Pharmaceutical Benefits Advisory Committee



(PBAC). Specifically, there was no way of accurately recording vaccine administrations for shingles and therefore no way to assess the effectiveness of Zostavax or other vaccination programs. Ultimately, the Australian Government endorsed the development of the whole-of-life vaccination register (26).

The Australian Immunisation Register Rule, 2015 was amended in February 20, 2021 to include mandatory reporting of vaccinations, including COVID-19 vaccines given on or after 20 February 2021, to the AIR (27,28). This is described in Part 3 section 9 of the Australian Immunisation Register Rule (see e-Appendix A). The Australian Immunisation Register Rule, 2015 also describes the minimum data elements that are required to be reported to the AIR for all vaccines (see e-Appendix B).

The COVID-19 Vaccination Policy describes the key responsibilities of all levels of government, including the role of each jurisdiction in data collection, reporting, and monitoring (19). The *Australian COVID-19 Vaccination Policy* also outlines the role of AIR and how vaccination data will be used; this includes monitoring vaccine effectiveness and safety, identifying at-risk areas, informing immunisation policy, and monitoring vaccination coverage.

#### Structures and mechanisms related to COVID-19 vaccine data sharing/reporting

- **Technical resources**: COVID-19 vaccination providers report through pre-existing infrastructure that is centrally housed and has the capability to be shared with different levels of government. Vaccine providers can report through practice management software or directly through AIR. This process is eased by using Australian residents' Medicare records as a pre-existing identifier, as all Australian residents are automatically enrolled in the national health insurance scheme known as Medicare.
- Human resources: To report COVID-19 vaccinations, health professionals and organisations must be recognized as vaccination providers in AIR. The COVID-19 vaccination policy specifies that training is required for all vaccine providers (20). There are specific policies for vaccine reporting available for private providers and community pharmacies (29,30). In addition, the Australian Government provides further assistance and training to providers who do not comply with reporting (31).
- **Financial resources**: Since its inception, the national AIR receives federal funding. In response to the COVID-19 pandemic, the AIR received additional investments to increase its role and expand its capabilities, including additional features, data options, and reporting options.
- Broader health data context: In the early 2000s, Australia moved towards establishing electronic health information exchange systems that would support safe and quality health care. In 2003, the Australia Health Minister's Advisory Council proposed the development of a national e-health system that would be funded by Commonwealth, state, and territorial bodies. Since then, several strategies and initiatives have highlighted federal, state, and territorial support for electronic health records, as well as concerns regarding their clinical utility and data privacy. For example, the Personally Controlled Electronic Health Record (PCEHR) was launched in 2012 and aimed to contain various health information including healthcare and immunisation data. Due to resistance from the medical community and poor uptake, another health data strategy was developed and in 2016 the PCEHR was subsequently revised and renamed as the My Health Record. These revisions focused on ease of use, e-health incentives for practices, and technical modifications to ensure privacy and security (32), and helped pave the way for the consolidated AIR.



#### Challenges and opportunities with the state of data sharing

There are challenges and opportunities with managing and reporting COVID-19 vaccine data in Australia. First, despite a national vaccine registry for COVID-19 vaccinations in Australia, not all vaccine providers were set up to report or transfer vaccine data to the AIR. For example, state-run facilities (e.g., hospitals, community health centres) were not previously set up for mass vaccine entries to AIR. State-run vaccination clinics required specialized solutions to transfer data to AIR, which resulted in significant delays in reporting vaccination numbers from state run clinics. Ultimately, this was resolved by mid-August 2021. Second, before the pandemic, there were limited human resources or expertise available to prepare vaccine data for the wider public. Part of the *Australian COVID-19 Vaccination Policy* involved reviewing the technical capacity of the AIR to perform new functions (19). This resulted in additional investments in human resources, as well as a consultation period to improve the AIR.

The use of Medicare information as pre-existing identifiers in the AIR allows vaccinations to be matched to existing records, which can reduce the risk of duplication or gaps. Information is matched deterministically using residents' Medicare number, name, and address. This process ensures records are accurate and reliable, no individual is recorded twice, and everyone receives the right dose. However, the matching process requires additional time, costs, and resources to ensure there are no discrepancies in data fields (e.g., when a Medicare number does not match listed name or address). Since the COVID-19 vaccination program aims to vaccinate nearly all Australians (approximately 26 million individuals), a 1% discrepancy rate in the AIR requires additional resources to review and correct discrepancies.

The broader immunization data system in Australian also offers positive insights for data sharing initiatives between health and social sectors. As mentioned above, the AIR is administered by Services Australia, which delivers social, health, and child support services (33). Since the 1990s, immunization registers have been linked to childcare subsidies, family tax benefits, and welfare payments. In the past, the Commonwealth Government used these data linkages to set up financial incentives to increase vaccine uptake; this included reducing fortnightly benefit rates for children who were not fully immunised in accordance with the childhood vaccination schedule (34).



#### Germany

The German government shares decision-making responsibilities with federal and sixteen state (*Länder*) governments. The Federal Joint Committee determines services to be covered by sickness funds and sets out quality measures (35). The COVID-19 vaccination rollout was coordinated across all levels of government and the Robert Koch Institute (RKI) through a phased approach. COVID-19 vaccinations were initially carried out in vaccination centres and mobile teams, but have expanded to be available through medical facilities, registered doctors, and private doctors (36).

#### COVID-19 vaccine data, reporting, and linkage

Based on the National COVID-19 Vaccination Strategy, COVID-19 vaccination data are reported to the RKI (36). Depending on the vaccination provider, data are either reported directly to the RKI by federal and *Länder* vaccination centres, or aggregate data is submitted to the RKI by Social Health Insurance (SHI)-accredited and private medical practices. Federal- and *Länder*-operated vaccinations centres forward information on vaccine recipient and date-of-vaccination to the RKI in real time through an online vaccine-rate monitoring system known as the Digitales Impfquotenmonitoring (DIM). SHI-accredited medical practitioners send aggregated datasets in real time to RKI that include information on total vaccinations per day by place of vaccination, vaccine, dose, and age groups (<18, 18–59, 60+years). In addition, regional associations of SHI-accredited physicians transmit vaccination data available through SHI billing data directly to RKI. However, due to a six-month time lag, private medical practices also submit data in aggregate form to RKI (37). The DIM contains de-identified individual records from vaccination centres, and it is not considered a vaccine registry.

There is no individual-level record linking of RKI COVID-19 vaccination data to other datasets, such as hospitalizations or deaths. While Germany reports COVID-19 cases and hospitalization rates by vaccination status, this data appears to be based on routine mandatory reporting of COVID-19 hospitalizations to local health authorities known as the *Gesundheitsaemter* (38). Other estimates, such as the number of vaccinated COVID-19 cases in intensive care units, are obtained through specific registries where data is collected at the time of admission or point-of-care. Notably, there have been reliability concerns related to reporting the vaccination status of COVID-19 cases. For example, it has been estimated that 20% of cases do not contain information on vaccination status (39).

#### Related policies, legislation, and ordinances

The national COVID-19 vaccination strategy was developed on November 6, 2020 (37). The strategy outlined production, procurement, distribution, storage, organization, implementation, financing, and reporting of the vaccine. The updated vaccination strategy (June 2021) includes a description on the legal basis for COVID-19 vaccination activities and is detailed in Appendix A (36). The updated strategy also outlines the stakeholders involved in different stages of the vaccine strategy.

