Smarter Health Care
National Research Programme

Synthesis Working Paper: Health Care Data

April 2022

About this Synthesis Working Paper

The NRP 74: Research for better health care

The National Research Programme "Smarter Health Care" (NRP 74) aims to promote innovative health services in Switzerland and to tackle the practical challenges the health care system is facing today. To this end, researchers are investigating a wide range of aspects, from the better use of health data and the care of older people at home to case management in emergency wards.

The NRP 74 includes 34 research projects at universities and higher education institutions throughout Switzerland. It is implemented by the Swiss National Science Foundation (SNSF) on behalf of the Federal Council, has a budget of CHF 20 million and runs from 2016 to 2022.

Six critical areas with a Synthesis Working Paper for each

To address some of the overarching issues facing the health care system today, the NRP 74 has integrated significant research findings from single projects into six topic-specific syntheses. In these six critical areas, researchers analysed their results from different professional perspectives, putting them in a larger context and devising recommendations to meet the current challenges in today's health care system.

These areas are:

- Quality of care
- Patient participation
- Coordination and care models
- Cost and reimbursement
- Health care data
- Building a strong research community (EHCL+)

All six topic-specific syntheses can be consulted on www.nrp74.ch.

The Synthesis Team

This synthesis working paper on the theme of "Health care data" has been compiled by a team led by a member of the NRP 74 steering committee, a principal investigator, and two doctoral students engaged in NRP 74 projects and part of NRP 74's Emerging Health Care Leaders (EHCL) programme.

- Marcel Zwahlen, NRP 74 Steering Committee, University of Bern (lead)
- Holger Dressel, Principal Investigator, University of Zurich
- Lester Darryl Geneviève, Emerging Health Care Leader EHCL, University of Basel
- Yael Rachamin, Emerging Health Care Leader EHCL, University Zurich
- Editorial advisor: Stéphane Praz, Leporis Communication, Zurich

Swiss National Science Foundation
Programmes division
National Research Programmes
Wildhainweg 3, P.O. Box
3001 Berne

+41 31 308 22 22
nrp74@snf.ch
www.nrp74.ch

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Editorial

For several years, it has been claimed that the “smart” use of data routinely collected in the health care system (“real-world health care data”) provides important insights for improving diagnostic, therapeutic, and preventive health care services. In recent years, more and more refined methods for the appropriate use of real-world health care data have been developed and used in countries where their implementation is feasible. At the same time, researchers in Switzerland (and elsewhere, but not in all countries) face numerous obstacles if they want to use these data. Due to the fragmented health care system in Switzerland, there is no central overview of the many existing databases, what type of information they contain and whether the data are interoperable across data “silos”. In addition, there is often uncertainty about the requirements and legal hurdles for using of these data for research. In short, the immense potential that real-world health care data hold for health care research can currently be exploited to a very limited extent only.

Against this background, the National Research Programme "Smarter Health Care" (NRP 74) of the Swiss National Science Foundation commissioned our group to identify the most important obstacles from the perspective of health care services research and to formulate possible suggestions/recommendations for improvement. In doing so, we were able to draw on the knowledge and experience of many NRP 74 researchers, some of whom we consulted in discussions and others in writing. We also benefited greatly from the insights shared with us by key stakeholders at a dialogue meeting in September 2021, where we presented and discussed our main conclusions. And finally, the findings of the NRP 74 project "Promoting the merging of health data in Switzerland", led by Prof. Bernice Elger, also substantially contributed to this report.

Special thanks and appreciation go to the two doctoral students and members of the NRP 74 Emerging Health Care Leaders (EHCL) community, Yael Rachamin and Lester Darryl Geneviève, who did much of the work to compile this report. They reviewed the literature, interviewed researchers, engaged with stakeholders, and ultimately wrote significant portions of this synthesis working paper.

We arrived at two central suggestions/recommendations for improvement:

1. the introduction of a Unique Personal Identifier for all routinely collected health care data, and
2. The establishment of a national institution or commission in charge of coordinating and preparing

    a) the approval steps for the research use of routinely collected data in the health care sector for research and

    b) the technical solutions for accessing the required data (e.g. remotely, on-site, as data download).

Neither idea is new, but so far the availability of data in the (in many ways) fragmented Swiss system has been accepted as sufficient. We think that we present good evidence and arguments to conclusively show that the current situation is not adequate for a health care system aiming at continuous learning and thus improving the organisation of health care services. We hope for broad support for our proposal from researchers and stakeholders.

Bern, in April 2022, Marcel Zwahlen in the name of the whole team

Executive Summary

Context: Many hurdles hinder the use of routinely collected data for health services research

New information technologies and digitalization of health care leads to more and more data being routinely collected in the health care system. These include, among others, insurance billing data, hospitalisation data, and - in the future - information in the electronic health record. Many of these real-world data (if of good enough quality) are of great interest to those who conduct health care research and, ultimately, to those who make decisions to improve the provision of medical care.

So far, however, researchers in Switzerland have been able to exploit the potential of routinely collected data only to a limited extent. This is due to several technical, legal, organisational, and political reasons. Many of them are closely related to the specific ways the health care system and the framework for governing health care research are organised in Switzerland. The NRP 74 programme, with its focus on health care research, was directly affected by this and, against this background, prepared the present synthesis working paper on the use of routinely collected data for research in Switzerland.

NRP 74: Possible solutions from a research perspective

The Synthesis Working Group examined the current scientific and grey literature and compared it with new research results from NRP 74. Furthermore, it gained first-hand insights into difficulties and possible solutions through written and oral interviews with NRP 74 researchers who themselves work with routinely collected data. Finally, it discussed its main conclusions with national stakeholders, as they play a central role in implementing the recommended measures.

This paper summarises the main challenges related to the use of routinely collected data for health care research in Switzerland and discusses possible solutions. Finally, it presents two key recommendations on which there is broad consensus in academia and practice. They are considered to be important next steps to improve the use of routinely collected data for health care and health services research.

Two key recommendations

1. **Introduce a Unique Personal Identifier for all routinely collected data in the health care sector.**
   A Unique Personal Identifier (UPI) is an individual code for each person living in Switzerland, which all health care providers can use to uniquely assign data to that person. With a UPI, data on the same person from different databases can be linked, which is an indispensable requirement for many research projects and their statistical analyses. The technical implementation of the UPI must, among other things, ensure data protection and, if necessary, the anonymity of the data vis-à-vis researchers or for other purposes of use. There are various practicable solutions for this. However, adjustments to ordinances or laws may be necessary.

