Task 3.2 –Integrate clinical information on hospitalized patients with microbiological data (typing and microbial resistance), in Member States using nation-wide register-based public health surveillance.

Surveillance of hospital admissions with respiratory tract infections in Norway – possibilities and hurdles

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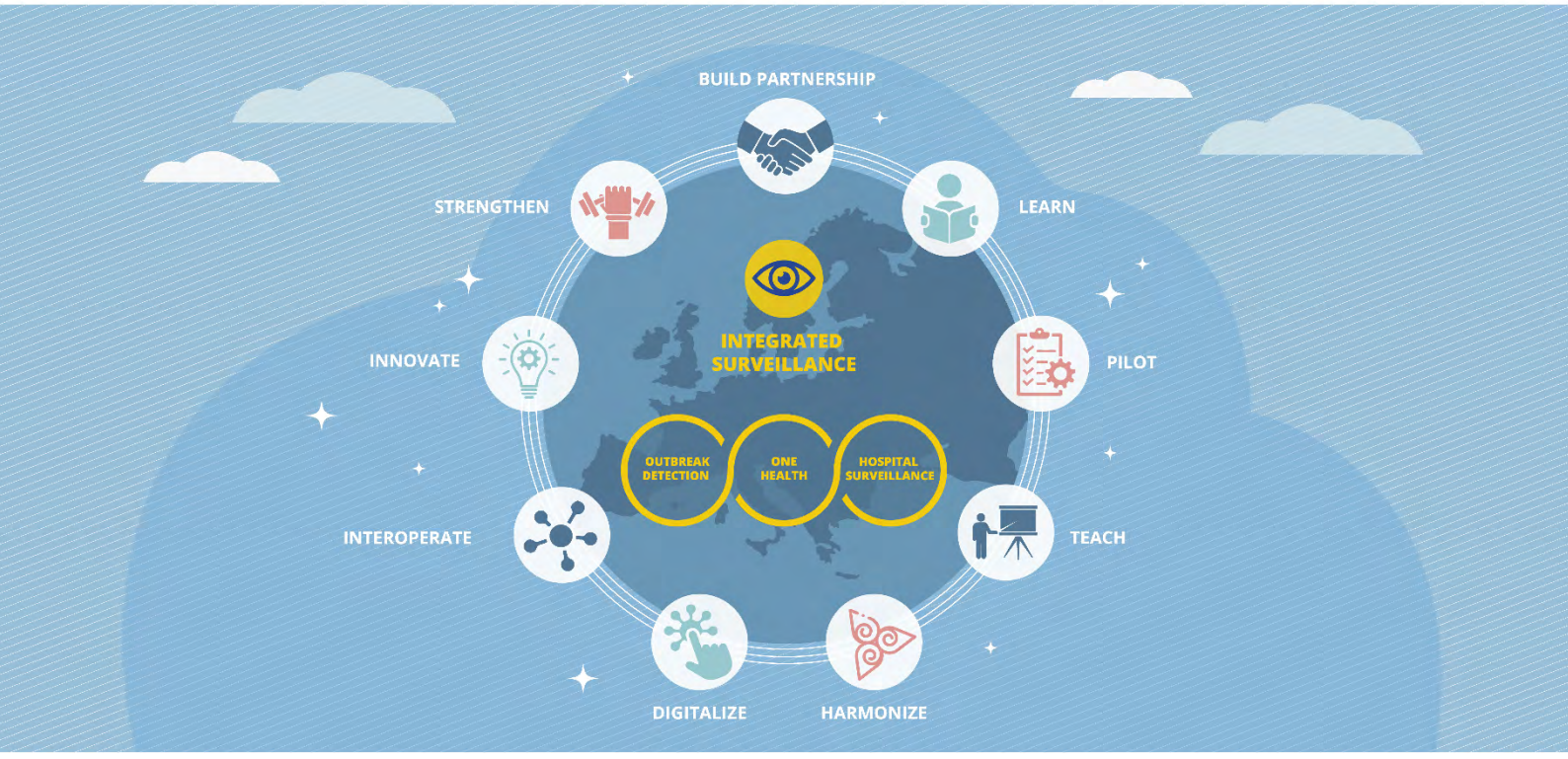

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EXECUTIVE SUMMARY

This document outlines the necessity for developing a system for surveillance of hospital admissions with laboratory-confirmed respiratory infections in Norway. Its basis is drawn from the learnings and knowledge of the system (Beredt C19) that we established during the COVID-19 (Coronavirus disease 2019) pandemic and seeks to further describe the building blocks for a new system to be operated in peacetime.

During the COVID-19 pandemic, using linked data sources for real-time monitoring of respiratory infections played a vital role in producing timely knowledge to support decision making. Participating in the Joint Action - Union and National Capacity Building 4 IntegraTED Surveillance (UNITED4Surveillance) has given the Norwegian Institute of Public Health (NIPH), alongside the Norwegian Directorate of Health, the opportunity to apply the insights gained from the pandemic.

The NIPH pilot focuses on planning and designing a concept for a surveillance system that utilizes existing data sources to provide routine surveillance data for respiratory infections. The system aims to be capable of scaling up in case of a crisis while ensuring legal and privacy aspects, addressing infrastructure deficits, and identifying necessary data sources.

Norwegian data sources typically cover the entire population and can be linked through unique personal identifiers. Those relevant for the surveillance system are identified and described in the current report. By linking data from the hospital database (NPR), the laboratory database (MSIS) and the population registry (FREG) the number of laboratory-confirmed hospital admissions, including severity indicators and deaths can be supplied. With the addition of data on vaccinations (SYSVAK), primary health care utilization (KPR) and medications (NorPD), the system can give important information about vaccination status and medical risk factors, while the remaining four identified registries (AA-register, SSB, NiPAR and CoDR) can give supplementary information e.g., in studies of vaccine effectiveness.

Since January 1st, 2024, the NIPH has been data controller for the main health registers in Norway, although the operational data controller responsibility is delegated to the different units within NIPH. The legal framework concerning the processing of personal health data and coexistence between relevant laws are discussed. Based on NIPH's interpretation of the Personal Health Data Filing System Act ("helseregisterloven") §§ 19 – 19c, this is now considered the main legal basis to allow the continuation of a SARI (severe acute respiratory infection) surveillance system. Routine surveillance in peace time may be achieved by compiling health data from the health registries, producing anonymous statistics to contribute to fulfilling the NIPH's obligation for surveillance of communicable diseases.

Additionally, technical challenges related to data timeliness, security, protocols, and necessary resources are highlighted. It is important to build on the advantages that exist with current systems in place and look to re-use parts or entire infrastructure, components, and solutions for future development. In the case of this pilot, we have used the system of Beredt C19 as an illustration of how data sharing was operated within NIPH during the COVID-19 pandemic.

This pilot forms the basic framework for the development of such a surveillance system, and the recommendations will lay the groundwork for the implementation of the NORSURV Direct Grant (see "definitions") to make improvements to the Norwegian surveillance systems for infectious diseases.

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Glossary

AA-register	State Register of Employers and Employees
Beredt C19	The preparedness register for COVID-19
COVID-19	Coronavirus disease 2019
CoDR	The Norwegian Cause of Death Registry
FREG	National Population Register
GDPR	Generalt Data Protection Regulation
"Helseberedskapsloven"	Act on health and social preparedness
ICUs	Intensive Care Units
KPR	Norwegian Register for Primary Health Care
KUHR	Norwegian Control and Payment of Health Reimbursements Database
MSIS	The Norwegian Surveillance System for Communicable Diseases
MSIS laboratory database	The Norwegian Surveillance System for Communicable Diseases Laboratory Database
"Folkeregisteret"	National Population Register Act
NDH	The Norwegian Directorate of Health
NHN	The Norwegian Health Network
NIPaR	The Norwegian Intensive Care and Pandemic Register
NIPH	The Norwegian Institute of Public Health
NORSURV	Improvements to the Norwegian surveillance systems for infectious diseases
NorPD	Norwegian Prescribed Drug Registry
"Personopplysningsloven"	Norwegian Personal Data Act
NPR	Norwegian Patient Register
"Helseregisterloven"	Personal Data Filing System Act
"Reservasjonsrett"	reservations right
RSV	Respiratory Syncytial Virus
"Forskrift"	Regulation
SARI	Severe Acute Respiratory Infection
SARS-CoV-2	Severe acute respiratory syndrome – coronavirus 2
"Smittevernloven"	Act relating to control of communicable diseases
SSB	Statistics Norway
"Statistikkloven"	Act on National Statistics
SYSVAK	The Norwegian Immunisation Registry
UNITED4Surveillance	Union and National Capacity Building 4 IntegraTED Surveillance

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Definitions

Surveillance of communicable diseases is the continuous and systematic collection, compilation, and analysis of data on infectious diseases, infections, infectious agents, immunity, vaccination, and possibly relevant behaviour, as well as presentation of the monitoring results for infection control purposes.
Surveillance of infections, infectious diseases and infectious agents shall contribute to infection control by measuring the incidence over time and according to geographical and demographic conditions, help to detect and resolve outbreaks of infectious diseases and provide knowledge about the characteristics of the infectious agent and the nature of the disease.