There is no legislation that explicitly mentions data sharing or health information exchange between levels of government. There is also no legal basis for federal or state-owned vaccination registries. The German *Data Protection Act* regulates the processing of personal data, and Section 2 of the "Law on Successor Facilities of the Federal Health Office" (*BGA Successor Act – BGA-NacfG*) describes the roles and responsibilities of the RKI as the Federal Institute for Infectious Diseases and Non-Communicable Diseases (40–42). There are three legislative tools that govern COVID-19 vaccine data sharing activities. First, Book V of the *Social Code* (SGB) stipulates the role of the RKI in the collection and transmission of anonymized



data (see Appendix A). The *Coronavirus Vaccination Ordinance* (established August 30, 2021) describes the vaccination data elements that must be submitted to RKI as well as the process of electronic reporting to the RKI (Section 4 – *Impfsurveillance*) (see Appendices A and B) (43). It also stipulates data usage for the RKI and Paul Ehrlich Institute and the role of each institution. Third, the *Protection Against Infection Act* (IfSG) (S14, Paragraph 1, Clause 1) formed the legal basis for the development of a digital vaccination rate-monitoring system (44). Appendix A provides excerpts of each legislation.

#### Structures and mechanisms related to COVID-19 vaccine data sharing

- **Technical resources**: Based on legislation (IfSG), the RKI and the Federal Printing Office (*Bundesdruckerei*) developed the DIM online vaccination rate monitoring system for use in vaccination centres and by mobile teams. The DIM is also used by SHI physicians.
- **Human resources**: There is limited information available on the human resources in place to support vaccine data sharing between subnational and national governments.
- **Financial resources**: Vaccination centres receive federal and state funding to carry out their activities. Specifically, 50% of operating costs for vaccination centres are reimbursed from federal funds and the other 50% is reimbursed by the *Länder* (37). There appear to be no financial incentives for vaccine data sharing between subnational and national governments.
- Broader data context: There are historical and legal underpinnings to the strong regime of data protection in Germany. For example, Germans endured mass surveillance activities during World War II and then later by the secret police, known as the *Stasi*, in East Germany. In the 1970s, Germany passed its first data protection law to safeguard individual information and limit the collection of data. As well, since 1983, Germans have the constitutional right to "informational self-determination" where public offices are only allowed to process personal data if a law allows it or individuals have given explicit consent (45). In January 2021, Germany published a data strategy that outlines the current state of data in Germany, and includes support for integrating data, the use of electronic health data, and the establishment of research data centres (46).

#### Challenges and opportunities with the state of data sharing

There have been concerns with the accuracy of vaccine data that have been obtained from different data sources in Germany. In early October 2021, the RKI issued a statement acknowledging the discrepancy of vaccination coverage estimates between data available through the RKI's DIM software and results from periodic COVID-19 vaccine rate monitoring surveys, known as COVIMO. The RKI attributed the discrepancy to methodological issues (e.g., selection bias among survey respondents, lack of multilingual versions of the survey), reporting discrepancies with the single-dose Janssen vaccine, and low registration of company (private) doctors in the DIM (47–49). Due to these discrepancies, the RKI has re-estimated the extent of under recording. In an October 2021 COVIMO report, it is estimated that vaccination rates obtained through the DIM are 10 to 12 percentage points lower than rates obtained from the COVIMO survey (49). Despite this discrepancy, there do not appear to be any initiatives or activities in place to resolve provider reporting issues with vaccine data. There have also been discrepancies in reporting vaccination rates at the state level. For example, the RKI reported vaccination rates higher than 100% for some states (50). These discrepancies have been attributed to reporting vaccination status based on the site of vaccination rather than the place of residence of individuals.



As a result of the COVID-19 pandemic and data availability issues, there has been growing interest in establishing a national vaccination registry in Germany. For example, there has been discussion about establishing a central data authority that would replace the RKI in its current role of collecting and summarizing COVID-19 vaccination data. However, such initiatives have been met with political opposition and, to date, there have been no steps taken to establish a centralized vaccination registry (51).



#### Switzerland

Switzerland has 26 regional-level states, known as cantons. The federal, cantonal, and municipal governments share decision-making responsibilities and duties (1,2). According to the *Epidemics Act*, also known as the *Federal Act on Protection Against Infectious Diseases in Humans* (EpG SR818.101, Art 77), the federal government coordinates and oversees the execution of cantonal activities, including vaccination plans, in order to ensure uniform implementation across cantons (52). In Switzerland, vaccines are administered in hospital, vaccination centres, retirement and care homes, medical practices, mobile units, and pharmacies (53).

#### COVID-19 vaccine data, reporting, and linkage

COVID-19 vaccines are recorded by vaccination providers. Cantons send anonymized individual-level vaccination data daily to the Federal Office of Public Health (FOPH). Data is transmitted from cantons through the federally developed vaccination documentation system (OneDoc) or in electronic format to a central databank known as the Vaccination Monitoring Data Lake. Data reporting details, including data formats and a minimum data set, are outlined in the FOPH instruction to cantons (See Appendix B) (54,55). This includes information on reporting age, gender, type of vaccination site, and indication for vaccine (e.g., chronic disease, healthcare worker with patient contact/carer for people at high risk, close contact with people at high risk, and living in a communal facility with an increased risk of infection) (53). Reporting instructions to cantons have also been updated to accommodate information on third dose/booster COVID-19 vaccinations (42).

At the federal level, vaccination data is not linked to COVID-19 cases, hospitalizations, or death data. Cantons link death and vaccination data and report this information directly to the FOPH as the numbers of deaths for vaccinated, unvaccinated, and partially vaccinated individuals (53).

#### Related policies, legislation, and ordinances

There is no legal basis for federal or cantonal vaccine registries in Switzerland nor is there legislation for linking vaccination data. However, subnational-to-national COVID-19 vaccine data sharing in Switzerland is guided by legislation related to epidemics. The *Epidemics Act 2012* EpG (SR 818.101) describes federal and canton requirements for vaccination measures and includes a requirement for cantons to regularly report to the FOPH (Article 24). Specifically:

The competent federal authorities, with the involvement of the cantons, regularly review the appropriateness and effectiveness of the vaccination measures. The competent cantonal authorities record the percentage of people vaccinated and regularly inform the FOPH about the vaccination rate and the measures that have been taken to increase it. (Translated from German to English) (52)

#### Further details are available in Appendix A.

The *Epidemics Ordinance EpV* (SR8 18.101.1) describes the tasks of the federal government and cantons, which includes data sharing (Art. 39 and 40) (56). The ordinance (EpV; SR818.101.1) describes the purpose of reporting vaccine data to the FOPH, including reasons such as situational assessments and for public view (Item 2) (56). The COVID-19 vaccine strategy (issued June 22, 2021) also describes the role of the FOPH in setting data collection requirements, including reference to the *Epidemics Act* (Art.24, Para2 EpG, Art. 39 EpV, Art. 40 EpV) in section 9.3 (57). Between 2006 and 2015, Swiss epidemics legislation underwent a review and was subsequently revised to address technical and legal gaps related to addressing rapidly spreading diseases in epidemiological emergencies; such deficiencies were identified in



the 1990s with the spread of HIV/AIDS and in 2003 with Severe Acute Respiratory Syndrome (SARS) (58). The 2016 revisions involved structural changes to the *Epidemics Act* and associated legislation. Highlights from the 2016 revisions emphasized work-sharing and coordination between the federal government and cantons, including clarity on the roles of each level of government (59).