2. **Establish a national institution or commission in charge of coordinating and preparing approval steps and the technical solutions for the use of health care data**.
   The proposed institution/commission would have a coordinating role between regional research ethics committees, data protection officers, and data owning institutions. The proposed institution/commission would ensure clarity and transparency for researchers and data owners about all steps necessary to use routinely collected data for research. The commission's instructions would need to be binding on both parties. Its establishment must therefore be planned and implemented in a broadly agreed process involving all relevant stakeholders.

1. Introduction - Focus and method of this Synthesis Working Paper

Summary

This chapter introduces the topic of health care research with health data. It explains that health care research, and by extension, the health care system can benefit greatly from the analysis of such data. And it outlines the focus of this paper on routinely collected data which are particularly important for research.

Regarding Switzerland, the paper explains key characteristics in which health data differ from other databases and which prevent the comprehensive use of health data for research. These include the fact that health data are usually held in silos with heterogeneous formats and limited interoperability, or that their special legal status makes access and processing difficult. A spotlight on current processes in health care development shows that policymakers have recognized the problem in principle.

Finally, an overview of the methods and foundations used to develop the contents of this synthesis working paper and its two key recommendations is provided.

1.1 Real world data for health care research: huge potential, numerous hurdles, and systemic difficulties

Routinely collected data open up a huge potential for health care research

Using routinely collected data in the health care sector has a great potential for health services research [1]. This data and information are collected within health care provision without specific a priori research questions, thus explicitly excluding data collected for a clinical trial or other specified clinical studies [2]. Routinely collected health data can be collected for various purposes, such as “provision of broad resources for research (e.g., disease registries), clinical management (e.g., primary care databases), health system planning (e.g., health administrative data), documentation of clinical care (e.g., electronic health record data repositories), or epidemiological surveillance (e.g., cancer registries and public health reporting data)”[2].

Routinely collected health care data offer important epidemiological information that can be used to inform decisions in clinical medicine, health services planning, and public health [3-5]. They are “Real World Data” which can generate “Real World Evidence”, as opposed to artificial settings in clinical research. They thus complement randomised controlled trials by mirroring actual care, offering timely information, and providing insights if trials are not possible (e.g., due to ethical issues). For instance, during the current COVID-19 pandemic, routinely collected health care data have proven useful in assessing the effectiveness and side effects of the COVID-19 vaccine [6, 7] as well as the indirect contribution of the COVID-19 pandemic to a higher incidence of potentially missed/delayed diagnoses and subsequent treatment of certain high risk medical conditions [8]. Moreover, routinely collected health care data, if shared adequately, will increase transparency in the health sector, which may reduce costs [9-11].

Even though the analysis of routinely collected health care data is undoubtedly also relevant for clinical practice and monitoring, this synthesis working paper maintains a focus on health care research - other use of health care data (E.g. for governance activities, quality monitoring, etc.) are not explicitly covered. In this regard, we use the definition of health services research provided by the US Institute of Medicine committee (Note: the terms "health services research" and "health care research" are used synonymously in this document):

> "Health services research is a multidisciplinary field of inquiry, both basic and applied, that examines the use, costs, quality, accessibility, delivery, organization, financing, and outcomes of health care services to increase knowledge and understanding of the structure, processes and effects of health services for individuals and populations" [12](p.3).

In Switzerland, numerous hurdles hamper the exploitation of the given potential

The advent of new information technologies, coupled with the digitalization wave in the health care domain, has led to the generation of an increasing number of health datasets (e.g., through electronic health records). Such datasets are falling increasingly under the umbrella term *big biomedical data* [13] or simply *Big Data* [14]. In fact, more and more insights can be drawn from these data. But at the same time, their full exploitation is prevented by a distinct set of challenges, some of which are particularly pronounced in the Swiss setting [15-17]. In contrast to industrial datasets that can benefit more efficiently from *Big Data* approaches (e.g. being more readily available and having a lower information density, etc.), health care datasets have a more complex status: They are usually held in silos with heterogeneous formats, limited interoperability, higher generating costs, and with a higher information density [14, 15]. In addition, health data are bestowed with a special status under the legal and regulatory framework, due to their sensitive nature [18, 19]. Such a heightened legal protective stance renders access to and processing of such health care datasets more complicated, often with restrictions for health services research, unless there is no potentially identifiable information [20].

Recent political and research initiatives aim to improve the situation

In Switzerland, political appreciation of the importance of health care data and commitment to improving the situation/infrastructure have already been expressed in the "Health 2020" strategy released in 2013, with the Federal government emphasising the objective of improving the health data framework of the country [21]. More recently, it was confirmed as a priority with the launch of the strategy "eHealth Schweiz 2.0" [22] and by the new federal health policy for the period 2020-2030 [23]. Improving the health care data framework has also repeatedly been the focus of parliamentary requests, e.g. in the postulates 15.4225 and 18.4102 "Bessere Nutzung von Gesundheitsdaten für eine qualitativ hochstehende und effiziente Gesundheitsversorgung" and "Kohärente Datenstrategie für das Gesundheitswesen" and the motions 16.4011 ("Digitalisierung. Keine Doppelspurigkeiten bei der Datenerhebung"), 20.3923 ("Besseres Datenmanagement im Gesundheitsbereich") and 21.4373 ("Einführung eines eindeutigen Patientenidentifikators") (see Annex I for an overview of parliamentary requests on the topic). Moreover, in response to the COVID-19 pandemic, several parliamentary requests highlighted the importance of a well-functioning health care data infrastructure and data foundation (e.g. postulate 21.3195: "Covid-19-Pandemie. 'Lessons learned' für den Wissenschaftsstandort Schweiz" and interpellation 21.3631: "Bessere Daten zur Kinder- und Jugendgesundheit"). And in January 2022, the Federal Office of Public Health (FOPH) published a report with a list of measures it proposes to improve health data management ("Bericht zur Verbesserung des Datenmanagements im Gesundheitsbereich"). The Federal Council has instructed the departments concerned to report on their intended action by July 2022.

1.2 NRP 74: Developing recommendations based on scientific results as well as researchers' and stakeholders' expertise and experiences

Focus on routinely collected data for research

As mentioned above, this Working Paper is concerned with the use of data routinely collected in the provision of health care and its use for research purposes. This explicitly excludes health care data derived from randomised controlled trials (as they are not routinely collected), and the use of data for governance activities such as monitoring (i.e. not research).