A monitoring system consists of infrastructure and processes that are necessary to achieve the purpose of the system. The key processes are collection or retrieval of data (and biological material), data cleaning and quality control, collation, handling, analysis, production of monitoring results and interpretation, and presentation and sharing of surveillance results (and data) to those who need them for infection control.

Scalability of a system is the ability of the system to adapt quickly to situations where larger production of surveillance data is required, e.g., major outbreaks or pandemics. This may include retrieval of more data than usual, data from new data sources, more frequent data transfers, carrying out analytics faster and more often, and deliverables more often and to new consumers. Scalability requires efficiently increasing administrative resources and personnel, e.g., having a good access management system and routines for on-boarding. It is equally important to efficiently scale down when the situation normalizes.

Statistics are quantifiable information about a group or a phenomenon, obtained by compiling and processing information about the individual units in the group or a sample of these units, or by systematic observation of the phenomenon, cf. the Norwegian Act on Statistics paragraph 3 a). Statistics are associated with anonymous information in the GDPR, and it is a requirement in the Norwegian Personal Health Data Filing System Act that statistics based on health register data are anonymous. The anonymous information is information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable, cf. recital 26 GDPR.

Personal data means any information relating to an identified or identifiable natural person ("data subject"); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

Processing of personal data means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

Real-time data means data that is transferred continuously. For surveillance purposes daily or weekly data is often sufficient, which we will address as "near real-time data" in this document.

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"SARI (severe acute respiratory infections) surveillance" in this document refers to the surveillance of hospital admissions with acute respiratory infections in Norway, including intensive care and/or respiratory support given during the admission, and in-hospital deaths.

Emergency preparedness register
In Norway, the Act on health and social preparedness ("helseberedskapsloven") allows for establishing registers containing personal health data in emergency and preparedness situations, to gain an overview of the extent, causes and development of the disease, which can form the basis for measures to meet the situation.
The information collected shall be used by the data controller, and as such, they shall determine the purpose of the register. The register is temporary, and the information must be deleted or anonymised when the issue has been clarified and evaluated. There are strict access control and strict routines for handling information in the register.

Outbreak register
According to the act relating to control of communicable diseases ("smittevernloven"), an outbreak register can be established when necessary for the implementation of measures or for overview and control in connection with suspected outbreaks of infectious diseases. These are temporary registers, and the information should be deleted or anonymized when the incident is clarified and evaluated.
Outbreak registers may contain health data with direct personally identifying information. By collecting information about patients, knowledge about the prevalence and development of disease outbreaks can be obtained, as well as the causes and health consequences of the disease.

Digital infrastructure is technical systems, data collections and software systems that are available for the development of services, both for private and public actors, and which are important for society to function.

Clinical information
In this document, by clinical information we refer to data on hospitalised patients, including diagnostic codes describing the condition(s) the patient was hospitalised for, length of stay, and severity of illness in terms of ventilatory support, intensive care and other procedures administered during the stay, and in-hospital deaths.

Medical risk factors for SARI
By medical risk factors for SARI, we refer to any underlying medical risk factors that increase the risk of being hospitalised, receiving intensive care and/or dying because of acute respiratory infections. Such risk factors may vary slightly between different infectious diseases, and can include e.g., cancer, conditions and treatments leading to immunosuppression, chronic pulmonary and cardiovascular diseases, obesity, and prematurity.

Surveillance system qualities
The benefits and shortcomings of the data sources for a SARI surveillance system have been classified as "surveillance system qualities", adapted to our needs from ECDC's surveillance attributes used for data quality monitoring and surveillance system evaluation[1].

[1] European Centre for Disease Prevention and Control. Data quality monitoring and surveillance system evaluation – A handbook of methods and applications. Stockholm: ECDC; 2014. Available from: https://www.ecdc.europa.eu/en/publications-data/data-quality-monitoring-and-surveillance-system-evaluation-handbook-methods-and

Introduction

The Norwegian setting

Through the early days of the COVID-19 (Coronavirus disease 2019) pandemic, it became clear that enhanced surveillance was needed to monitor the situation in Norway and support decision making at governmental level. The pandemic was considered a "case of crisis" in which the Act on Health and Social Preparedness allows the Norwegian Institute of Public Health (NIPH) to establish emergency preparedness registers, where processing of personal health data is allowed for the purpose of handling the situation. Such registers may include data from pre-existing health registers. Hence, during the spring of 2020, the Norwegian emergency preparedness register for COVID-19[2] ("Beredt C19") was established to give NIPH an ongoing overview and knowledge of the prevalence, causal relationships, and consequences of the COVID-19 epidemic in Norway. Shortly after the register was established, most surveillance indicators for COVID-19 were supplied from within this infrastructure, as well as numerous reports and publications producing real-time knowledge.

Emergency preparedness registers such as Beredt C19 must, however, be temporary registers and data processed within those registers must be deleted as soon as the situation is handled. Since the waves of COVID-19 have been less severe throughout the 2023-24 winter season, the data stored in the register will be deleted by summer 2024. The NIPH is working on assessing how the technical infrastructure of the Beredt C19 could be continued.

During the early fall of 2021, measures against COVID-19 were gradually eased globally, with the consequent return of other respiratory pathogens than SARS-CoV-2 (severe acute respiratory syndrome – coronavirus 2). These infections occupy the same healthcare capacities as COVID-19, and the need for integrated surveillance of severe acute respiratory infections (SARI) in Norway became apparent. A comprehensive register-based SARI surveillance system was established within Beredt C19 and produced surveillance outputs from November 2021[3]. Case-based hospital data were linked with laboratory data, giving near real-time information about hospital admissions with SARI, including COVID-19, influenza, and RS-virus.

Epidemiological real-time monitoring of respiratory infections using linked data sources for knowledge production is unprecedented in Norway. It has been a game changer in providing useful, robust, and timely information to answer public health questions during crisis, and for the recommendation of interventions and measures. Building on the experiences of Beredt C19 and the SARI surveillance, NIPH wants to build a similar system for routine surveillance in peacetime.

NIPH recognize the potential for positive synergies between addressing these tasks and engaging in the Joint Action – Union and National Capacity Building 4 IntegraTED Surveillance (UNITED4Surveillance). Work package 3, Hospital surveillance: Surveillance of severe infectious diseases that lead to hospitalization, suits our over-arching goal of developing surveillance systems for respiratory infections used in routine surveillance. We have already learned that integrating clinical information about hospitalized patients with microbiological data for nation-wide register-based public health surveillance is useful and can produce robust and timely data.

[2] https://www.fhi.no/en/id/corona/coronavirus/emergency-preparedness-register-for-covid-19/

[3] https://www.fhi.no/contentassets/8a971e7b0a3c4a06bdbf381ab52e6157/vedlegg/3.-alle-ukerapporter-2021/ukerapport-uke-47-22.11---28.11.21.pdf

The scope of our pilot

The purpose of this pilot is to plan and design a concept for a surveillance system of hospital admissions with laboratory confirmed respiratory tract infections using data from pre-existing sources. The system shall routinely provide surveillance data in a peacetime setting, with the capability to scale up in case of crisis. We describe the basic principles for such a system with emphasis on some general legal and privacy aspects, infrastructure deficits, necessary data sources and possibilities and hurdles for receiving data. The pilot is limited to investigating the basic framework for a surveillance system. Further assessment of the impact on personal data protection will need to be carried out. The testing, implementation and operation of the system is not within the scope of the planned pilot, but it will hopefully form a clear recommendation for follow-up.
Production of a SARI surveillance protocol describing surveillance indicators and defining case definitions is not within the scope of this pilot, nor is validating or evaluating a SARI surveillance system and its indicators. For such work, please see a brief listing of relevant outputs below.
The recommendations from this pilot will lay the groundwork for the NORSURV Direct Grant (CP-g-23-01[4]) to make improvements to the Norwegian surveillance systems for infectious diseases.

The objectives of the SARI surveillance system

The types of data sources needed for the surveillance of SARI depends on the objectives of the surveillance system. For this pilot, we have defined the following surveillance objectives:

- To monitor incidence, burden, and trends of hospital admissions with SARI, both overall and associated with specific respiratory pathogens such as SARS-CoV-2, influenza virus, and RS-virus;
- To estimate the burden of SARI on specialist healthcare services and to inform capacity planning in the healthcare sector;
- To monitor disease severity among patients hospitalised with SARI in terms of length of stay, need for ventilatory support and/or intensive care, and in-hospital deaths;
- To describe risk factors for and protective factors against SARI and their most severe outcomes;
- To ensure the early detection and response to unusual and unexpected events caused by common or emerging respiratory pathogens; and
- To assess the impact of public health interventions, including vaccination, on SARI and inform disease preparedness, prevention, and control.