The *Federal Act on Data Protection* covers the broader use of personal information, including health data (60). Article 3 defines health data as sensitive personal data, where the use of data must be justified by informed consent, by an overriding public interest, or by specific legislation. However, this legislation has not been leveraged for vaccine data linkage at the federal level.

#### Structures and mechanisms related to COVID-19 vaccine data sharing

- Technical resources: Each canton is responsible for vaccination rollout including the establishment of COVID-19 vaccine management, booking, and reporting systems. There is variation in the type of recording system used across cantons. For example, 22 cantons use OneDoc as their management and reporting system whereas 4 cantons use OneDoc for management, but record vaccinations through a separate process (61). Due to this variation in reporting systems, some cantons experienced delays in reporting demographic breakdowns of vaccine data, which resulted in a phased rollout of reporting national-level statistics.
- Human resources: COVID-19 vaccine data reporting is carried out at the cantonal level. Training requirements for reporting varies by canton and there is no systematic or mandatory reporting for such information.
- Financial resources: Article 64 of the EpV Ordinance includes a clause that the federal government will cover the cost of COVID-19 vaccines conditional on service providers meeting canton requirements. This includes the costs for systems for reporting for vaccination monitoring (56). The FOPH funded the procurement of the vaccination management system used by many cantons (OneDoc) and the COVID certificate on its budget. Cantons are responsible for the operational costs of the systems as well as of their vaccination centre infrastructure.

#### Challenges and opportunities with the state of data sharing

Concerns were raised by key informants regarding the completeness and precision of current vaccination recording processes in measuring vaccination coverage since there is no legal basis for vaccination registries in Switzerland, nor were there established reporting mechanisms prior to the pandemic (61). In addition, vaccine data in Switzerland is not linked to the relevant datasets that would be required to assess vaccination efficacy (e.g., demographics, co-morbidity status, status of COVID-19+ patients tested, hospitalized, or fatality).



#### **United Kingdom**

The United Kingdom (UK) is comprised of four nations and national territories of England, Scotland, Wales, and Northern Ireland. Scotland, Wales, and Northern Ireland have separate parliaments and governments and are responsible for health care services within their territories (each runs their own National Health Service) while the UK Parliament legislates on behalf of England and for policies and programs (e.g., defense) not devolved to the other three national parliaments.

The UK government supplies COVID-19 vaccines to all nations, and each national government is responsible for management and delivery of its respective vaccination programs. For example, in England, COVID-19 vaccines are offered through vaccination centres, pharmacies, and in some instances, through local National Health Service (NHS) services (e.g., hospitals, general practitioner [GP] surgeries, and schools for 12- to 15-year-olds).

#### COVID-19 vaccine data, reporting, and linkage

Each national government records and stores COVID-19 vaccine data through its own immunisation information system. Each national government developed new immunisation information systems to manage the delivery of COVID-19 vaccinations. England developed the National Immunisation Management Service (NIMS) in 2020, which acts as a national data store for influenza and COVID-19 vaccination records (62,63). COVID-19 vaccine data in England is recorded through various systems (e.g., Outcomes4Health/Pinnacle, National Immunisation Vaccination System/NIVS, or NIMS), transferred to GP records and to NIMS as the national data store for vaccine records (64). Northern Ireland developed a Vaccination Management System to facilitate mass vaccination and to replace a pre-existing system of manual reporting of vaccinations (65). COVID-19 vaccine data in Scotland is recorded to the Vaccine Management Tool, which was developed in response to the pandemic (66–68). In Wales, COVID-19 vaccines are recorded in the Welsh Immunisation System (69), which is integrated with GP records.

Through collaboration with public health and/or government representatives from each nation, high-level aggregate COVID-19 vaccine data is shared with the UK Coronavirus dashboard team and published on a regular basis (70). The dashboard receives record-level data from England and aggregate/headline data from Scotland, Wales, and Northern Ireland. Aggregate COVID-19 vaccine data in Scotland is also publicly available through existing open-data initiatives (71). The dashboard also includes information on vaccinations by dose (first, second, booster, or third) (70).

There are no UK-wide COVID-19 vaccine data linkage activities. However, within countries, immunisation data has been linked to cases, hospitalisations, and deaths data to help understand vaccine effectiveness (72).

#### Policies, legislation, and guidance on vaccine data sharing

There is no legislation or policy basis for COVID-19 vaccine data sharing across nations (e.g., England, Wales, Scotland, and Northern Ireland) or to the UK Government itself, though nations collaborate to share data outputs with the UK dashboard through shared interests and values. Representatives from each nation meet on a weekly basis to work on setting common definitions for vaccine measures. This is in part due to guidance from the Office of Statistics Regulation (OSR), which regulates all official statistics in the UK (73). Specifically, in December 2020 and January 2021, the OSR released a statement to set out expectations for data producers in each nation to consider when developing COVID-19 vaccine statistics.



In the statement, the OSR encouraged nations to work together to create comparable statistics for COVID-19 vaccine data (74,75).

Data for the UK Coronavirus dashboard is based on public reporting of national statistics. Through the *Statistics Registration Service Act* (2007), the UK COVID-19 dashboard receives pre-release access to some data for the purposes of reporting vaccination rates in each nation, whereas other data is obtained through published reports (76).

#### Structures and mechanisms related to COVID-19 vaccine data sharing

- Technical resources: Each government has its own immunisation recording system.
- **Human resources**: Vaccine data producers in each nation comprise small teams and have various responsibilities. As there is no legislative framework or policy to support data sharing, there is limited reporting to the UK.
- **Financial resources**: There is no readily available information on financial resources available to support vaccine data sharing between nations and the UK.

#### Challenges and opportunities with the state of data sharing

There have been several challenges with reporting and sharing consistent COVID-19 vaccine data across nations and the UK. The frequency of reporting varies by nation and there is no set time frame for reporting data. For example, Wales does not report estimates on the weekends (Saturday and Sunday), which affects the accuracy of estimates on the UK Coronavirus dashboard (77). Each nation also relies on the performance and capabilities of their own national immunisation system rather than a centralized and unified system, which has been shown to lead to delays in reporting due to technical issues in one or more systems (78,79). In addition, nations may use different standards and definitions for common variables, such as age, which can impact the ability to share comparable data. Details on reporting discrepancies are published and described on the UK Coronavirus dashboard (80).



## Comparison of Approaches

As reviewed above, there are varying governance structures and approaches for reporting COVID-19 vaccine data to the federal or quasi-federal level. Each of the approaches has different strengths and weaknesses.

In three jurisdictions, the basis for data sharing is guided by general legislation on immunizations (Australia), legislation related to epidemics that are operationalized through different levels of government (Switzerland), or through broad networks including government and non-governmental stakeholders (Germany). In each of these three federations, data sharing processes and responsible parties were also outlined in national COVID-19 vaccination strategies. The UK serves as an outlier in this regard, with data sharing occurring on an ad hoc basis through partnerships with data producers, public health, and/or government representatives from each nation. Thus, there is much more limited capacity in the UK for UK-wide vaccine data reporting, analysis, or surveillance than in the other three countries.