In Switzerland, many health care data exist in digital form but are often stored in unconnected, inconsistent data silos (see section 2.1). Therefore, the Synthesis Team paid particular attention to issues of usability (i.e. access and legal constraints) and the linkage of available data between silos.

Project results and expertise from NRP 74

Within the NRP 74, one project focused specifically on finding solutions to improve the health care data infrastructure in Switzerland ("Promoting the merging of health data in Switzerland", led by Prof. Bernice Elger). The findings of this project have contributed significantly to this working paper and are discussed at various points in the document.

Important guidance on the topic was also provided by numerous NRP 74 principal researchers. Their experiences in NRP 74 projects, but also in research activities in general, directly point to key challenges encountered in practice. In addition, many researchers have extensive theoretical expertise to develop possible solutions. Thus, the Synthesis Team gathered NRP 74 researchers' input at the 2020 NRP 74 Programme Conference and with a targeted written survey. Chapter 4.2 provides an overview of the challenges and possible solutions that were identified.

Stakeholder involvement on findings and conclusions

For the purposes of developing and validating the recommendations given in this Working Paper, key stakeholders were invited to a dialogue meeting with the Synthesis Team as well as the president of the NRP 74 Steering Committee, its Programme Manager and its Head of Knowledge Transfer. The meeting took place on 15 September 2021 in Bern. Stakeholders were provided with the teams' most important findings and conclusions in advance and asked for a first (written) feedback on aspects, which are of great concern to them. At the meeting, the Synthesis Team presented more background on its recommendations, before stakeholders met in smaller groups to discuss the relevance and feasibility of the insights and recommendations. A final plenary discussion provided another opportunity to point out missing or particularly critical points and differing opinions. The meeting revealed widespread agreement on the key recommendations, while regarding implementation many valuable suggestions were voiced from different perspectives (see section 5.3).

2. Current situation in Switzerland: A fragmented health care data framework

Summary

This chapter highlights the technical and legal frameworks that shape access to and use of health care data in Switzerland. In terms of the technical aspects, it points out that data are often stored in disconnected and inconsistent data silos, and that the situation regarding available data differs greatly between the inpatient and the outpatient health care sector, with greater gaps and inconsistencies in the latter. With respect to the legal basis, the most important laws - the Swiss Human Research Act and the Federal Act on Data Protection - are outlined, but also the fact that 25 cantonal data protection laws and the associated ordinances have to be taken into account, thus complicating the legal situation.

Finally, a brief overview of national initiatives to improve the health care data framework that may impact the use of routine health care data for research shows how the issue is being considered in current developments at the policy level.

2.1 Collection and storage of (potentially available) health care data

In Switzerland, many health care data are routinely collected and stored in the process of clinical care or to meet the regulatory requirements (e.g. in terms of billing) [11]. Even though many health care data exist in digital form, they are often stored in unconnected, inconsistent data silos, each with their own acquisition, transport, storage and validation processes [11]. Many important health data sources are referenced in different platforms, two of which include the opendata.swiss [24] and the Swiss platform for medical registries [25].

Importantly, there is an apparent difference between data collection in ambulatory versus stationary health care [11]. While in the stationary sector, detailed data per case on services and costs are available, data from ambulatory care are largely lacking. Moreover, in the stationary sector, diagnoses are coded according to the International Classification of Diseases, 10th revision (ICD-10), whereas no systematic coding of diagnoses or reasons for encounter (e.g. International Classification of Primary Care, 2nd edition, ICPC-2) is used in the ambulatory sector.

2.2 Legal basis for using health care data for research

A multitude of federal and cantonal laws regulate the use of health data for research

There are different pieces of legislations regulating the processing of health care data for research in the Swiss context: At the federal level, the Swiss Human Research Act (HRA), its ordinance the Human Research Ordinance (HRO), and the Federal Act on Data Protection (FADP), and at the cantonal level, 25 cantonal data protection laws [26] and their associated ordinances.

Given the multitude of data protection laws, research involving health care data is often challenging for researchers, who are often inexperienced in dealing with certain interpretative and implementation aspects of the law [16, 17]. This results in a climate of legal uncertainty whereby the sharing of health data, essential for health services research, is often hindered or impacted [16].

The use of health data in biomedical research, including the secondary use of health care data for research, is governed by the HRA [27], which aims to protect the health, dignity and personality of human subjects in research [27], and its ordinance the HRO [28]. The HRA and HRO are superseding the FADP (which provides a general regulatory framework) or cantonal data protection laws in this specific domain [29].

Degree of data anonymization is a key legal criterion

The legal requirements for the processing of health data for research under the HRA depend on the genetic nature (genetic or non-genetic health data) and the degree of anonymization of the health care datasets (identified, coded, anonymized or anonymously collected, e.g. see Table 1) [29].

Definitions of anonymization or de-identification vary between European and US/Canadian legislations [30]. In Switzerland, the main distinction is between identified data, coded data and anonymized data:

- *Identified data* is so comprehensive that it is possible to identify data subjects without the need to rely on additional data
- *Coded data* covers every personal information linked to a specific person via code (independent of whether researchers have direct access to the key for re-identification).
- *Anonymized data* requires deletion of all items that would enable the data subject to be identified without disproportionate effort, including particularly metadata such as name, address, date of birth, and unique identification numbers (e.g. the SSN) (HRO, art. 25.2 [28]).

It is important to note that only the processing of personal data falls under the remit of data protection laws and HRA, which means that anonymously collected datasets are not governed by the abovementioned laws [18, 26, 27].

Table 1: Requirements for the secondary use of health data for research in Switzerland

	Secondary use of identified data	Secondary use of "coded" data	Anonymization of data for secondary use	Secondary use of anonymous information
Genetic data	Explicit consent must be obtained for every single research project [Human Research Act (HRA), 2014, art. 32.1].	Explicit consent is required, but it can cover multiple research projects (broad consent). (HRA, 2014, art. 32.2)	Explicit consent is NOT required, but data subjects have right to dissent (presumed consent). (HRA, 2014, art. 32.3)	No requirements.
Other health-related data	Explicit consent is required, but it can cover multiple research projects (broad consent). (HRA, 2014, art. 33.1)	Explicit consent is NOT required, but data subjects have right to dissent (presumed consent). (HRA, 2014, art. 33.2)	No requirements.	No requirements.