Relevant outputs

This document focuses on the necessity for developing a SARI surveillance system in Norway integrating clinical and laboratory information for routine surveillance in peacetime. Its basis is drawn from the learnings achieved by building a temporary SARI surveillance system in the COVID-19 preparedness register (Beredt C19) in a time of crisis. This document will be most valuable when viewed in the light of other reported material concerning SARI and registry-based surveillance in Norway from the learnings throughout the COVID-19 pandemic, e.g.:

- Protocol for establishment of a registry-based national SARI surveillance system in Norway (October, 2021)

[4] EU4H-2023-DGA-MS-IBA-01 — Direct grants to Member States' authorities: improving and strengthening national surveillance systems (Regulation 2022/2371 of the European Parliament and of the Council on serious cross-border threats to health)

- Protocol for Severe Acute Respiratory Infections (SARI) surveillance in Norway (01.07.2022)[5]
- EHR-SARI evaluation protocol; Evaluation of SARI surveillance – Norway (05.05.2023) [5]
- General description of the Norwegian SARI surveillance system as of 2023-W20 (17.02.2023) [5]
- EHR-based SARI surveillance; Annual report; NORWAY (28.04.2024) [5]
- EHR-based SARI surveillance; Annual report; NORWAY (06.02.2024) [5]
- Registry-based surveillance of severe acute respiratory infections (SARI) in Norway during 2021-2024. Seppälä E et al. Submitted to Eurosurveillance June 2024.
- Hospitalisations for COVID-19 - a comparison of different data sources. Whittaker R et al. Tidsskr Nor Legeforen. 2020 Dec 14;140(18). English, Norwegian. doi: 10.4045/tidsskr.20.0759
- A comparison of two registry-based systems for the surveillance of persons hospitalised with COVID-19 in Norway, February 2020 to May 2022. Whittaker R et al. Euro Surveill. 2023;28(33):pii=2200888.
- Ruiz MAS et al. Surveillance of severe acute respiratory infections associated with SARS-CoV-2, influenza virus and RSV using ICD-10 codes: a case definition accuracy study across six European countries, 2021-2023. Work ongoing[5]
- Impact of the emergence of SARS-CoV-2 on the seasonality of hospital attended influenza and Respiratory syncytial virus in Norway, 2017-2024. Bøås H et al. Work ongoing.
- Surveillance of hospitalisations with laboratory-confirmed respiratory infections using the national laboratory database, Norway, 2022-2024. Seppälä et al. Work ongoing.

Not all of these documents are readily available online. Please contact corresponding author Trine Hessevik Paulsen (*trinehessevik.paulsen@fhi*) for access.

[5] This activity was partially supported by the projects "Vaccine Effectiveness, Burden and Impact Studies (VEBIS) of COVID-19 and Influenza", funded by the European Centre for Disease Prevention and Control through service contracts with Epiconcept (ECD.13350 and ECD.15029, implementing framework contract ECDC/2021/016), and "Design and implementation of multinational surveillance systems using routinely collected electronic health records in EU/EEA", funded by the European Centre for Disease Prevention and Control through service contracts with the E-Sure Consortium (ECD.13629, ECD.14898, and ECD.16380, implementing framework contract ECDC/2022/003).

Legal clarification

Introduction

Systems for surveillance of communicable diseases need access to health data. When personal identifiers are included, such health data is categorized as a special category of data according to The General Data Protection Regulation 2016/679 ("GDPR")[6]. This chapter is about the legal framework in Norway concerning the processing of personal data (including health data) from public registers (including health registers) relevant to surveillance of hospital admissions with respiratory infections.

This chapter does not aim to provide an exhaustive analysis of the legal situation concerning such a system. Instead, it provides insights into potential legal challenges that may arise, based on the information currently available. Further legal discussions should therefore be anticipated.

Among them, the co-existence between the laws related to the processing of personal health data, which can create uncertainty as to the applicable legal scope, and the legal status of the surveillance system once personal data is transferred.

Data controller and data processing

NIPH has national responsibility for surveillance of communicable diseases, as stated in the Act relating to control of communicable diseases § 7-9. To fulfil this obligation, NIPH can process necessary personal health data and other personal data.

Since January 1st 2024 NIPH has been data controller for the main health registers[7] in Norway, including the Norwegian Patient Register (NPR) (see chapter 1 under data sources) and the Norwegian Surveillance System for Communicable Diseases Laboratory Database (MSIS laboratory database) (see chapter 2 under data sources), which are essential to this system. The operational data controller responsibility is however delegated to the different units within NIPH, which daily administers each of the health registers.

When receiving data for surveillance activity from other registers, which NIPH is not the data controller for (for instance the National Population Register (FREG), see chapter 3 under data sources), NIPH also becomes data controller with regard to the data received.

Data can be processed within the main health registers or within other types of registers/systems, as demonstrated with Beredt C19 (as noted in The Norwegian setting under the Introduction). When the processing is done within the health registers listed in the Personal Data Filing System Act paragraph 8-12, the legal purpose of the data processing must be compatible with both the Act and the purposes of each of the concerned registers. Surveillance purpose is not always clearly described as a legal purpose in each of the health registers' regulations, but it can be interpreted as being compatible with more general purposes as stated in the regulations, such as preparedness or planning.

In all cases it is necessary to ensure that the data is processed in accordance with the requirement of

[6] https://eur-lex.europa.eu/eli/reg/2016/679/oj

[7] https://www.fhi.no/en/hd/access-to-data/about-health-registries/

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the GDPR and the Norwegian Personal Data Act, as well as in accordance with the relevant national legislation (outlined below). We choose to focus on some of the laws in Norway which apply to the processing of register data as relevant for this system. We therefore exclude any introduction on the well-known general principles in the GDPR, as implemented in the Norwegian Personal Data Act.

Note: secondary use of personal data through the health register system in Norway is currently under review at the Ministry of Health and Care services and several changes in the Norwegian legislation are expected.

Relevant legislation

Act relating to control of communicable diseases § 7-9 and § 2-2 (8)[8]*:*
Paragraph 7-9 rules that NIPH shall monitor the epidemiological status of communicable diseases nationally. NIPH is allowed to process personal data including health data for this purpose. However, it is our understanding that paragraph 7-9 does not give NIPH the right to collect personal health data regardless of the duty of confidentiality as such but is rather understood as a statement of an official task or obligation.

Paragraph 2-2 (8) states that NIPH has the right to request/demand personal data regardless of the duty of confidentiality *when* it is necessary to implement measures or to get control or/ and overview of communicable diseases. This paragraph also gives NIPH the opportunity to retrieve and link directly identifiable data.

NIPH, together with the Norwegian Directorate of Health (NDH), has recently assessed that such a rule must be interpreted as giving NIPH the right to establish local emergency registers in case of a minor infectious disease outbreak and that the Act relating to the control of communicable diseases paragraph 2-2 (8) shall overrule the Act relating to Personal Health Data Filing System Act (with regulations). This means that the registers do not have to assess the legality of the data sharing and the process of data sharing might therefore be more efficient. NIPH has also interpreted such a rule as giving NIPH the right to maintain such a register for infectious disease surveillance in normal time (i.e. without a minor infectious outbreak), for diseases which NIPH is responsible for according to the Act relating to the control of communicable diseases paragraph 7-9. This interpretation has recently been confirmed by the NDH. Please note that the NDH nevertheless recommends considering having a legal basis which clearly allows the continuous and prolonged access to a large amount of personal data for ongoing surveillance with regard to the principle of legality.

This means that the Act relating to the control of communicable diseases paragraph 2-2 (8) can be the appropriate legal basis for maintaining such a register for the purpose of ongoing surveillance of infectious diseases.

Act on health and social preparedness § 2-4[9]*:*
Paragraph 2-4 rules that NIPH among others can establish emergency preparedness registers during war, crises, and disasters in peacetime, where processing of personal health data is allowed for the purpose of handling the situation. Such registers can be established to provide an overview and knowledge of the prevalence, causal relationships and consequences of environmental incidents, suspected outbreaks of disease related to exposure to harmful environmental factors and other types of crises and emergency situations. In addition, emergency registers can be established to fulfil international reporting obligations, as well as administrative tasks during an emergency.

[8] Lov om vern mot smittsomme sykdommer [smittevernloven] - Lovdata
[9] Lov om helsemessig og sosial beredskap (helseberedskapsloven) - Lovdata

NIPH, together with the NDH, has recently assessed that the Act on health and social preparedness paragraph 2-4 should be the legal basis for the establishment of emergency preparedness registers in case of major crises (such as a pandemic), whereas the Act relating to control of communicable diseases paragraph 2-2 (8) should be the legal basis for the establishment of emergency preparedness registers in case of minor/local crises.

In practice, this means that NIPH can request health data and other personal data considered necessary for fulfilling the above-mentioned purposes from both the organisations in the healthcare system which process personal health data (including the health registers) and directly from the health professionals. Health data can be collected/transferred regardless of the duty of confidentiality.

The storage of data in an emergency preparedness register can only be maintained during an ongoing crisis. When the crisis is resolved, the data must be erased or anonymized.

Personal Health Data Filing System Act §§ 19 – 19c[10]*:*
This Act rules on the processing of personal health data for secondary use. It applies therefore to all health registers mentioned in this report.