At an operational level, when reported, data quality issues (e.g., completeness, accuracy, and timeliness) commonly related to aspects and decisions around technical infrastructure, interoperable systems, and the ability for systems to accommodate or respond to changes in policy or vaccination programs. For example, in Australia, reporting systems for state-run mass vaccination centres required specialized software, and yet these settings still faced challenges with reporting data to the national AIR during the early stages of the vaccine rollout. As well, in Germany, the process of reporting of complete vaccinations did not fully accommodate one or two dose vaccines and is one of the reported reasons for discrepancies in national estimates of vaccine coverage. Finally, in Switzerland, cantons had the option to use either a federally developed reporting system or a different (canton-specific) system. However, reporting delays were experienced by cantons who opted to use their own reporting systems.

In all four countries, there did not appear to be any legislation that directly enabled linkage of vaccination data at the federal level. Issues around data linkage tended to be tied to broader privacy and data protection laws and handling of sensitive data. In Australia, linkage of health or social datasets is governed through the *Census and Statistics Act* (1905), the *Privacy Act* (1998), and specific legislation relevant to each dataset or agency. In Switzerland, through general data protection laws, health or sensitive data could be linked under specific circumstances; however, this is not currently being used for vaccination data. We did not identify details on such legislation in Germany or the UK.

Beyond the legislation or national strategies described above, there were no additional governance mechanisms or incentives to support data sharing between subnational and national governments. For example, none of the national governments imposed conditions on subnational governments or have proposed to withhold funds or resources from jurisdictions that do not comply with reporting requirements. Notably, federal legislation shaped decisions on reporting requirements for vaccine providers and subnational governments in all jurisdictions except the UK.

In two jurisdictions (Germany and Switzerland) past public health emergencies influenced activities around health data privacy and sharing as well as the relationships between national and subnational governments. For example, past negative experiences with mass surveillance led to Germany enacting strict privacy laws, whereas epidemics have prompted the need for a central authority, such as the RKI, to monitor and report health issues. Further, in Switzerland, operational challenges associated with unclear legislation during the spread of HIV/AIDS in the 1990s and well as SARS in 2003 led to legislative revisions



to coordination among national and subnational governments and their delegated agencies. In addition, in Australia, iterations of broader health data strategies, gaps in existing immunisation programs, and lessons learned from the adoption of electronic health records, influenced decisions around data privacy and security as well as the development of the AIR. While there were no consistent legislative drivers found across countries, social and political contexts appear to have shaped these decisions around data sharing and privacy.



## Lessons for Canada

Drawing on this comparison of COVID-19 vaccines data governance in four federal and quasi-federal jurisdictions, there are five key considerations for the development of governance structures and mechanisms for facilitating and standardizing COVID-19 vaccine data, and health data more broadly, across governments in Canada:

- 1. **Broader immunization legislation** or legislation specific to epidemics help set out expectations on the roles of subnational and national governments and expectations concerning data sharing among governments. Such legislation could include stipulations related to establishing immunization registries (as in Australia), data reporting standards and data needs (as in Australia, Switzerland, and Germany), as well as data infrastructure needs.
- Data governance arrangements in place in each of these countries is shaped by their respective historically rooted health system context. Some key drivers of the current data governance mechanisms include public health emergencies, and system-wide health data strategies. The COVID-19 pandemic may similarly motivate legislative and health data governance changes in Canada.
- 3. Variation in **immunization management and reporting systems** across vaccination settings and by provider can contribute to time lags and data quality problems that impede appropriate surveillance as well as the evidence needed for rapid and effective policy interventions by national and subnational governments. These were present for both centralized and decentralized immunization information systems. While details on mechanisms to overcome these issues were not identified, ongoing financial and technical support may be important considerations for overcoming these challenges.
- 4. Legislation and guidelines around COVID-19 vaccine data collection and reporting tended to include minimum data sets and data variable descriptions at the national level for use within federal/national jurisdictions. Countries that did not have national frameworks, such as the UK, or where participation in the national data system was voluntary (as in Switzerland) tended to report discrepancies and inconsistencies in data across nations. These discrepancies can have an impact on the accuracy of reporting vaccination rates at the national level.
- 5. Data reporting and sharing processes can be impacted by changes in practices occurring within the healthcare system or at the public health level. While change cannot be anticipated, governance should **build in capacity for change or adaptation to processes** around data collection, reporting, and use. For example, all countries appear to have adapted vaccination reporting to include information on third dose/booster vaccinations. In Switzerland, this included updating instructions on minimum data requirements to regional-level governments.



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## Appendix A. Stipulations in Legislation Relevant to Vaccine Data Sharing Between Subnational and National Governments

Jurisdiction	Legislation/Policy	Excerpt
Australia	<u>Australian Immunisation</u> <u>Register Amendment</u> <u>(Reporting) Act</u> 2021	"Recognised vaccination providers are required to report certain information in relation to certain relevant vaccinations that have been administered. This information will be included in the register. A recognised vaccination provider may be required to give information, or be given a formal warning, if the provider is not complying, or has not complied, with the requirement to report." (Section 7, amendment)
		"Division2A—Reporting obligation etc. 10A Requirement to report information relating to certain relevant vaccinations (1) If:(a) a recognised vaccination provider administers a relevant vaccination in Australia; and(b)the relevant vaccination: (i) is of a kind prescribed by the rules; and(ii)is administered in the circumstances prescribed by the rules; the provider must report, within the period prescribed by the rules and in the manner prescribed by the rules, the information prescribed by the rules for that vaccination for inclusion in the AI Register.
		 (5) A person is liable to a civil penalty if the person contravenes subsection(1) or (3). Civil penalty: 30 penalty units.
		10B Secretary may require recognised vaccination provider to give information (1)If the Secretary reasonably believes that a recognised vaccination provider is not complying with subsection10A(1) or (3), the Secretary may, by written notice, require the provider to give, within the period specified in the notice and in the manner specified in the notice, information relating to that non-compliance. (2)The period specified in the notice must not be shorter than14days after the notice is given.(3)A person is liable to a civil penalty if the person fails to comply with a notice given to the person under subsection(1). Civil penalty:30penalty units.
		 10C Secretary may give formal warning to recognised vaccination provider. If the Secretary reasonably believes that a recognised vaccination provider may have contravened subsection10A(1) or (3), the Secretary may, by written notice given to the provider:(a)inform the provider of that matter; and(b)warn the provider that the provider may be liable to a civil penalty under subsection10A (5).
Australia	<u>Australian Immunisation</u> <u>Register Rule</u> , 2015	<ul> <li>"Part 3—Reporting</li> <li>9 Reporting requirement relating to certain relevant vaccinations administered in Australia</li> <li>For the purposes of subsection 10A(1) of the Act:</li> <li>(a) the following kinds of relevant vaccinations are prescribed:</li> <li>(i) a relevant vaccination for the coronavirus known as COVID-19;</li> <li>(ii) a relevant vaccination for influenza;</li> </ul>