Table reprinted (adapted) from Martani A, Geneviève LD, Pauli-Magnus C, McLennan S, Elger BS. Regulating the Secondary Use of Data for Research: Arguments Against Genetic Exceptionalism. Frontiers in Genetics. 2019;10(1254).

The FADP aims to protect the privacy and the fundamental rights of persons when their data are processed [18]. Article 3 of the FADP defines health data as "sensitive", meaning that this category of personal data benefits from a heightened legal protection. Therefore, their processing is more regulated, by either setting up stricter requirements that need to be fulfilled for their collection and use (e.g. requiring the explicit consent of data subjects, see FADP Art. 4 [18]) or by simply restricting their processing [29]. However, the FADP also provides exemption for research (Art. 13 and Art 22.) if certain conditions are met (e.g. the data are no longer considered personal - i.e. anonymized - and the data subjects cannot be identified in the published results) [18]. Regarding biomedical research, the FADP and cantonal data protection laws are only subsidiary to the HRA, "i.e., they can be considered to supplement the rules of the HRA. In other words, the general data protection regulations remain applicable in cases where the provisions of the HRA are not exhaustive enough" [26].

2.3 National initiatives to improve the health care data framework

There are several national initiatives aiming to improve the health care data framework that may impact the use of routine health care data for research. A selection is presented in the following paragraphs. It should be noted that cooperation between the different initiatives is limited [31]. However, there are some promising drivers of centralization and standardisation. For instance, the Federal Statistical Office (FSO) has recently started to perform data linkages between their data and/or external data for third parties (e.g. researchers) [32]. Moreover, the Swiss Personalized Health Network SPHN is creating a Federated Query System that would allow researchers to quickly verify what data is available within the datasets of different university hospitals [33]. For cancer specifically, the National Agency for Cancer Registration [34]) - a national coordination centre - has recently been created. While it is currently limited to cancer health data, Article 24 of the Cancer Registration Act [35] creates opportunities in the future to

use this legal framework to also collect data on other widespread or dangerous non-communicable diseases [36].

The eHealth Switzerland Strategy 2.0

Switzerland formally has a national "e-health strategy", but this is almost exclusively focused on the introduction of a nationwide interoperable electronic patient dossier (EPD). Importantly, the EPD foresees the creation of an identification number assigned to the record of each patient [37]. This number is derived from, but also different to the social security number (SSN) normally used by citizens (e.g., for tax purposes, or to buy health insurance).

The Swiss Personalized Health Network (SPHN)

The SPHN is a consortium promoted and financed by the Swiss Federal Government and other important institutional partners with the objective of promoting personalised medicine through a better use of health data. It aims to build a sustainable data infrastructure that ensures interoperability of clinical health data while allowing secure data access for researchers.

The "Modules Ambulatoires des Relevés sur la Santé" (MARS) project

The purpose of the MARS project by the Federal Statistical Office (FSO) is to provide statistical bases on ambulatory health care. Basically, it provides data records of ambulatory patients in hospitals (PSA) and structural data of medical practices and ambulatory centres (MAS).

The Lovis report

In response to a report by international experts on measures to contain the rising health care costs in Switzerland, Christian Lovis received a mandate from the FOPH to propose a strategy to improve the efficiency and effectiveness of data collection and use for governance purposes. The resulting report suggested to follow an incremental approach by first aiming at optimising the use of existing data (optimising data flows, avoiding duplicate data acquisition, transport and storage, unifying validation processes and clarifying usage), and then to gradually improve the flows based on the experience gained.

The "Nationale Datenbewirtschaftung" (NaDB) programme and its pilot projects

The multiple use of data is a goal of the "Digital Switzerland Strategy" and the "eGovernment Strategy Switzerland". In line with this, the Federal Council has decreed a "once-only principle": Individuals and companies should have to report certain information to the authorities (such as the FSO) only once. As a consequence, four pilot projects were issued within the NaDB programme of the FSO, which are intended to demonstrate the feasibility of more uniform data flow management and the "once-only principle". A promising pilot project is "Spitalstationäre Gesundheitsversorgung" (SpiGes), which - in accordance with the proposition of the Lovis report - aims to implement the necessary optimizations in terms of data flows and data needs for both administrative and statistical purposes in the stationary setting. Importantly, it foresees the use of unambiguous identifiers for both the hospitals (i.e., the business and company register (BUR) number) and the patients (i.e., the SSN). SpiGes is intended to serve as a precursor project for further redesigns in other areas.

Reports in fulfilment of postulates

The federal administration is working on reports in fulfillment of the postulates 18.4102 "Kohärente Datenstrategie für das Gesundheitswesen" and 15.4225 "Bessere Nutzung von Gesundheitsdaten für

eine qualitativ hochstehende und effiziente Gesundheitsversorgung", which contain, among other things, a proposition for a system for the further use and linking of health data in compliance with data protection regulations, which will be submitted to the Federal Council.

3. Challenges in accessing and using health care data for research

Summary

This chapter discusses the main challenges related to accessing and using health care data for research purposes. These are summarised based on the current literature, a specific NRP 74 research project, and the survey of NRP 74 researchers in the following dimensions:

- Technical challenges (e.g. data quality issues and lack of data standards).
- Ethical-legal challenges (e.g. legal uncertainty and health data ownership issues)
- Sociocultural challenges (e.g. hypercompetitive research environment and declining trust in institutions that collect health data)
- Procedural challenges to data access (e.g. lack of oversight of health data sources)

In order to use health care data for research, data must a) be available in principle, i.e. stored digitally in a structured way etc., and b) be usable, i.e. accessible. The availability of health care data relies on a multitude of factors, many of which are related to a digitalised health system. The overall operationalization and implementation of digital health in Switzerland is still in a developing phase [38]. Accordingly, the OECD highlighted in a report a few years ago that there is room for improvement in how health data are collected and shared between stakeholders in Switzerland [39].

We identified a number of key challenges regarding access and use of health care data for research, which are based on the current literature on the one hand, and on the other hand are confirmed by NRP 74 researchers based on their experiences. These challenges are summarised and discussed in the subsequent subsections (for responses from NRP 74 researchers, see also section 4.2). They have been classified under four broad categories, namely technical, ethico-legal, sociocultural and data access challenges.