Please note that each health register has its own regulation, which governs in more detail the processing of health data, including collection, storage, and disclosure. Those regulations are based on the same framework (GDPR/Personal Data Act and Personal Data Filing System Act), but with some differences for instance, MSIS regulation focuses on surveillance purpose, whereas the NPR regulation focuses on administration, management, and quality assurance of specialist healthcare services, including financing. Relevant content in those regulations is further described in this report for the data sources/registers deemed as essential or important.

Paragraph 19, 19a, 19b and 19c in the Act relate to the legal conditions for production of statistics based on register data, disclosure of register data, exceptions from the duty of confidentiality, and compiling register data. Those paragraphs are therefore most relevant for the system.

Which rule applies to which type of processing depends on the purpose of the targeted processing and the identifiable grade of the data. Requesting access to directly identifiable personal health data requires that several legal conditions must be fulfilled, and thus can be more time consuming than requesting access to statistics (per definition anonymous/not personal data).

It is our understanding that processing data for statistical purposes may not present significant challenges. However, processing of data for research purposes or purposes where the register data will be disclosed as identifiable health data, may raise complicated legal questions.

Even though NIPH is now data controller for the national health registers in Norway, the rules for accessing register data are the same and still apply to each of the departments within NIPH which have been delegated the operational responsibility of managing the health registers.

Data from the health registers can be made available for purposes covered by the Act, which are promoting health, preventing illness and accidents, and giving better healthcare services. In addition,

[10] Lov om helseregistre og behandling av helseopplysninger (helseregisterloven) - Lovdata

the targeted processing must be compliant with the purposes of the concerned health register as stated in its regulation. As informed above, not every regulation clearly mentions surveillance as a purpose of the register. However, some of the regulations have broader purposes, which surveillance can be interpreted as being part of.

Processing health data is subject to a duty of confidentiality. The Act gives some exceptions to this duty, for instance when health data from the main health registers are being compiled as part of producing statistics.

At the present time, it is NIPH's understanding that the surveillance purpose of the system might be achievable by compiling health data from the health registries with statistics as an outcome, according to the Personal Health Data Filing System Act paragraph 19 c, cf. paragraph 19. Compiling health data from the health registers with personal data from the National Population Register Act – FREG and other public registers (such as the Employer and Employee register, see data source nr. 7, or data from Statistics Norway, see data source nr. 8) is also possible if it relates to demographical and socio-economical personal data[11]. In such instance, exception to the duty of confidentiality also applies.

Note: answer to the technical question of where the surveillance system will be placed (i.e. within / outside of an existing register might impact some of the legal assessments given in this document).

The National Population Register Act §§ 10-1 and 10-2[12]:
This Act applies to the processing of personal data in the National Population Register (FREG). This register does not include health data, but demographic information such as dates of birth and death and residence, are examples of personal data in the FREG which are relevant for the surveillance system.

Paragraph 10-1 and 10-2 in the Act are most relevant for the system since they rule on the disclosure of FREG-data (both data subject to a duty of confidentiality and data not subject to a duty of confidentiality). Such rule of laws state that public authorities such as NIPH have the right to collect data from the FREG as long as they have a legal basis to do so, and such legal basis covers specifically the collection of personal data.

Paragraph 14 in the Personal Health Data Filing System Act is such a legal basis and gives NIPH the right to collect personal data within its registers from the FREG without regard to the duty of confidentiality.

[11] As the law does not give a definition of what "demographical and socio-economical personal data" includes a workgroup (NIPH, NDH, SSB, Directorate of E-Health, Cancer register) has been settled to define its content. The document "*sammenstilling mellom helseregistre og demografiske og sosioøkonomiske personopplysninger – versjon 1.0 - 14.04.2023*"

[12] Lov om folkeregistrering (folkeregisterloven) - Lovdata

Technical clarification

In the planning and designing of a nation-wide register-based surveillance system, it is important to build on the advantages that exist with current systems in place and look to re-use parts or entire infrastructure, components, and solutions for future development.

In the case of this pilot, we have used the system of Beredt C19 as an illustration of how data sharing was operated within NIPH during the COVID-19 pandemic. It is useful to look at data sharing from both the sender and receiver perspective to get a clear indication of how well the current system adheres to the principles explained below.

Principles

There are several technical requirements that a system that processes data must meet, which include the following:

- Information security

The practice of protecting information by mitigating information risks. It encompasses various strategies and measures to ensure the confidentiality, integrity, and availability of information.

- Usability

The degree to which a system or product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use.

- Dependency

The relationship between different components or systems where one component relies on another to function correctly or provide necessary resources.

- Deployment

The process of making a software application or system available for use in a particular environment, typically involving installation, configuration, and testing.

- Operability

The ability of a system to be operated easily and efficiently by its users or administrators, often measured by factors such as simplicity of interfaces, clarity of documentation, and ease of maintenance.

- Failure management

The process of detecting, diagnosing, and recovering from failures or errors in a system, often through proactive measures such as redundancy, monitoring, and fault tolerance mechanisms.

- Fault tolerance

The ability of a system to continue operating or degrade gracefully in the event of component failures or errors, often achieved through redundancy, error detection, and error recovery mechanisms.

- Flexibility

The degree to which a system can adapt to changing requirements, environments, or user needs without requiring significant modifications or redesign.

- Reusability

The extent to which components, modules, or design patterns can be reused in multiple contexts or projects, thereby reducing development time, cost, and complexity.

- Integrability

The ease with which a system can be integrated with other systems, components, or technologies to form a cohesive and interoperable solution.

- Compatibility

The ability of a system or component to function properly with other systems, software, hardware, or protocols without requiring modifications or special configurations.

- Cost

The total expenditure associated with the development, deployment, operation, and maintenance of a system or product, including both initial investment and ongoing expenses.

- Privacy

The right of individuals to control the collection, use, and disclosure of their personal information, as well as the measures taken by organizations to protect this information from unauthorized access or misuse.

- Portability

The ease with which a system or application can be transferred or adapted to different environments, platforms, or devices without requiring significant modifications.

- Reliability

The ability of a system to perform consistently and predictably under normal operating conditions, often measured by factors such as uptime, availability, and mean time between failures.

- Response time

The time it takes for a system to respond to a user request or input, often measured from the initiation of the request to the completion of the corresponding action.

- Scalability

The ability of a system to handle increasing workloads or user demands by adding resources or scaling horizontally without sacrificing performance, availability, or quality of service.

- Testability

The degree to which a system or component can be effectively and efficiently tested to verify its correctness, reliability, and conformance to requirements.

- Maintainability

The ease with which a system or software application can be modified, updated, repaired, or extended over time, often measured by factors such as modularity, documentation, and ease of debugging.

Co-funded by the European Union

Challenges

There are common technical challenges related to the development, implementation and maintenance of systems receiving, storing, processing and analysing data from the mentioned data sources in this document. In the below list, we have identified the challenges relevant for a surveillance system which would be used, regulated, and maintained by NIPH:

- Timeliness - getting updated data on a regular basis (as close to real-time as possible) from the relevant data sources
- Secure data transfer, data management and data storage close to "best practice"
- Available versus required data transfer protocols and formats
- Necessary logging and monitoring of all data-processing
- Necessary maintenance of systems, applications, routines, and processes
- Data-governance and data-engineering
- Need of identity and access management
- Access to necessary resources and competence
- Access to necessary funding

Note: it is not clear yet where the surveillance system which is planned will be placed (i.e. within an existing register or outside an existing register/be established as a new register).

Data sources

The objectives of the SARI surveillance system described in this pilot are listed in the Introduction. Based on these objectives, we have identified three data sources that are essential for SARI surveillance, namely:

- The Norwegian Patient Register (NPR),
- The Norwegian Surveillance System for Communicable Diseases laboratory database (MSIS laboratory database), and
- The National Population Register (FREG).

We have also identified data sources that provide important additional information on the patients hospitalised with SARI. These data sources and their main use/function are summarized in Table 1 and are described in more detail in the sections to follow. Additionally, we have identified data sources deemed as supplementary as they make it possible to carry out analysis to estimate vaccine effectiveness and for quality assurance of the surveillance system. The additional data sources will only be briefly described in the sections to follow.

Table 1. Short description of the data sources regarding their main functions and importance in the surveillance of hospitalisations with severe acute respiratory infections (SARI).

Data source	Main function of interest to the pilot	Importance
Norwegian Patient Register (NPR)	Identifying hospital admissions with different diagnoses/ diseases Indicators for severity Identifying medical risk factors for SARI	Essential
Norwegian Surveillance System for Communicable Diseases (MSIS) laboratory database	Identifying positive and negative test results for respiratory pathogens among hospitalised patients	Essential
National Population Register (FREG)	Identifying deaths and potential risk factors for SARI Population under surveillance (denominator)	Essential
The Norwegian Immunisation Registry (SYSVAK)	Defining vaccination status of patients hospitalised with SARI *Surveillance of vaccine effectiveness*	Important
Norwegian Register for Primary Health Care (KPR)	Identifying medical risk factors for SARI *Identification of long-term care facilities residents*	Important
Norwegian Prescribed Drug Registry (NorPD)	Identifying medical risk factors for SARI	Important
State Register of Employers and Employees (AA-register)	Identifying healthcare personnel to assess vaccine coverage in this group *Assessing vaccine effectiveness and risk of severe disease by profession* *Investigation of outbreaks in healthcare institutions*	Supplementary
Statistics Norway (SSB)	Controlling for confounding in vaccine effectiveness analyses	Supplementary

	Assessing association between socioeconomic factors and risk of SARI	
Norwegian Intensive Care and Pandemic Register (NIPaR)	Quality-assurance of information on intensive care	Supplementary
The Norwegian Cause of Death Registry (CoDR)	Quality-assurance of information on deaths *Assessing sequelae of severe acute respiratory infections that lead to death*	Supplementary

1. Norwegian Patient Register (NPR)

1.1. Value-adding

Description

The Norwegian Patient Register (NPR) was established in 2008, and since January 1st 2024, the register has been governed by NIPH. Processing of NPR-data regulated in the regulations on the collection and processing of health information in the NPR[13] ("NPR-forskriften").