Jurisdiction	Legislation/Policy	Excerpt
		<ul> <li>(iii) a relevant vaccination of a person with a specified national immunisation program vaccine; and</li> <li>(b) the prescribed circumstance is that a relevant vaccination is administered: <ul> <li>(i) for a relevant vaccination for the coronavirus known as COVID-19—on or after the commencement of this section; or</li> <li>(ii) for a relevant vaccination of a person with a specified national immunisation program vaccine—on or after 1 July 2021; and</li> <li>(c) the prescribed period is the period of: <ul> <li>(i) if it is reasonably practicable to do so—24 hours after a relevant vaccination is administered; or</li> <li>(ii) otherwise—10 business days after a relevant vaccination is administered; and</li> </ul> </li> <li>(d) the prescribed manner is an electronic form or, if that is not reasonably practicable, a written form; and</li> <li>(e) the following information is prescribed: <ul> <li>(i) if that individual has a medicare number (within the meaning of Part VII of the National Health Act 1953)—that number;</li> <li>(ii) if that individual has a healthcare identifier (within the meaning of the Healthcare Identifiers Act 2010)—that identifier (if known);</li> <li>(iv) provider identification information for the recognised vaccination provider who administers a relevant vaccination;</li> <li>(v) the day of the vaccination;</li> <li>(vi) the brand, dose number and batch number of the administered vaccine;</li> <li>(vii) for a relevant vaccination for the coronavirus known as COVID-19—the vial serial number of the administered vaccine;</li> <li>(vii) for a relevant vaccination for the coronavirus known as COVID-19—the vial serial number of the administered vaccine (if known)."</li> </ul> </li> </ul></li></ul>
Australia	Australian COVID-19 Vaccination Policy, 2021 (Last updated Sep 25, 2021)	<ul> <li>"The Australian Government is responsible for: • setting data collection and reporting requirements and adverse event monitoring via the TGA," (Page 6, Part 3. The approach to COVID-19 vaccination during this pandemic).</li> <li>"For the COVID-19 vaccine the AIR will be used to, among other things:</li> <li>• monitor immunisation coverage levels and service delivery, which can help to identify regions at risk during disease outbreaks;</li> <li>• measure vaccination coverage at a local, state, and national level.</li> <li>• determine an individual's immunisation status, regardless of who immunized them</li> <li>• provide an Immunisation History Statement to prove their immunisation status for child care, school, employment, or travel purposes.</li> <li></li> <li>The AIR will be the unifying national system to monitor both overall immunisation levels and individual immunisation status. It will be mandatory for vaccination providers to make timely recordings of any COVID-19 vaccinations into AIR.</li> </ul>



Jurisdiction	Legislation/Policy	Excerpt
		The Australian Government is undertaking a review of AIR functionality to support this role, including an anticipated large number of new registrants and new providers, to ensure technical capacity to fulfil the key monitoring role," (Page 19, Part 6. Data and Reporting).
Germany	<u>National Vaccination</u> <u>Strategy</u> (June 22, 2021)	<ul> <li>* RKI is responsible for monitoring the vaccination rates.</li> <li>* RKI has developed an online vaccination rate monitoring system (DIM) for nationwide use in vaccination centres and by mobile teams. Data from occupational physicians and occupational medicine service providers is also submitted using DIM. The dataset to be submitted is specified in the Coronavirus Vaccination Ordinance.</li> <li>* RKI designs and conducts parallel studies and surveys to monitor vaccination rate and vaccination acceptance," (Page 20).</li> </ul>
Germany	Sozialgesetzbuch (SGB) Fünftes Buch (V) - Gesetzliche Krankenversicherung - (Artikel 1 des Gesetzes v. 20. Dezember 1988, BGBI. I S. 2477) [Social Code (SGB) Book Five (V) - Statutory Health Insurance - (Article 1 of the Act of December 20, 1988, Federal Law Gazette I, p. 2477)]	<ul> <li>§ 20i Leistungen zur Verhütung übertragbarer Krankheiten, Verordnungsermächtigung [below translated to English]</li> <li>§ 20i Benefits for the prevention of communicable diseases, authorization to issue prescriptions <ul> <li>"(3) The Federal Ministry of Health is authorized, after hearing the Standing Vaccination Commission and the Central Association of Health Insurance Funds, to determine by ordinance without the consent of the Federal Council that insured persons are entitled to further specific protective vaccinations or to specific other measures of specific prophylaxis. If the German Bundestag has determined an epidemic situation of national scope in accordance with Section 5 (1) sentence 1 of the Infection Protection Act, the Federal Ministry of Health is authorized to determine by ordinance without the consent of the Bundesrat that</li> <li>1. Insured entitled to</li> <li>a) have certain vaccinations or certain other measures of specific prophylaxis, in the case of a vaccination against the SARS-CoV-2 coronavirus, especially if they have a significantly increased risk of a serious or fatal course of the disease due to their age or state of health, if they are such people treat, supervise or maintain or if they have a key role in maintaining central government functions, critical infrastructures or central areas of services of general interest,</li> <li>b) have certain protective masks if they belong to a risk group to be determined in the statutory ordinance with a significantly increased risk of a serious or fanibodies against this pathogen,</li> <li>c) have certain protective masks if they belong to a risk group to be determined in the statutory ordinance with a significantly increased risk of a serious or fatal course of the disease after infection with the SARS-CoV-2 coronavirus,</li> <li>2. Persons who are not insured in the statutory health insurance are entitled to benefits according to number 1.</li> <li>The claim according to sentence 2 can be limited to certain partial services; it</li></ul></li></ul>



#### Jurisdiction Legislation/Policy

Excerpt disability, Occupational or residence-related SARS-CoV-2 exposure risk as well as their systemic relevance in central government functions, critical infrastructures or central areas of services of general interest are taken into account. A claim according to sentence 2 number 1 letter b does not exist if the person concerned is already entitled to the services specified in sentence 2 number 1 letter b or would be entitled to reimbursement of the expenses for these services. If a right to protective masks is stipulated in the statutory ordinance according to sentence 2 number 1 letter c, the agreement with the Federal Ministry of Finance must be established and an additional payment can be provided by the authorized group of people. If the statutory ordinance under sentence 2 stipulates a right to vaccination against the SARS-CoV-2 coronavirus for people who are not insured in statutory health insurance, the private health insurance companies will contribute 7 percent of the costs as far as these are not borne by the federal government or the states. The ordinance according to sentence 2 is to be issued after hearing the Central Association of Health Insurance Funds and the National Association of Statutory Health Insurance Physicians. If the statutory ordinance under sentence 2 stipulates a right to vaccinations or other specific prophylaxis measures, the Standing Vaccination Commission at the Robert Koch Institute must also be heard before it is issued. Insofar as a right to protective masks is stipulated in the statutory ordinance according to sentence 2, the German Pharmacists' Association must also be heard before it is enacted. If the ordinance according to sentence 2 contains provisions for people who are privately insured, the Association of Private Health Insurance must also be heard before the ordinance is issued.

Further details can also be regulated in the statutory ordinance according to sentence 2

1. on the prerequisites, the type and scope of the services according to sentence 2 number 1,

2. to the service providers authorized to provide the services mentioned in sentence 2, including the test centers and vaccination centers set up for the service provision, to the remuneration and billing of services and costs as well as to the payment procedure,

3. for the organization of care, including the obligations of the Association of Statutory Health Insurance Physicians and the National Association of Statutory Health Insurance Physicians to provide the services specified in sentence 2 number 1 letter a,

4. to fully or partially finance the services and costs from the liquidity reserve of the health fund,

5. for the proportional cost bearing by the private health insurance companies according to sentence 8, in particular for the procedure and the payment modalities, and

6 to collect and transmit anonymized data, in particular to the Robert Koch Institute, on the measures taken on the basis of the statutory ordinance.