3.1 Technical challenges

Typically a concern for bigger countries, Switzerland is also experiencing considerable technical challenges

The technical challenges to maximising the use of health care data (e.g. sharing and re-use for research purposes) have been identified and extensively covered in the scientific literature [15, 40-42]. Nonetheless, proposed solutions have been limited in resolving these challenges due to difficulties associated with their sustainable implementation, with sometimes limited financial and political commitment [41]. At the European level, it is observed that the adoption of nationwide and standardised electronic health records - a valuable asset for research [43, 44] - varies significantly between European countries, with larger countries, such as France or Germany, experiencing more difficulties than smaller ones (e.g., Denmark or Sweden) [42].

Although a small country, Switzerland is also experiencing several technical challenges limiting the sharing and use of health care data for research purposes as revealed by several research projects of

the NRP 74 (e.g. see [15]). These include non-exhaustively, data quality issues (e.g. incompleteness of collected datasets, including potentially inaccurate data due to classification mistakes), the lack of data standards (e.g. issues with data semantics and structure) but also other technical limitations (e.g. the absence of a Unique Personal Identifier for data linkage activities) [2]. These different issues are discussed below.

The federal health system hinders data sharing and coordination

Data quality and data standards issues in the Swiss health care context are likely the result of many interconnected factors. For instance, cantons in Switzerland have a high degree of autonomy in organising their health care systems [45]. The result is a decentralised health care system, leading to significant inter-cantonal variations concerning the supply structure and per capita health expenditures to name a few [45]. Consequently, fragmentation of the Swiss health care system - at both the institutional and provider levels - is a known barrier to the sharing of data, on top of being a source of limited coordination, low transparency of health care processes and potentially "a threat to health care safety" [46].

The federal law on the electronic patient dossier (EPD) [46, 47] - which aims to improve the overall efficacy of the Swiss health care system by the compulsory implementation of interoperable electronic health records by nursing homes and hospitals - also has some inherent limitations with respect to the completeness of health care datasets. Indeed, opening an EPD is voluntary and requires the written informed consent of patients (see Art. 3 EPDG) [47]. Since there is no obligation for patients to use the EPD, and patients using the EPD can decide to hide or eliminate certain recorded data [36], obtaining a comprehensive and transparent picture of the Swiss health care status at present time is challenging. Additionally, the EPD in its *current form* contains mainly data in PDF format, which makes their retrieval and analysis difficult in practice [48], but more interactive forms will be introduced in the near future, which should cater for these limitations [49]. The importance of data standards has also been raised at the level of the IT infrastructures of registries and hospitals, which are also deemed to have limited capabilities [36].

The lack of a Unique Personal Identifier complicates data linking

There is no Unique Personal Identifier (UPI) in Switzerland, which would allow to easily combine (pseudonymized) data on the same person across different databases and sectors, like in the case of Denmark [15, 36]. Although the Swiss social security number SSN could be a suitable candidate for a UPI, the Swiss system relies on sector-specific identifiers because of privacy concerns [50, 51]. Another approach could be the use of deterministic and probabilistic linkage techniques, which have achieved good results for the Swiss National Cohort. However, such techniques cannot guarantee that all available records can be linked. Indeed, these methods are largely dependent on certain linkage variables that may not be present for all patients or to the high mobility of certain subgroups of the population (e.g. younger adults) [52]. Therefore, some experts argue that there is a need for a national data centre that would not only coordinate with different data sources available in Switzerland, but would also carry out linkage activities using a designated UPI. Such a centre would also function as a one-stop shop for researchers by standardising and streamlining the whole process of data access and linkage activities [36].

3.2 Ethico-legal challenges

It is interesting to note that most research projects in Europe fail to effectively use or share health datasets because of complexities associated with ethico-legal factors rather than being limited by

technical issues [40]. This is particularly important for Switzerland given the complexity of its health care system, with cantons being also responsible for the health legal framework [53]. Indeed, the fragmented nature of the ethical and legal framework governing data sharing activities in the health care research sector has led to a series of challenges specific to the decentralised approach adopted in Switzerland.

Some ethical and legal challenges identified in the Swiss context include:

- the *legal uncertainty* governing health data collection/sharing activities in particular for multi-cantonal or international research projects [16]. For instance, it was found that the same piece of legislation could be interpreted very differently depending on the type of stakeholders involved, or that some researchers experience difficulties in ascertaining which cantonal law should prevail in a given context in multi-cantonal research projects. Furthermore, it was reported that by fulfilling differing data protection requirements imposed by cantonal laws, or that heterogeneous evaluations of the same project or similar projects by research ethics committees (RECs) had led some project leaders to reduce the scope and impact of their respective projects [16];
- *informed consent issues*, where Swiss projects still favour the "consent or anonymize" approach, i.e. the solution adopted for ethico-legal problematics in using health data is either to anonymize the collected datasets or to obtain the explicit consent of data subjects [15, 54]. Given how medical or health services research is gradually becoming data-intensive and falling increasingly under the realm of *big data*, the "consent or anonymize" approach may no longer be a viable option in a near future, in particular given that irreversible anonymization would significantly reduce the ability to update and link datasets [54]. Additionally, by imposing different requirements for the secondary use of different types of health data (e.g. genetic versus non-genetic data), the Swiss legislation complicates the consent process while unnecessarily hindering health care research [29];
- *health data ownership issues*, where there is a lack of conceptual clarity on the meaning of data ownership and its ramifications. Therefore, it is important to not only ascertain who is the data owner (e.g. patients or data processors) and what exactly health data ownership entails. These important questions need to be answered in order to be able to promote a proper data governance framework adapted to the local context [17];
- *fear of data misuse or misinterpretation* that led data owners or custodians to come up with different solutions, such as contractual data sharing/transfer agreements [55].

3.3 Sociocultural challenges

Here, we refer to sociocultural challenges as those factors negatively influencing the collection and/or sharing of health datasets between different stakeholders, and which are deep-rooted in the norms, mindset, functioning and cultural organisation of the health care and/or academic system.