The NPR is a mandatory national register with personal health data on all patients receiving healthcare in the publicly funded[14] specialist healthcare services in Norway. This means that it is a legal obligation for the health institutions to report personal health data to the NPR.

Personal health data about the registered/data subjects (patients) is processed without consent and without the possibility to restrict or object.

The NPR contains data on administration, healthcare, rehabilitation, and injuries. The data is case-based, with unique personal identifiers that allow for linkage with other data sources. Data is collected from electronic patient records and normally transferred to the NPR on a monthly basis, however, during the COVID-19 pandemic, data has been transferred daily due to the emergency of the situation.

The main aim of the register is to form the basis for administration, management, and quality assurance of specialist healthcare services, including financing.

Relevant data

Data from the NPR on hospital admissions with personal, administrative, and clinical information is relevant to the SARI surveillance system. Relevant variables include admission and discharge date, urgency, medical procedures, including ventilatory support, intensive care, ICD-10 diagnostic codes at discharge and status at discharge (alive/dead).

Importance

Data from the NPR is needed to identify individuals hospitalised with severe acute respiratory infections, but also to identify medical risk groups for severe respiratory infections. The NPR is the only register in Norway which can provide such data for all hospital admissions. The data source is graded as essential to SARI surveillance.

[13] Forskrift om innsamling og behandling av helseopplysninger i Norsk pasientregister (Norsk pasientregisterforskriften) - Lovdata

[14] The Ministry of Health and Care Services is currently assessing whether the NPR should also include personal data from patients receiving health care in the **privately** funded specialist healthcare services in Norway, see: https://www.regjeringen.no/no/dokumenter/horing-registrering-av-aktivitet-fra-privatfinansiert-helse-og-omsorgstjeneste-og-krav-til-format-ved-avlevering/id3028430/

Table 2. Summarizing the benefits and shortcomings of the Norwegian Patient Register (NPR) for a SARI surveillance system.

Surveillance system qualities	**Benefits**	**Shortcomings**
Coverage	- Mandatory nationwide register with unique identifiers for linkage. - Nearly 100% coverage for admissions with acute infectious diseases. - Historical data available from 2008 onward.	- Cannot collect data from fully privately funded health services currently.
Timeliness		- Data updated at discharge, leading to suboptimal timeliness for ongoing surveillance. - May have to perform monthly data collection post-pandemic, affecting weekly surveillance. - Lacks information on time of registration of diagnostic codes, complicating timeliness assessment and trend forecasting.
Suitability	- Well suited for syndromic surveillance using ICD-10 codes.	
Data Quality		- Data prone to changes before complete quality assurance, which may affect data quality.

This table provides a structured view of the strengths and weaknesses of the NPR in terms of data collection, availability, and its suitability for surveillance purposes. The shortcomings highlight areas that may require improvement or consideration for the system to function optimally for surveillance, especially in a post-pandemic scenario.

1.2. Legal considerations

As described in the Legal clarification above, the Act related to the control of communicable diseases § 2-2 last section gives other departments in NIPH the right to request data from the NPR in times of minor (local) crises and the Act on health and social preparedness § 2-4 gives the same right in times of major crises. As also mentioned, the rule of law in the Act related to the control of communicable diseases can constitute the legal basis for the collection of the NPR data for ongoing surveillance purpose, i.e. without any crises related to the outbreak of a disease. The rules in the Personal Health Data Filing System Act and the NPR regulation can also be the legal basis for the processing.

It is important to point out that the NPR regulation has not recently been updated. Among others, its purposes are limited and do not explicitly include preparedness and surveillance. But it does allow, as mentioned above, the use of the NPR data for the management/planning of specialist healthcare services, which preparedness and surveillance might be interpreted as being part of. It was for instance undisputable under the pandemic that the NPR had to be used as a key knowledge base for the Norwegian Authorities in managing the pandemic.

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The need for better access and use of key health registries such as the NPR for preparedness, also in normal time, has also been pointed out by an expert group[15] after the pandemic. It is therefore our understanding that the NPR could be used for the surveillance system.

1.3. Technical capabilities

Note: In the case of this pilot, we have used the system of Beredt C19 as an illustration of how data sharing currently operates within NIPH

Sender / Receiver

The data source is currently using a temporary infrastructure to transfer relevant data on a daily basis to NIPH. The technological, content, and organizational aspects of the infrastructure are not robust or well-developed. The data transfer is secured using standard transfer protocols and certificates, and the transferred data within NIPH is also secured through encryption and storage on an isolated offline network (NIPH's "secure zone").

The extraction of data from the source is done automatically and involves receiving data through a database-restore operation conducted by the Norwegian Health Network (NHN), and the datasets transferred are "full dumps" rather than incremental changes. The extraction and transfer of data is currently not a standard routine but are performed as a temporary measure during the COVID-19 pandemic. Metadata is transferred along with the data, and the process is monitored and logged.

The current way to transfer data is through Secure File Transfer Protocol. There are backup capabilities in place at NIPH, where the received data is stored until a new complete dataset is received from the source. There are no known thresholds regarding the amount of data being transferred.

Data minimization is implemented after integration and before analysts are given access to the data. Minimization is done at the column, row, and field levels to ensure privacy and reduce the amount of data being accessed (meaning that not all diagnosis codes are transferred or available in detail).

2. Norwegian Surveillance System for Communicable Diseases laboratory database (MSIS laboratory database)

2.1. Value-adding

Description

In Norway, there is a communicable diseases register (MSIS register) and a laboratory database (MSIS laboratory database). For the purpose of the SARI surveillance system, only the laboratory database is relevant. The laboratory database contains all microbiological test results, including negative test results, which medical microbiological laboratories must report. Processing of data from both the

[15] https://www.regjeringen.no/no/aktuelt/mandat-for-kjernegruppen-for-et-bedre-kunnskapssystem-for-handtering-av-kriser/id2965367/

MSIS register and the laboratory database is regulated in the regulations on Notification System for Communicable Diseases ("MSIS-forskriften")[16].

The MSIS laboratory database was established in April of 2020 and is governed by NIPH. Its main aim is the surveillance of infectious diseases in humans in Norway through continuous and systematic collection, analysis, interpretation and reporting of information about the occurrence of communicable diseases. Such surveillance shall participate in fulfilling several purposes, such as to detect and contribute to the detection of outbreaks of infectious diseases.

The laboratory database is fully electronic, and data is reported on an ongoing basis. As of April 2024, 25 out of 26 laboratories send all positive and negative microbiological test results to the MSIS laboratory database. The data is reported as individual level data with unique person-ID. After a quality assurance period however, personal identifiers can only be stored for positive, and in some cases negative, test results for some specific pathogens. For these pathogens, linkage to other data sources through a common personal identifier is possible.

A temporary legal authorization related to the COVID-19 pandemic grants access to keep directly identifiable characteristics for positive and negative "COVID-19 related test results" until the end of June 2024. This applies to the pathogens adenovirus, influenza virus, human metapneumovirus, parainfluenza virus, respiratory syncytial virus (RSV), rhinovirus, SARS-CoV-2, *Bordetella pertussis, Chlamydia pneumoniae* and *Mycoplasma pneumoniae*. After June 2024, personal identifiers can only be kept, and hence linked, for positive test results of SARS-CoV-2 and *Bordetella pertussis*, and for positive and negative test results of influenza virus and likely also RSV.

Relevant data

Data on microbiological test results for pathogens known to cause respiratory tract infections are relevant to the SARI surveillance system. Additionally, demographic data, date of testing and reporting, laboratory, type of sample and requisitioning person / unit (allows to categorize inpatients and outpatients), are also relevant.

Individual level data with personal identifiers for all respiratory pathogens are useful for the SARI surveillance but is available only for the selected pathogens specified above.

Importance

The data is needed to identify individuals who tested positive or negative for different respiratory pathogens and thus identify individuals hospitalised with laboratory-confirmed infection. The data source is graded as essential to SARI surveillance.

Table 3. Summarizing the benefits and shortcomings of the Norwegian Surveillance System for Communicable Diseases laboratory database (MSIS laboratory database) for a SARI surveillance system.

Surveillance system qualities	**Benefits**	**Shortcomings**
Coverage	- Mandatory nationwide register with unique identifiers for linkage.	- Not all laboratories report data for all pathogens yet.