In the period from January 1, 2021 to December 31, 2021, amounts paid from the liquidity reserve of the health fund will be reimbursed from federal funds on the basis of ordinances pursuant to sentence 2 number 1 letters a and b, also in conjunction with number 2, as well as sentence 13 number 4, unless the reimbursement has already been made in accordance with Section 12a of the Budget Act 2021. Insofar as services according to sentence 2 number 1 letter c are financed from the liquidity reserve of the health fund, these are to be reimbursed from federal funds; in the ordinances according to sentence 2 number 1 letters a and b, also in conjunction with number 2, a reimbursement from federal funds for further services according to sentence 2 number 1 letters a and b, also in conjunction with number 2, a reimbursement from federal funds for further services according



#### Jurisdiction Legislation/Policy

to sentence 2 can be regulated. An ordinance issued on the basis of sentence 2 shall expire no later than one year after the German Bundestag repeals the determination of the epidemic situation of national scope in accordance with Section 5 (1) sentence 2 of the Infection Protection Act. Until it expires, an ordinance in accordance with sentence 2 can be amended of national scope even after the epidemic situation has been lifted. Insofar as and for as long as an ordinance issued on the basis of sentence 1 or sentence 2 is in force, the Federal Joint Committee has, in deviation from paragraph 1 sentence, insofar as the Standing Vaccination Commission has made recommendations for protective vaccinations to which there is a claim under the respective ordinance 5 details of requirements, To determine the type and scope of these protective vaccinations according to paragraph 1 sentence 3 for the period after the expiry of the respective statutory ordinance in guidelines according to § 92; the vaccinations recommended by the Standing Vaccination Commission may be provided after the statutory ordinance has expired until the guideline is available."

#### § 13 Weitere Formen der epidemiologischen Überwachung; Verordnungsermächtigung [below translated to English] § 13 Other forms of epidemiological surveillance; Authorization to issue ordinances

"(5) The Association of Statutory Health Insurance Physicians and, insofar as the information is available from them, the vaccination centers set up for the implementation of vaccination services must be assigned to the Robert Koch Institute for the purpose of determining the use of protective vaccinations and vaccination effects (vaccination surveillance) and for the purpose of monitoring security of vaccines (pharmacovigilance) to transmit the following information to the Paul Ehrlich Institute at these specified time intervals:

1. Patient pseudonym,

2. Month and year of birth,

3. Gender,

Excerpt

4. Five-digit postcode and district of the patient,

5. District of the attending physician or the vaccination center,

6. Specialty of the attending physician,

7. Date of vaccination, check-up, doctor-patient contact and quarter of diagnosis,

8. antigen-specific documentation number of the vaccination, in the case of preventive examinations, the performance according to the uniform evaluation standard,

9. Diagnostic code according to the International Statistical Classification of Diseases and Related Health Problems (ICD), diagnostic reliability and diagnostic type in the sense of an acute or permanent diagnosis,

10. In the case of vaccinations against Severe-Acute-Respiratory-Syndrome-Coronavirus-2 (SARS-CoV-2), the vaccinespecific documentation number, the batch number, the indication and the start or end of the vaccination series.

The Federal Ministry of Health is authorized to stipulate by ordinance without the consent of the Bundesrat that persons or institutions responsible for carrying out protective vaccinations shall send certain information pursuant to sentence 1 on protective vaccinations carried out by them for the purposes of vaccination surveillance and pharmacovigilance to Robert Koch Institute, the Paul Ehrlich Institute or the responsible association of statutory health insurance physicians. The Association of



Jurisdiction	Legislation/Policy	Excerpt
		Statutory Health Insurance Physicians are authorized to process the data transmitted to them in accordance with sentence 2, insofar as it is necessary to fulfill their obligation in accordance with sentence 1."
Germany	Verordnung zum Anspruch auf Schutzimpfung gegen das Coronavirus SARS- <u>CoV-2</u> (Coronavirus- Impfverordnung - CoronalmpfV) [Ordinance on the right to vaccination against the SARS-CoV-2 coronavirus]	<ul> <li>§ 4 Impfsurveillance</li> <li>[below translated to English]</li> <li>§ 4 Vaccination surveillance</li> <li>(1) The service providers according to § 3 paragraph 1 sentence 1 numbers 1 to 3 as well as the service providers according to § 3 paragraph 1 sentence 1 number 6 who do not participate in the care provided by a contract doctor have the following information daily according to § 13 paragraph 5 sentence 1 of the Infection Protection Act to be submitted to the Robert Koch Institute:</li> <li>1. Patient pseudonym,</li> <li>2. Month and year of birth,</li> <li>3. Gender,</li> <li>4. five-digit postcode and district of the person to be vaccinated,</li> <li>5. Identification number and district of the service provider according to Section 3 Paragraph 1 Clause 1 Numbers 1, 2, 3 or 6,</li> <li>6. Date of vaccination,</li> <li>7. Start or end of the series of vaccinations (initial, follow-up or booster vaccination),</li> <li>8. vaccine-specific documentation number (vaccine product or trade name),</li> <li>9. Batch number.</li> <li>The service providers according to § 3 paragraph 1 sentence 1 numbers 4 and 5 as well as the service providers according to § 3 paragraph 1 sentence 1 number 6 to 8 as well as information on whether the vaccinated person has either not yet reached the age of 18 or has reached the age of 60, broken down into first, follow-up or booster vaccination in accordance with the procedure under paragraph 3 or paragraph 4 to the To the Robert Koch Institute.</li> <li>(2) For the data transmission according to paragraph 1 sentence 2, the service providers according to § 3 paragraph 1 sentence 1.</li> <li>(3) For the data transmission according to paragraph 1 sentence 2, the service providers according to the service providers according to § 3 paragraph 1 sentence 1 number 6 to 8 as well as information on whether the vaccinated near the idistrict in aggregated form, which are listed in sentence 1 number 6 to 8 as well as information on whether the vaccination in accordance with Paragraph 3 o</li></ul>
	SARS-CoV-2 coronavirus]	<ol> <li>Gender,</li> <li>Gender,</li> <li>five-digit postcode and district of the person to be vaccinated,</li> <li>Identification number and district of the service provider according to Section 3 Paragraph 1 Clause 1 Numbers 1, 2, 3 or 0.</li> <li>Date of vaccination,</li> <li>Start or end of the series of vaccinations (initial, follow-up or booster vaccination),</li> <li>vaccine-specific documentation number (vaccine product or trade name),</li> <li>Batch number.</li> <li>The service providers according to § 3 paragraph 1 sentence 1 numbers 4 and 5 as well as the service providers according to § 3 paragraph 1 sentence 1 numbers 4 and 5 as well as the service providers according to § 3 paragraph 1 sentence 1 number 6 to 8 as well as information on whether the vaccinated person has either not yet reached the age of 18 or has reached the age of 60, broken down into first, follow-up or booster vaccination in accordance with the procedure under paragraph 3 or paragraph 4 to the To the Robert Koch Institute.</li> <li>(2) The electronic reporting and information system in accordance with Section 14 of the Infection Protection Act is to be use for data transmission according to paragraph 1, Clause 1.</li> <li>(3) For the data transmission according to paragraph 1 sentence 2, the service providers according to § 3 paragraph 1 sentence 1 number 4 and the service providers according to § 3 paragraph 1 sentence 1 number 6, who participate in statut health care, have to use the electronic reporting system of the National Association of Statutory Health Insurance Physicians to the National Association of Statutory Health Insurance Physicians a to the respective country. The data of the National Association of Statutory Health Insurance Physicians as to the respective country. The data of the National Association of Statutory Health Insurance Physicians to the Robert Koch Institute.</li> <li>(4) For the data transmission according to paragraph 1 sentence 2, the service provi</li></ol>