Hypercompetitive research environment

One important sociocultural challenge in that regard is the *hypercompetitive environment* in which researchers or institutions have to navigate and its repercussions on the collection or sharing of health datasets for research purposes [16]. Indeed, the Swiss academic system and others still provide incentives for career advancements (e.g. the number of first-author or last-author publications) that nudge researchers to adopt individualistic behaviours and refrain from sharing datasets. In addition, there are no systemic attribution mechanisms implemented in the Swiss context that incentivize data sharing activities as an integral component for the evaluation of academic performance. Therefore, it is important to recognize the plurality of scientific outputs in allocating the scarce resources (e.g. grants or

academic positions) for the acceptance and promotion of the open data movement in the scientific and health care community [16]. In this perspective, the Swiss National Science Foundation has piloted a new form of scientific CV ("SciCV") where data sharing activities are included as an integral component (https://scicv.ch/about/). Besides academic considerations, the health care sector is also facing some resistance from owners of datasets (e.g. health insurers, service providers and disease registers to name a few) and data protection officers concerning the merging of datasets from different sources, which need to be taken care of [3].

Moreover, NRP 74 results also showed that researchers and other stakeholders (e.g. heads of disease registries) feel entitled to some sort of financial or academic compensation (e.g. in terms of co-authorship opportunities) in return for the efforts they put in managing and sharing datasets [55]. Financial compensation was also perceived as being a prerequisite for sharing datasets to ensure the sustainability and quality of data collections. Therefore, such behaviour or positions adopted by researchers and other stakeholders need to be given due consideration [55] as they may play a bigger role in the data sharing ecosystem than initially thought.

Little coordination and strategic planning between national initiatives

Additionally, there are attitudinal or "mindset" challenges hindering the advancement of the health data framework in the Swiss context. Some of those include (i) a lack of communication or proactive exchange of information between key national initiatives (e.g. the Swiss Personalized Health Network SPHN, the Swiss National Cohort SNC, and the Swiss Data Science Center to name a few) to allow a better coordination of efforts in improving the health data framework, and (ii) the absence of a clear and concerted long-term data strategy where priorities for the health data framework have been agreed by relevant stakeholders to positively influence their mindset while reducing the costly multiplication of efforts [36]. Such challenges need to be proactively tackled since they conflict with the priorities set forth in the health policy strategy of the federal council for 2020-2030 (Health2030), where the potential of health data needs to be harnessed for research, public health and the organisation of health care, and where there needs to be a more coordinated approach between the different stakeholders in the digitalization of the health system [56].

Declining trust in institutions collecting health data

From a societal perspective, it has been observed that the Swiss population's trust in institutions collecting health data has diminished over the past few years, in particular concerning the respect of privacy, but the origin of such a decline is unknown and needs to be investigated [36, 57]. Additionally, the societal preference for a decentralised approach needs to be respected. Therefore, elaborated solutions to improve access and sharing of health care data should align with this preference for decentralisation (e.g. by highlighting the need for a UPI for linking decentralised databases across Switzerland) [36].

3.4 Procedural challenges to data access

There is a need to tackle the fragmentation of data access procedures [58], which can lead to unclear legal situations and therefore complicates compliance with data protection regulations and consent procedures in Switzerland. Indeed, heterogeneous data access requirements (e.g. in multicenter projects due to different cantonal regulations) can hinder not only the sharing of health datasets for health services research but they can also make it challenging to determine whether data sharing activities are occurring within ethical and legal margins [16, 36]. Additionally, it is currently challenging for researchers in Switzerland to identify existing sources of health data - which are often underutilised

- that could be re-used for their respective research projects [36]. In contrast, Danish researchers have access to an online catalogue of existing health care data sources (with information on the application procedures to access data from each source), named Healthcare Data Exchange, which was initiated by the Copenhagen Healthtech Cluster [59].

4. Possible solutions based on NRP 74 research and expertise

Summary

This chapter presents possible solutions to the key challenges outlined in the previous chapter. First, the relevant findings of the NRP 74 Project "Promoting the merging of health data in Switzerland" are presented, followed by an overview of inputs from NRP 74 researchers based on their individual experience and expertise. There is strong consensus among them on the importance of a legal basis that provides a more research-friendly environment by better balancing individual data protection and the ability to improve health care. More specifically, many researchers emphasise the need for a reliable Unique Personal Identifier to enable linkage.

4.1 Results of NRP Project "Promoting the merging of health data in Switzerland"

NRP 74 project ("Promoting the merging of health data in Switzerland", principal investigator Prof. Dr. Bernice Simone Elger, University of Basel) conducted extensive literature analysis, interviews with experts as well as a Delphi survey to identify international best practices in health data harmonisation and challenges and facilitators for such models in Switzerland. Based on their findings, the researchers formulated a set of solutions and recommendations, which could facilitate the collection, sharing and linkage of health datasets for health services research in Switzerland (some are listed Figure 1 [36]). These have been categorised under technical, ethico-legal, socio-cultural and data access recommendations and solutions, and are discussed in the following subsections.

Figure 1: Recommendations to improve the Health Data Framework in Switzerland

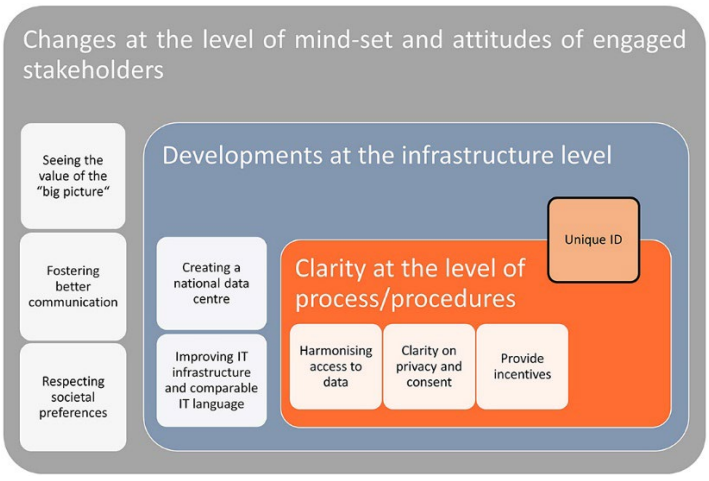

Figure reprinted from Martani A, Geneviève LD, Egli SM, Erard F, Wangmo T, Elger BS. Evolution or Revolution? Recommendations to Improve the Swiss Health Data Framework. Frontiers in Public Health. 2021;9(638).