[16] Forskrift om Meldingssystem for smittsomme sykdommer (MSIS-forskriften) - Lovdata

		- Linkable data not permanently available for most pathogens due to legislation. - Captures only patients who are tested, missing certain respiratory infections. - Point of care-tests not included, except for SARS-CoV-2 antigen rapid tests.
Timeliness	- Data is timely due to ongoing updates.	
Simplicity	- Completely electronic and automated, reducing reporting burden.	
Suitability	- Includes information usable as a proxy for hospitalisation.	- Does not include admission and discharge dates, diagnosis codes, etc., affecting ideal surveillance use.

This structured view highlights the MSIS laboratory database's efficiency in data handling and its potential for timely surveillance. However, it also points out the limitations in data completeness and legislative restrictions that could impact its effectiveness for comprehensive surveillance, especially when used independently of other data sources like the NPR.

2.2. Legal considerations

As described in the Legal clarification above, the Act related to the control of communicable diseases § 2-2 last section gives other departments in NIPH the right to request data from the MSIS laboratory database in times of minor (local) crises and the Act on health and social preparedness § 2-4 gives the same right in times of major crises. As also mentioned, the rule of law in the Act related to the control of communicable diseases can constitute the legal basis for the collection of the MSIS data for ongoing surveillance purpose, i.e. without any crises related to the outbreak of a disease. The rules in the Personal Health Data Filing System Act and the MSIS regulation can also be the legal basis for the processing.

Note: For MSIS laboratory database the MSIS regulation mandates the collection of all microbiological test results, however, does not regulate the acquisition of additional information used in surveillance as well as restricts the type of personal data which can be processed in the database.

Contrary to the NPR regulation, the MSIS regulation specifically mentions surveillance as a purpose. It is no doubt that data from the MSIS laboratory database can be used for the surveillance system.

2.3. Technical capabilities

Note: In the case of this pilot, we have used the system of Beredt C19 as an illustration of how data sharing currently operates within NIPH

Sender / Receiver

The data source, MSIS laboratory database, transfers relevant data to NIPH on a regular basis, with daily transfers for most diseases/tests, and weekly transfers for SARS-CoV-2 PCR/antigen and Influenza. The transport of data is secured as the data remains within the "secure zone". The transferred data is secured at rest through access rights to folders in the secure zone.

The extraction of data from the source is a combination of automated and manual processes. Most SARI data is extracted automatically, while SARS-CoV-2 PCR/antigen and Influenza data is extracted manually. The datasets transferred are either full dumps or delta/changes, depending on the type of data.

The extraction and transfer of data have become a standard routine during the pandemic. Metadata is transferred along with the data, and the extraction and transfer processes are logged, although the logs are not stored centrally. Monitoring is done semi-manually but not implemented in a best-practice way.

The current way to transfer data is through secure file transfer, there are multiple channels, protocols, and formats supported for data transfer. There are no standardized backup routines or capabilities in place, with the data from the last transfer serving as the backup until new data is received. There are thresholds in place for data extractions, with manual extraction required for large amounts of data, while smaller amounts are automatically extracted.

Access and identification management capabilities are in place, with some identification management capabilities implemented through Active Directory. Access management is handled by an external provider, NHN, based on orders given by the data source.

NHN is involved in the storage, extraction, and transfer of data. The extraction of data is performed within the secure zone using SQL and/or Stata scripts.

Data minimization is implemented authorized individuals who work with the data in the MSIS laboratory database, with procedures such as filtering, and truncation used to minimize the data.

3. National Population Register (FREG)

3.1. Value-adding

Description

The National Population Register, established in 1964, is maintained by the Norwegian Tax Administration and contains information of everyone that resides or have resided in Norway. Processing of FREG-data is regulated in the National Population Register Act[17], as mentioned previously.

The register forms the basis for the tax register, the electoral register and population statistics. The data is individual case-based with unique personal identifier that allows for linkage with other data sources. The aim of the register is to provide information for official tasks and public administration, research, statistics and to look after basic societal needs.

[17] Lov om folkeregistrering (folkeregisterloven) - Lovdata

Relevant data

The register contains data on e.g., dates of birth and death, sex, place of birth and residence, citizenship, resident status, civil status, and family relations.

Importance

The register includes important information about the population under surveillance. Some other variables provide important supplementary information about the individuals, such as country of birth and date of death. These are needed for assessing the risk of hospitalisation by country of birth and to identify deaths that occur right after discharge from hospital. Regular (weekly) updates of this data source enable precise calculations of hospitalisation rates in different geographical areas and age groups. The data source is graded as essential to SARI surveillance.

Table 4. Summarizing the benefits and shortcomings of the National Population Register (FREG) for a SARI surveillance system.

Surveillance system qualities	**Benefits**	**Shortcomings**
Coverage	- Mandatory nationwide register with unique identifiers for linkage. - Can be used for population statistics, though may differ from official SSB statistics.	
Timeliness	- Provides a timely denominator for calculating population counts.	
Data Quality		- Accuracy of certain dates, like date of death, needs validation.

This table outlines the advantages of having a comprehensive population register for data linkage and statistical analysis, while also noting the importance of validating critical data points to ensure accuracy.

3.2. Legal considerations

Since the FREG is not a health register, it is not directly ruled by the Personal Health Data Filing System Act with regulations.

As mentioned above in Legal clarification, the FREG can disclose data to NIPH in accordance with the National Population Register Act §§ 10-1 and 10-2 and NIPH can collect such data in accordance with the Personal Health Data Filing System Act § 14. However, this assumes that the collection of the FREG data happens in a system/register subject to the Personal Health Data Filing System Act.

It is NIPH's understanding that the surveillance purpose of the system might be achievable by compiling health data from the health registries with personal data from the FREG with statistics as an outcome, according to the Personal Health Data Filing System Act paragraph 19 c, cf. paragraph

19.[18] Note that this is only possible as long as it relates to demographical and socio-economical personal data[19]. In such instance, exception to the duty of confidentiality also applies.

The Act related to the control of communicable diseases § 2-2 last section can also be the legal basis for the processing of the personal data in the system/register. This paragraph gives public authorities such as NIPH the right to request data from public registers when establishing and maintaining surveillance systems in minor crises. This naturally includes the FREG.

Note the Act on health and social preparedness § 2-4 does however not specifically mention public registers / personal data from public registers. The expert group created after the pandemic (*see footnote 9*) has pointed out that the legislator should make it clear that also personal data from public registers such as the FREG and SSB data can be collected to the emergency preparedness registers established and maintained in case of major crises.

3.3. Technical capabilities

Note: In the case of this pilot, we have used the system of Beredt-C19 as an illustration of how data sharing currently operates within NIPH

Sender / Receiver

The sender, FREG, is currently transferring relevant data to NIPH on a weekly basis as changes, and in the future, the method of transfer may involve a stream of events. The data can be requested in a synchronous manner, either one by one or in bulk. The data transferred to NIPH-Beredt is currently stored in a central database within a secure zone, providing security.

The transferred data is secured by Tieto EVRY and NHN. The extraction of data from the source is performed automatically and the transfer of data are standard routines performed on a weekly basis.

Metadata is transferred along with the data, and although the extraction and transfer of data is logged, they are not actively monitored. The preferred way to transfer data is through file transfer or database backup-and-restore operations. There are currently no backup capabilities in place, so data would need to be transferred again if needed.

There is no capacity, competence, or funding in place to maintain and develop the infrastructure needed over time, and there are access and identification management capabilities in place, although they are not well-maintained. There are no thresholds concerning the amount of data. Tieto EVRY and NHN are involved in the storage, extraction, and transfer of data.

Data minimization is implemented by Tieto EVRY based on agreements between them and NIPH. In the near future, data minimization will be managed by the data-controller of each health register or cohort study.

[18] "*FHIs muligheter for utvikling, produksjon og offentliggjøring av statistikk og andre anonyme opplysninger ihht. Helseregisterloven §§19 og 19c mv.*"

[19] Document "*sammenstilling mellom helseregistre og demografiske og sosioøkonomiske personopplysninger – versjon 1.0 - 14.04.2023*"

4. The Norwegian Immunisation Registry (SYSVAK)

4.1. Value-adding

Description

The Norwegian Immunisation Register was established in 1995 and is governed by NIPH. Processing of data in the Norwegian Immunisation Registry (SYSVAK) is regulated in the regulations on the collection and processing of health information in the National Vaccination Register ("SYSVAK-registerforskriften")[20]. It is a mandatory, national, electronic register that records individuals' vaccinations. Since 2020, it has been mandatory to register all vaccinations without consent. The data is individual case-based with unique personal identifier that allows for linkage with other data sources. The main aim of the register is to keep track of the vaccination status of the individual and of the vaccination coverage in the country. The register also aims to evaluate vaccination programmes, keep track of adverse events following vaccinations and contribute to international statistics. In addition, the register can be used for vaccine-related research.

Relevant data

Vaccines that protect against respiratory infections are relevant for the SARI surveillance. This includes vaccines against influenza, COVID-19, whooping cough and in the future also RSV. Relevant variables include demographic characteristics, type of vaccine and date of vaccination.