Jurisdiction	Legislation/Policy	Excerpt
		transmission to the Association of Private Medical Clearing Offices e. V. to use. The services provided by the Association of Private Medical Clearing Offices e. V. merged data of the service providers according to § 3 paragraph 1 sentence 1 number 5 are electronically transmitted to the Robert Koch Institute.
		(5) The data collected on the basis of paragraph 1 may only be used by the Robert Koch Institute for the purpose of determining the use of protective vaccinations and vaccination effects (vaccination surveillance) and by the Paul Ehrlich Institute only for the purpose of monitoring the safety of vaccines (pharmacovigilance). are processed. The Robert Koch Institute makes this data available to the Paul Ehrlich Institute. According to Section 12 (5) sontenee 4 of the Information
		Protection Act, the Robert Koch Institute determines the technical transmission standards for the data to be transmitted within the framework of vaccination surveillance and pharmacovigilance, as well as the procedure for creating the patient pseudonym according to paragraph 1 sentence 1 number 1.
		(6) The service providers in accordance with Section 3 (1) sentence 1 number 4 and the service providers in accordance with Section 3 (1) sentence 1 number 6 who take part in statutory health care shall transmit the information in accordance with paragraph 1 sentence 1 without prejudice to paragraph 1 sentence 2 to the Association of Statutory Health Insurance Physicians in whose district the service provider is domiciled, monthly or quarterly in connection with the billing according to §
		6 Paragraph 6. The statutory health insurance associations transmit this data as part of vaccination surveillance in accordance with § 13 Paragraph 5 of the Infection Protection Act for from April 1st Vaccinations carried out in 2021 at the Robert Koch Institute. Paragraph 5 applies accordingly. (7) The convice providers can only use one of the transmission channels montioned in paragraphs 2 to 4 to report the
		information in accordance with paragraph 1."
Germany	<u>Gesetz zur Verhütung und</u> Bekämpfung von	§ 14 Elektronisches Melde- und Informationssystem; Verordnungsermächtigung
	Infektionskrankheiten beim	[below translated to English]
	Menschen	"§ 14 Electronic reporting and information system; Authorization to issue ordinances
	(Infektionsschutzgesetz -	(1) For the fulfillment of the tasks in accordance with the purposes of this Act, the Robert Koch Institute shall set up an electronic reporting and information system in accordance with the instructions of the Federal Ministry of Health and in
	Issued 07/20/2000	accordance with the technical possibilities. The Robert Koch Institute is the controller in terms of data protection law. The
		Robert Koch Institute can commission an IT service provider with the technical implementation. The electronic reporting and
	[Law for the prevention and	information system uses suitable services of the telematics infrastructure according to the fifth book of the Social Security
	diseases in humansl	the Social Security Code supports the Robert Koch Institute in the development and operation of the electronic reporting and
		information system. Third-party costs arising directly from the commissioning of third parties for the fulfillment of the task
		according to sentence 5 at the Gesellschaft für Telematik are borne by the Robert Koch Institute. A joint planning council lays
		information system. If there is an obligation to use the electronic reporting and information system, users must be provided with at least one free software solution."



Jurisdiction	Legislation/Policy	Excerpt
Switzerland	SR 818.101 Bundesgesetz über die Bekämpfung übertragbarer Krankheiten des Menschen (Epidemiengesetz, EpG) [Federal law on combating communicable diseases of the human ( <i>Epidemics Act</i> , EpG)]	<ul> <li>Art. 24 Überwachung und Evaluation [below translated to English]</li> <li>Art. 24 Monitoring and evaluation (Section 2: Vaccinations) <ul> <li>"1. The competent federal authorities, with the involvement of the cantons, regularly review the appropriateness and effectiveness of the vaccination measures.</li> <li>2. The responsible cantonal authorities record the percentage of people vaccinated and regularly inform the FOPH about the vaccination rate and the measures that have been taken to increase it.</li> <li>3. The FOPH regularly prepares reports for monitoring and evaluation and publishes them in a suitable form."</li> </ul> </li> <li>Art. 77 Aufsicht und Koordination [below translated to English] <ul> <li>Art. 77 Supervision and coordination</li> <li>"1. The Confederation oversees the implementation of this Act by the cantons.</li> <li>2. It coordinates the enforcement measures of the cantons if there is an interest in uniform enforcement.</li> <li>3. To this end, he may: <ul> <li>a. prescribe measures for uniform enforcement in the cantons;</li> <li>b. if there is a risk to public health, instruct the cantons to implement certain enforcement measures;</li> <li>c. oblige the cantons with guidelines for their preparation and emergency plans."</li> </ul> </li> </ul></li></ul>
Switzerland	SR 818.101.1 Verordnung über die Bekämpfung übertragbarer Krankheiten des Menschen (Epidemienverordnung, EpV) [Regulation on combating communicable diseases of the human (Epidemic Ordinance, EpV)]	<ul> <li>Art. 39 Überwachung und Evaluation der Impfmassnahmen [below translated to English]</li> <li>"Art. 39 Monitoring and evaluation of vaccination measures (Section 2: Vaccinations)</li> <li>The FOPH performs the following tasks when reviewing the appropriateness and effectiveness of the vaccination measures: <ul> <li>a. It defines the indicators for reviewing the measures to promote vaccinations.</li> <li>b. Taking the indicators into account, it regularly collects data on the cantonal measures taken to achieve the goals set.</li> <li>c. It coordinates cantonal surveys to determine the percentage of people vaccinated."</li> </ul> </li> <li>Art. 40 Kantonale Erhebungen zur Feststellung des Anteils geimpfter Personen (Section 2: Vaccinations) <ul> <li>"Art. 40 Cantonal surveys to determine the proportion of people vaccinated</li> <li>In order to determine the percentage of people vaccinated, the FOPH stipulates the following in consultation with the cantons: <ul> <li>a. vaccinations to be collected;</li> <li>b. Age groups in which the proportions of vaccinated persons are recorded;</li> <li>c. methodology to be used;</li> <li>d. representative samples to be collected;</li> </ul> </li> </ul></li></ul>