Technical solutions and recommendations

One of the main technical recommendations put forward to improve access, sharing and linkage of health data for health services research is the creation of a *national data coordination centre*. The national data centre would provide a unique point-of-entry for researchers needing data (e.g. registry data) for their respective research projects. The data centre would have the responsibility of streamlining and standardising the procedural requirements for data access whilst managing the linkage of databases across Switzerland [36]. However, it is important to highlight that such a national data centre will not be a centralised repository for all health services databases - given the societal preference for decentralisation - but rather functions as a "one-stop-shop" where researchers could request access to and link numerous databases across Switzerland to answer their research questions [36].

Similarly, in Denmark, numerous national institutions have been acting as one-stop-shops for researchers to get access to health datasets (e.g. *Statistics Denmark* [60], and the *Danish Health Data Authority* for register data [61]). For instance, *Statistics Denmark* has long been acting as a one-stop-shop where Danish researchers can get access to anonymized micro data, under the conditions that they have to (i) work on them on the dedicated research server, (ii) not transfer data outside the server (e.g. on their personal computer) and (iii) not attempt to re-identify data subjects or enterprises (for more information, see [60]). In a similar vein, the Swiss Federal Statistical Office (FSO) has also started performing linkage activities for researchers, who can request it via a standardised request form. However, as a condition for approving the linking of external data sources, the FSO requires researchers to first clarify the content of the external databases and subsequently obtain the approval of data owners for the linking procedure [62]. Therefore, the *modus operandi* of the FSO in its current form does not seem to meet the expectations of Swiss researchers concerning a national data coordination centre as identified in the NRP 74 project "Promoting the merging of health data in Switzerland"[36]. Connected with the idea of having a national data centre, two further technical recommendations have been formulated: (i) improving the IT infrastructure and languages, and (ii) the introduction of a Unique Personal Identifier (UPI) for linkage purposes [36].

It has been argued that the general IT infrastructure in the Swiss context also needs to be improved, in particular regarding how data is being collected (structure and semantics) to improve the interoperability of existing IT systems collecting health data [36]. In that regard, the SPHN has proposed a *semantic interoperability framework*, whose implementation is based on three pillars, namely "Semantic Representation", "Data transport and storage" and "Use cases" (for more information, see [63]). Also important for the proper functioning of a national data coordination centre is a Unique Personal Identifier (UPI). It should be created on a clear legal basis, aligned with societal preferences, and robust ethical and data security measures, so that it could be used for recording data on patients in the EPD and other databases (e.g. in the ambulatory sector, registries, etc.), and thereafter be used for the linkage activities of the national data coordination centre [36]. The technical recommendations are summarised in Table 2.

Table 2: Technical recommendations to improve the Swiss health data framework

Recommendation	Concrete implications
Create a national data centre	→ create an institution or an organisation that is capable of coordinating and combining the requests for data access and data linkage for the healthcare and research sector.
Improve IT infrastructure and promote comparable IT language	→ invest on a IT infrastructure that allows an effective reuse of health data. Also, ensure that data from different datasets are compatible by promoting the use of standard nomenclatures and formats
Unique Patient Identifier	→ in a decentralised system like Switzerland, a unique identifier to link data concerning the same person from different sources should be enabled.

Table reprinted (adapted) from Martani A, Geneviève LD, Egli SM, Erard F, Wangmo T, Elger BS. Evolution or Revolution? Recommendations to Improve the Swiss Health Data Framework. Frontiers in Public Health. 2021;9(638).

Ethico-legal solutions and recommendations

Many ethical and legal solutions (and recommendations) have been formulated that could help to promote the collection, sharing and linkage of health datasets in the Swiss context [15-17, 26, 36, 55]. To address the problem of *legal uncertainty* with regard to the processing of health data for research purposes locally and internationally, it has been argued that there is a need to clarify data protection regulations and the role of consent for processing health data (e.g. in the case of using routinely collected health data for research). In that regard, it is important that data protection commissioners and ethics committees are actively involved in this clarification procedure. Thereafter, they should set clear operational rules for the processing of health data in order for researchers to operate their projects in a legally- and ethically-compliant manner [36]. Additionally, it may be beneficial to provide funding and resources to cantonal data protection officers, so that they could collaborate and assist more effectively researchers in interpreting the legal framework [26].

Another solution that could help to reduce the legal uncertainty is to incentivize institutions processing health data to provide not only some education and training to their researchers on the regulatory landscape but also legally-compliant data transfer mechanisms (e.g. tools for sharing datasets) to guarantee that researchers are not left on their own in interpreting and implementing these legal and ethical requirements [16]. In that regard, implementation of codes of conduct or an adequacy model (e.g. data protection certification mechanisms specifically designed for health services research) could be an interesting option to tackle the legal uncertainty in the Swiss context [16, 64].

However, the training component on the regulatory landscape (e.g. in terms of data protection, information security and privacy) should not be neglected [26], as demonstrated by the course offered on “Data Privacy and IT security training” to researchers of the SPHN initiative [65].

Concerning informed consent procedures, the Swiss Human Research Act makes a distinction in terms of secondary use requirements for uncoded and coded genetic and non-genetic data (see HRA 2021 Art. 32.1 32.2, and Art. 33.1 and 33.2 [27]). However, it is argued that making a distinction between different types of health data (e.g. genetic versus non-genetic data) in terms of their secondary use requirements creates preventable barriers for health services research [29]. Indeed, these different secondary use requirements for genetic and non-genetic data are not based on empirical evidence concerning patients’ preferences. They also run the risk of neglecting the sensitive nature of some non-genetic data (since stronger requirements are imposed for the secondary use of genetic data).

Furthermore, they create unnecessary barriers to the elaboration of comprehensive consent forms, and hinder the “free flow of data between care and research without a convincing justification” [29]. Therefore, the researchers of the NRP 74 project “Promoting the merging of health data in Switzerland” conclude that the same regulatory standards should be applied to all types of health data, which would simplify the consent procedure and promote secondary use while safeguarding the trust of data subjects [29].

To have a proper data governance framework, a first necessary step is to clarify the concept of *data ownership* and its associated rights for patients and data processors [17]. Indeed, if data processors feel entitled to data ownership rights due to the work invested in collecting and managing these datasets, such a stance could limit their willingness to share “their” data. Therefore, there is a need to reduce this sense of entitlement by either providing enough resources to data processors when they create such datasets or for data requesters to offer a reasonable financial compensation in exchange for these datasets [17]. Another potential solution is to “favour the idea that these [data] are a sort of public good, which can be donated by patients and guarded by data-processors" but it would require that data are not commodified and therefore, less likely to be controlled by data processors for their own interests [17].