Importance

The data is needed for monitoring vaccination status among the hospitalised and assessing vaccine effectiveness, thus informing vaccination policies in the country. The data source is graded as important to SARI surveillance.

Table 5. Summarizing the benefits and shortcomings of the Norwegian Immunisation Registry (SYSVAK) for a SARI surveillance system.

Surveillance system qualities	**Benefits**	**Shortcomings**
Coverage	- High level of data completeness since 1996 for childhood vaccination program vaccines.	- Incomplete registration of influenza vaccinations in long-term care facilities and among healthcare workers.
Data Quality	- High level of completeness for most other vaccines since 2020.	
Flexibility		- The register needs technical modernization (currently undergoing).

This table provides an overview of the current state of vaccine data completeness, highlighting the robust historical data for childhood vaccines and recent improvements for other vaccines. It also points out the areas where data is lacking and the ongoing efforts to modernize the system for better data management and quality.

[20] Forskrift om innsamling og behandling av helseopplysninger i Nasjonalt vaksinasjonsregister (SYSVAK-registerforskriften) - Lovdata

4.2. Legal considerations

As described in the Legal clarification above, the Act related to the control of communicable diseases § 2-2 last section gives other departments in NIPH the right to request data from SYSVAK in times of minor (local) crises and the Act on health and social preparedness § 2-4 gives the same right in times of major crises. As also mentioned above, the rule of law in the Act related to the control of communicable diseases can constitute the legal basis for the collection of SYSVAK data for ongoing surveillance purpose, i.e. without any crises related to the outbreak of a disease. The rules in the Personal Health Data Filing System Act and SYSVAK regulation can also be the legal basis for the processing.

Contrary to the NPR regulation, SYSVAK regulation specifically mentions surveillance as a purpose in paragraph 1-6 (data processor), which refers to paragraph 1-3 (purposes of the register). Following up and evaluating vaccines and vaccination programs in the population, including side effects of vaccines, implies surveillance, making it clear that SYSVAK data can be used for the surveillance system.

5. Norwegian Register for Primary Health Care (KPR)

5.1. Value-adding

Description
The Norwegian Register for Primary Health Care (KPR) is a nationwide register. It was established in 2017 and has since January 1st 2024 been governed by NIPH. Processing of KPR-data is regulated in the regulation on the municipal patient and user register (KPR)[21].

The KPR is a mandatory national register with personal health data concerning healthcare services from primary healthcare. Primary healthcare providers are legally obliged to report to the KPR.

The KPR contains mostly data collected from the publicly funded primary healthcare services, but the legislator has recently ruled that the KPR can also contain data collected from the privately funded dental services, cf. the KPR regulation § 3-1 last section. It is also part of the discussion mentioned in footnote 10 above whether the KPR regulation should clarify that personal data from other privately funded primary healthcare services also can be included in the KPR.

Personal health data about the registered/data subjects (patients) is processed without consent and with a very restricted right to object to the processing in the KPR (for example, inhabitants can object to the disclosure of their health data together with their national identity number for research purposes but cannot object to the collection of data.

Note: this right is not completely similar to the right to object in GDPR art. 21. In practice, this right is called a reservation right ("reservasjonsrett"), cf. paragraph 2-2, however because it is a very restricted right, it is our understanding that it has very limited impact on the completeness of the KPR.

[21] Forskrift om kommunalt pasient- og brukerregister (KPR) - Lovdata

The KPR data is partially based on data from other registries and partially collected directly from the primary healthcare services, including from so-called "health stations" (e.g., pre-, and postnatal care, childhood controls), dental visits, visits of physiotherapists to home-based care services and care in long-term care facilities as provided by the municipalities. The Norwegian Control and Payment of Health Reimbursements Database (KUHR) is one of the registers that the KPR is based on. It contains reimbursement data from healthcare services provided at general practitioners' offices and in emergency rooms (i.e. not provided in hospitals).

The main aim of the KPR is to form the basis for planning, management, financing, and evaluation of the primary healthcare services. Preparedness is furthermore explicitly named as one of the additional purposes in KPR.

Relevant data

To identify medical risk groups relevant to a SARI surveillance system, diagnostic codes (International Classification of Primary Care; ICPC-2) from the KUHR are relevant. KPR-data about healthcare services to identify residents in long-term care facilities, is also relevant.

Importance

For SARI surveillance, the data is first and foremost needed to identify medical risk groups for severe respiratory infections. Supplementary, the data could be used for identifying residents in long-term care facilities among patients hospitalised with SARI. The data source is graded as important to SARI surveillance.

Table 6. Summarizing the benefits and shortcomings of the Norwegian Register for Primary Health Care (KPR) for a SARI surveillance system.

Surveillance system qualities	**Benefits**	**Shortcomings**
Coverage	- Mandatory nationwide register with unique identifiers for linkage.	- Does not capture services funded privately or through private insurance.
Timeliness	- Data from physicians expected to have a high grade of completeness after some weeks.	- Most physicians report data with some weeks' interval, affecting timeliness. - Data from long-term care facilities reported from municipalities to KPR only once per year.

This table provides an overview of the KPR system, highlighting the strengths in data linkage and anticipated completeness, while also noting the limitations in capturing privately funded services and the frequency of data reporting which may impact the timeliness for surveillance purposes.

5.2. Legal considerations

As described in the Legal clarification above, the Act related to the control of communicable diseases § 2-2 last section gives other departments in NIPH the right to request data from the KPR in times of minor (local) crises and the Act on health and social preparedness § 2-4 gives the same right in times of major crises. As also mentioned, the rule of law in the Act related to the control of communicable diseases can constitute the legal basis for the collection of KPR data for ongoing surveillance purpose

, i.e. without any crises related to the outbreak of a disease. The rules in the Personal Health Data Filing System Act and the KPR regulation can also be the legal basis for the processing.

Unlike the NPR regulation, the KPR regulation clearly states that its data can be used for preparedness. It is our understanding that surveillance is a prerequisite to preparedness. As mentioned previously, the need for better access and use of key health registers such as the KPR for preparedness, also in normal time, has been pointed out by an expert group after the pandemic. It is therefore our understanding that the KPR could be used for the surveillance system.

6. Norwegian Prescribed Drug Registry (NorPD)

6.1. Value-adding

Description

The Norwegian Prescribed Drug Registry (NorPD) is a mandatory nationwide register that contains information on medicines dispensed by prescription from pharmacies in Norway from and including 2004. Processing of NorPD-data is regulated in the regulations on the collection and processing of health information in the Medicines Register[22] ("LMR-forskriften").

The register includes information on medicines, the patient, the prescribing health personnel, and the pharmacy. For the period 2004-2021, data from the Norwegian Prescription Database has been transferred to the NorPD. The data is individual case-based with unique personal identifier that allows for linkage with other data sources.

The aim of the register is to collect and process information on medicine use in order to create statistics which are often used in quality assurance and research.

Relevant data

To identify medical risk groups relevant to a SARI surveillance system, individual case-based data on prescribed and delivered drugs (drug name, ATC-code, substance name, time of delivery, amount delivered) are relevant. Especially immunosuppressive medicines and medicines used for the treatment of known risk factors for severe respiratory infections (e.g. chronic pulmonary diseases) are of interest.

Importance

By linking the data with other sources, data could be used for better defining medical risk groups (e.g., immunosuppressed patients) for severe infections. The data source is graded as important to SARI surveillance.

Table 7. Summarizing the benefits and shortcomings of the Norwegian Prescribed Drug Registry (NorPD) for a SARI surveillance system.

[22] Forskrift om innsamling og behandling av helseopplysninger i Legemiddelregisteret (LMR-forskriften) - Lovdata

Surveillance system qualities	**Benefits**	**Shortcomings**
Coverage	- Mandatory nationwide register with unique identifiers for linkage. - Data available from 2004.	- Currently does not include over-the-counter medicines or medicines administered in hospitals or nursing homes. - Usage cannot be determined, only that medicines have been collected from the pharmacy.

This table highlights the register's extensive data availability and its potential for linkage with other data sources, while also noting the current limitations regarding the scope of medication information it contains. The ongoing project to include data from hospitals and other institutions may address some of these shortcomings in the future.

6.2. Legal considerations

As described in the Legal clarification, the Act related to the control of communicable diseases § 2-2 last section gives other departments in NIPH the right to request data from the NorPD in times of minor (local) crises and the Act on health and social preparedness § 2-4 gives the same right in times of major crises. As also mentioned, the rule of law in the Act related to the control of communicable diseases can constitute the legal basis for the collection of the NorPD data for ongoing surveillance purpose, i.e. without any crises related to the outbreak of a disease. The rules in the Personal Health Data Filing System Act and the NorPD regulation can also be the legal basis for the processing.

It is not clear yet whether prescribed medical data from the NorPD could be collected for surveillance purposes within the framework of the NorPD regulation. The NIPH has not concluded whether surveillance of communicable diseases which lead to hospitalization can also legitimate surveillance of medications, for identifying and defining risk group for serious pulmonary infection diseases. The NIPH needs therefore to work on such assessment.