Jurisdiction	Legislation/Policy	Excerpt
		e. Frequency of surveys."
Switzerland	Aktualisierung vom 11. November 2021 der Weisung des BAG an die Kantone vom 27. Januar 2021 Erhebung und Übermittlung der Monitoringdaten zu Covid- 19 Impfungen durch die Kantone an das BAG [Update of November 11, 2021 of the BAG's instructions to the cantons from January 27, 2021: Collection and transmission of the monitoring data on Covid- 19 vaccinations by the cantons to the FOPH]	<ul> <li>[below translated to English]</li> <li>"To ensure uniform implementation, the BAG issues the following instructions:</li> <li>1. The cantons are obliged to provide the FOPH with the data on each vaccination event for the national vaccination monitoring in accordance with Appendix 1 "Minimal Data Set Vaccination Monitoring" (status: 11.10.2021) to be provided.</li> <li>2. The report according to item 1 is made electronically in anonymised form and in principle on a daily basis. It is via the system for vaccination documentation recommended by the BAG (OneDoc)or any system used by the cantons in electronic form to the head office VMDL (Vaccination Monitoring Data Lake) database. The BAG designates the specification of the data format and the interface to VMDL and makes these available to the cantons coincidence.</li> <li>a. The data to be reported includes all of the data at the vaccination sites used since the last. Notification of vaccinations carried out per day.</li> <li>b. The vaccination data from the cantons are processed by the FOPH and, on the one hand, used for the Assessment of the situation and, on the other hand, for publication on the BAG Corona dashboard(https://www.covid19.admin.ch). Within the BAG-Corona dashboard, not only can national indicators can be viewed. As with the number of cases, there are also cantonal. Vaccination indicators can be displayed, e.g. number of vaccination carried.</li> <li>3. With a view to their reporting obligations vis-à-vis the FOPH in accordance with Numbers 1 and 2to organize the canton's internal reporting system in such a way that the implementation of their reporting obligations is guaranteed to the BAG at all times. In particular, in the context of the regulation the completely as well as the reporting formats and reporting frequency in accordance with the cantonal - Specifications are designed in such a way that a correct and timely transmission to the responsible agency (cantonal or VMDL) that forwards this data to the FOPH is guaranteed. It lies in</li></ul>
Switzerland	<u>Covid-19-Impfstrategie</u> ( <u>Stand 22.06.2021</u> ) Bundesamt für Gesundheit (BAG) und Eidgenössische	<ul> <li>9.3 Monitoring der Umsetzung</li> <li>[below translated to English]</li> <li>"9.3 Monitoring implementation</li> <li>The implementation of the vaccination recommendations for Covid-19 vaccination should be carried out with specific monitoring be tracked and analyzed. Based on the Epidemics Act (Art. 24 Para. 2 EpG and Art. 36 EpV and Article 40 EpV) the</li> </ul>



Jurisdiction	Legislation/Policy	Excerpt
	Kommission für Impffragen (EKIF)	FOPH sets the data to be collected after consultation with the cantons (minimum data set) and the methodology for documentation and monitoring. Starting from aggregated data from the documentation of the Covid-19 vaccinations carried out will be the development the vaccination activity and the acceptance of the vaccination in the various target groups closely and
	[COVID19 vaccination strategy (June 22, 2021). Federal Office of Public Health (FOPH) and Federal Commission for Vaccination Issues (EKIF)]	tracked promptly. Electronic processing of the vaccination data is essential for this."
United Kingdom	None identified	N/A



## Appendix B. Information on Sharing Standardized Data/Minimum data reporting for COVID-19 Vaccinations

Jurisdiction	Source	Description
Australia	Australian Immunisation Register Rule, 2015	<ul> <li>"e) the following information is prescribed:</li> <li>(i) the name, contact details, date of birth and gender of the individual to whom a relevant vaccination is administered;</li> <li>(ii) if that individual has a medicare number (within the meaning of Part VII of the National Health Act 1953)—that number;</li> <li>(iii) if that individual has a healthcare identifier (within the meaning of the Healthcare Identifiers Act 2010)—that identifier (if known);</li> <li>(iv) provider identification information for the recognised vaccination provider who administers a relevant vaccination;</li> <li>(v) the day of the vaccination;</li> <li>(vi) the brand, dose number and batch number of the administered vaccine;</li> <li>(vii) for a relevant vaccination for the coronavirus known as COVID-19—the vial serial number of the administered vaccine (if known)."</li> </ul>
Germany	National COVID-19 Vaccination Strategy (June 22, 2021)	<ul> <li>"For the purpose of vaccination rate monitoring, the following non-personal data is required:</li> <li>Data on the vaccine recipient: age, gender, place of residence (Land/district), vaccination indication</li> <li>Data on the vaccination: place of vaccination, vaccination date, vaccine product (name and batch number), vaccination dose administered (first vaccination or follow-on vaccination where applicable)" (Page 18).</li> </ul>
Switzerland	Update of November 11, 2021 of the BAG's instructions to the cantonsfrom January 27, 2021	<ul> <li>Minimum Data Set Vaccination Monitoring (presented in tabular format, translated to English)</li> <li>Personal information <ul> <li>Gender: female, male, diverse</li> <li>Age: In years of age</li> <li>Canton of residence: AG, AI, AR,, ZG, ZH or FL, AT, DE, F, I or unknown</li> <li>MedStat: Place of residence by health care region (MEdStat)</li> <li>Pregnancy: Yes No</li> <li>COVID-19 recovered: Yes No</li> <li>Person ID: Person specific code generated y the vaccination unit, the guarantees the anonymity of the person Vaccination indication according to vaccination strategy</li> <li>Age: Yes No</li> <li>Chronic diseases: Yes No. List according to EKIF vaccination recommendation</li> <li>Health workers or support staff of special vulnerable people: Yes No. Health and care personnel who through care, action and care direct contact with patients and patients as well as particularly vulnerable people</li> </ul> </li> </ul>



Jurisdiction	Source	Description
		<ul> <li>Close contact with particularly vulnerable people: Yes No. Persons aged 16 and older who are exposed to particularly vulnerable people living in the same household (e.g., partner, family member, roommates, housekeepers, au pairs or caring relatives)</li> <li>Communal facilities with increased infection and risk of breakage: Yes No. Homes and facilities for people with disabilities, psychosomatic and psychiatric clinics, federal asylum centers and cantonal collective accommodation for asylum seekers, shelters and institutions for imprisonment</li> <li>Further/Other: Yes No. Other vaccination indications.</li> <li>Information on the vaccination center: AG, AI, AR,, ZG, ZH or FL or army</li> <li>Type of vaccination site: Vaccination center, retirement and nursing home, doctor's practice, pharmacy, Others (legacy), hospital, army, others</li> <li>Identification reporting system: ID of the reporting system, e.g. OneDoc</li> <li>Identification of the vaccination unit: ID of the vaccination unit within the reporting system, e.g. Vaccination Center A or Hospital B, both of which use OneDoc.</li> <li>Indication of the vaccination file: ID of the vaccination file, generated by the vaccination unit</li> <li>Vaccination code: Global Trade Item Number (GTIN), specific to each vaccine</li> <li>Lot number: Specific to the batch</li> <li>Vaccination date: day of the vaccination event</li> <li>Vaccination counter: Vaccination assigned to a series"</li> </ul>
United Kingdom <sup>1</sup>	None	None

<sup>1</sup>There is no legislation or policy that describes a minimum data set shared COVID-19 vaccination data in the UK. However, the Director General for Regulation of the Office for Statistics Regulation described data elements that could be shared or reported by data producers in each nation (England, Scotland, Wales, Northern Ireland) in a memo to producers on January 20, 2021. <u>https://osr.statisticsauthority.gov.uk/wp-content/uploads/2021/01/Ed-Humpherson-to-all-producers-Numbers-of-COVID-19-vaccinations-administered-in-the-UK.pdf</u>



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