7. State Register of Employers and Employees (AA-register)

7.1. Value-adding

Description

The State Register of Employers and Employees (AA-register) is a register of employment in Norway. Processing of personal data in the AA-register is regulated in the regulations on the Register of Employers and Employees[23]. The register is governed by the Norwegian Labour and Welfare Administration and lists all employment relationships in Norway, with a few exceptions. The register was established in 1978 when the sick-pay scheme was introduced. Employers and contractors are obliged to report their employees and freelancers to the register. The data is individual case-based with unique personal identifier that allows for linkage with other data sources. The main aim of the

[23] Forskrift om Arbeidsgiver- og arbeidstakerregisteret - Lovdata

register is to serve the Norwegian Labour and Welfare Administration and others who need information about working conditions in connection with solving public tasks.

Relevant data

To identify healthcare workers and other occupational groups, individual case-based data on e.g., occupational code, occupation, contract start date, contract end date, and organizational number could be relevant.

Importance

The data could be used for comparing rates of hospitalisations by occupation, to indicate e.g., if exposure through work poses increased risk of severe disease. Data could also be used for assessing vaccine effectiveness against severe disease for different occupations, esp. healthcare workers. Data might also be used for identifying and investigating outbreaks in healthcare institutions. The data source is graded as supplementary to SARI surveillance.

Table 8. Summarizing the benefits and shortcomings of the State Register of Employers and Employees (AA-register) for a SARI surveillance system.

Surveillance system qualities	**Benefits**	**Shortcomings**
Coverage	- Mandatory nationwide register with unique identifiers for linkage.	- Unpaid internships not included. - Classification/identification of health care employee groups other than physicians and nurses is challenging. - Difficult to identify persons employed through subcontractors. - Limited information available for freelancers in the healthcare sector.

This table provides an overview of the AA-register, highlighting its capability for data linkage due to the unique personal identifiers. However, it also points out the limitations in capturing data on unpaid internships, certain employee classifications, subcontractor employment, and freelancers.

8. Statistics Norway (SSB)

8.1. Value-adding

Description

Statistics Norway (SSB) is the national statistical institute of Norway and the main producer of official statistics. Processing of data from SSB is regulated in the Act on National Statistics[24].

SSB is responsible for collecting, producing, and communicating statistics related to the economy, population, and society at national, regional, and local levels. SSB also conducts extensive research

[24] Lov om offisiell statistikk og Statistisk sentralbyrå (statistikkloven) - Lovdata

Co-funded by the European Union

and analysis activities. SSB collects and links data from various registries, owned either by SSB or other actors, to produce datasets that include e.g., socioeconomical information on individuals. These data are individual case-based with unique personal identifiers allowing for linkage with other data sources. The main aim of SSB is to promote the development, preparation and dissemination of official statistics that can contribute to public information and support analysis, research, decision-making and public debate. Access to data can be given to state bodies, county councils and municipalities (among others).

Relevant data

For SARI surveillance, the socioeconomic data from SSB which include individual case-based data on housing, earnings, and education may be relevant.

Importance

These data could be used for supplementing the surveillance dataset to enable the assessment of associations between housing and living conditions / country of origin / education and income and risk of hospitalisation. By including these factors in vaccine effectiveness analyses, it will improve the quality of the results as these factors are often confounders in such analyses (associated with both the likelihood of being vaccinated and risk of severe disease). The data source is graded as supplementary to SARI surveillance.

Table 9. Summarizing the benefits and shortcomings of the Statistics Norway (SSB) for a SARI surveillance system.

Surveillance system qualities	**Benefits**	**Shortcomings**
Coverage	- Provides individual case-based data with unique identifiers for linkage.	

This table highlights the capability of SSB to provide detailed data that can be linked with other sources.

9. Norwegian Intensive Care and Pandemic Register (NIPaR)

9.1. Value-adding

Description

The Norwegian Intensive Care and Pandemic Register (NIPaR) is a national medical quality register which houses two separate registries, the Norwegian Pandemic Register (NoPaR) and the Norwegian Intensive Care Register (NIR). NoPaR was established in the beginning of 2020 and includes information on patients admitted to the specialist healthcare service with infectious disease during epidemics or pandemics. NIR contains information on patients treated at intensive care units (ICUs) in Norway. NIPaR is governed by the Helse Bergen hospital trust, and the register is mandatory. Processing of personal data in NIPaR is regulated in the regulations on medical quality registers[25]. The aim of the register is to improve the quality of healthcare services, reporting to health services and health authorities and scientific research.

[25] Forskrift om medisinske kvalitetsregistre - Lovdata

For this pilot, only NIR is relevant. NIR, established in 1998, collects data on survival, length of stay, severity of illness scores, main reasons for admittance and the most relevant diagnose codes and ICU treatment modalities for intensive care patients treated in Norwegian ICUs. NIR has defined which ICUs shall report data to the register, and which stays shall be registered. Not all intensive care units report to NIPaR. It is possible for a patient to refrain from participation. In addition to the main data collection form that is filled out for all patients, separate forms are filled out for patients admitted to ICU with influenza (electronic form since 2018) and COVID-19 (electronic form since 2020). The data is individual case-based with unique personal identifiers that allowing for linkage with other data sources.

NIR has 3 main aims:

i. The register shall provide a basis for reports back to participating hospitals and to central health authorities related to activities at Norwegian ICUs and epidemics.
ii. The register shall prepare quality indicators for activities in Norwegian ICUs and related to epidemics.
iii. The register shall facilitate research related to activities in ICUs and epidemics.

Relevant data

NIR includes case-based data on ICU admissions according to predefined criteria. The register provides data on e.g., admission and discharge dates, use of ventilatory support, deaths in ICUs, and some information on the clinical picture / diagnosis of the patient (e.g. confirmed covid-19 with pneumonia).

Importance

Data from NIR could be used for identifying ICU admissions with influenza and COVID-19. Currently, NIR does not collect data on other respiratory infections besides influenza and COVID-19, and thus, the NPR must be used for identifying patients hospitalized with SARI receiving intensive care and / or ventilatory support. Data from NIR would be needed for quality assurance of the NPR-data. Apart from admission with COVID-19 and influenza, the registration of ICU admissions is not timely, and the data may thus not be suitable for routine surveillance. If NIR is to be used for surveillance of SARI, development of a new form for registering all these cases would likely be needed. The data source is graded as supplementary to SARI surveillance.

Table 10. Summarizing the benefits and shortcomings of the Norwegian Intensive Care and Pandemic Register (NIPaR) for a SARI surveillance system.

Surveillance system qualities	**Benefits**	**Shortcomings**
Coverage	- Nationwide register with unique identifiers for linkage.	- Patients can opt out, potentially biasing the data. - Not all intensive care units report to NIR.
Timeliness	- Timely registration of ICU patients with influenza and COVID-19.	

This table provides an overview of the NIPaR, highlighting its comprehensive coverage and timely data collection for critical cases, while also noting the potential data biases due to patient opt-out rights and the lack of reporting from all intensive care units.

10. Norwegian Cause of Death Registry (CoDR)

10.1. Value-adding

Description

The Norwegian Cause of Death Registry contains information on persons who have died in Norway and Norwegian residents who have died abroad. Processing of personal data in CoDR is regulated in the regulations on the collection and processing of health information in the Causes of Death Registry ("Dødsårsaksregisterforskriften")[26].

The information in the register is based on information in death certificates from physicians and from autopsy reports. Norwegian doctors are obliged to send notification of death to the Norwegian Cause of Death Registry. Electronic reporting of deaths has gradually increased since it was piloted in 2018. The register is governed by NIPH and contains digitalized data from 1951. The data is individual case-based with unique personal identifier that allows for linkage with other data sources.

The aim of the register is to:

- monitor causes of death and shed light on changes in causes of death over time
- provide a basis for the preparation of national, regional, and local cause of death statistics
- promote and provide a basis for research
- provide a basis for information and knowledge for planning, quality assurance and quality development of the health and care services and health and care administration

Relevant data

The register provides data on demographic characteristics, date of death, place of death, and underlying and contributory causes of death (ICD-10).

Importance

The data can be used for supplementing the surveillance data with underlying and contributory causes of death for patients who die in hospital, and for assessing sequelae of severe respiratory infections that lead to death. The data source is graded as supplementary to SARI surveillance.

Table 11. Summarizing the benefits and shortcomings of the Norwegian Cause of Death Registry (CoDR) for a SARI surveillance system.

Surveillance system qualities	**Benefits**	**Shortcomings**
Coverage	- Mandatory nationwide register with unique identifiers for linkage.	- The number of deaths from specific respiratory infections may be underestimated due to testing activity.
Timeliness	- Electronic reporting with relatively good timeliness.	

[26] Forskrift om innsamling og behandling av helseopplysninger i Dødsårsaksregisteret (Dødsårsaksregisterforskriften) - Lovdata

This table outlines the strengths of the Norwegian Cause of Death Registry in terms of data linkage and reporting efficiency. However, it also points out the potential underestimation of deaths associated with respiratory infections, which could be a significant shortcoming for accurate mortality data analysis.