Solutions and recommendations regarding sociocultural challenges

There is a need to reduce the impact of the hypercompetitive academic environment on the sharing of health data. One proposed solution is to implement systemic attribution mechanisms (e.g. at the level of funders) for data managers and researchers managing and sharing datasets, that would consider not only their data sharing activities but also the quality of the shared datasets in their decision to allocate the finite resources [16]. In addition, other incentives can be offered in the form of a reasonable financial or academic compensation for data owners in exchange for their datasets if certain conditions are met [55]. For instance, authorship opportunities in resulting manuscripts could be offered by data recipients to researchers sharing datasets, provided that the latter satisfy the authorship criteria specified by the International Committee of Medical Journal Editors (ICMJE) [66]. Or else, the concept of “data authorship” [67] can also be promoted and implemented in the scientific community as an additional criterion for evaluating stakeholders’ data contributions for resource allocation, which would incentivize data sharing and advance science [55].

Solutions and recommendations to improve processes and procedures for data access

In the NRP 74 project “Promoting the merging of health data in Switzerland”, expert stakeholders involved in the Swiss health data landscape (e.g. researchers, hospital directors, policymakers, public officials and administrators of databases, etc.) were interviewed to provide their recommendations on how to improve the Swiss health data framework [36]. Their recommendations to improve the procedures to access and share datasets are summarised in Table 3.

Table 3: Recommendations to improve procedures and processes for accessing and sharing data

Recommendation	Concrete implications
Harmonise access to data	→ ensure that access procedures to data are less fragmented and dispersed, to facilitate the identification of data sources and the transparency of the process to obtain access to such data.
Clarity on privacy and consent	→ educate researchers on the data processing legal rules and implement more broadly a simplified pathway to allow the reuse of health data with more relaxed consent requirements.
Provide incentives	→ create tools to favour the cooperation between the different institutional actors that need to collaborate in the fulfilment of the procedures for data sharing and access.

Table reprinted (adapted) from Martani A, Geneviève LD, Egli SM, Erard F, Wangmo T, Elger BS. Evolution or Revolution? Recommendations to Improve the Swiss Health Data Framework. Frontiers in Public Health. 2021;9(638).

Reducing fragmented data access procedures can occur via different means. First, the establishment of the previously described national data coordination centre, along with the setting up of adequate incentives, can help in standardising data access procedures. Indeed, such a centre would offer a unique one-stop shop structure for researchers, where request procedures to access and link datasets from different sources could be simplified and standardised [36]. Second, it can be useful if data custodians (e.g. institutions, hospitals, etc.) make their databases discoverable by providing clear access points, which researchers can easily use to request data in order to reduce fragmented data access procedures. Third, standardising data access procedures can also occur by implementing collectively data access requirements (e.g. permissions and documentations) [36]. The latter point can be seen as analogous to the documentation harmonising efforts made by the SPHN in drafting its legal agreement templates to facilitate exchange of data between participating institutions [36, 68].

4.2 Proposed solutions from NRP 74 researchers

At the NRP 74 Programme Conference 2020 and in a dedicated survey, researchers of NRP 74 projects have been asked about challenges and potential solutions regarding access to and use of health care data in Switzerland. There is great consensus on the importance of a legal basis that provides a more research-friendly environment by better balancing individual data protection and the ability to improve health care. More specifically, many researchers underlined the need for a reliable UPI to enable linkage. There is also broad agreement that certain data export capabilities and interoperability requirements should be made mandatory, and that a "minimum dataset" of patient-level health insurance data should be made available to researchers.

The below table gives an overview on the mentioned challenges and corresponding recommendations and contributions to solutions. The square brackets indicate the number of researchers from different projects mentioning the particular aspect.

Table 4: Overview mentioned challenges/problems and corresponding solutions/recommendations

Challenges/Problems	Potential solutions/recommendations
(General) data protection issues (prohibiting or delaying research projects) [x3]	Legal basis/law changes providing a more research-friendly environment (better balanced between individual data protection and ability to improve the health care) [x1] Better communication channels between health care researchers and legal compliance/data protection [x1]
Limited access (e.g. due to data protection rules) [x5]	
Sharing of a created database (with linked data) with other research groups/for further projects is (legally) not possible [x1]	
Missing regulatory framework for exchange [x1]	
Regulatory linkage difficulties [x3]	
Lack of standardisation/ harmonisation/ comparability/ interoperability [x4]	Adoption of SNOMED CT by the Federal Office of Public Health and its implementation by eHealth Suisse shall improve and harmonise the coding of clinical terms [x1] Mandatory data export capabilities and interoperability requirements [x1]
Lack of resources for data extraction, management [x2]	Securing that the collection of data is duly compensated / fair distribution of benefits and burdens, i.e. budgeting data sharing activities in project funding [x1]
Lack of competence (e.g. in hospitals, providers), data literacy [x2]	Proper training in data collection and curation [x1]
Lack of “pressure” (e.g. for primary care physicians to use a shared electronic medical record, or for health insurers to share data) [x2]	A mandatory "minimum dataset" of patient-level health insurance data should be made available to researchers [x1]
	Creation of an extensive inventory of different sources of health data in Switzerland [x1]
Technical difficulties with linkage (e.g. erroneous anonymous linkage codes of the medical statistic) / Unique identifier missing [x6]	Development of reliable anonymous linkage codes/Unique Personal Identifier (i.e. hashed social security number SSN), or creation of a data linkage or dissemination centre [x2]
Insufficient data quality: lack of structured data, incomplete or suboptimal coding [x6]	Data quality validation before research is required to determine potential and suitability [x1] Communication with the people that collect the data is important to gain insight and understand the data [x1]
“Technical” lack of access (e.g. existing but not available at all or in a usable format) [x2]	
Complexity of software [x1]	

Challenges/Problems	Potential solutions/recommendations
Lack of willingness to exchange/share data, both of providers and researchers; competition and conflicting interests; providers both desire and fear transparency [x3]	Promoting a “cultural change” that health data analysis is aimed at improving and not at benchmarking is needed [x1]
There is no shared vision across stakeholders (what are the concrete priorities that want to be pursued with better availability of data) [x1]	A common vision of the concrete objectives that are to be achieved through data collection and sharing is required [x1]
Fragmentation in terms of data organisation, access, structure. [x1]	
Heterogeneous project evaluation methods e.g. regarding ethical approbation/data protection (by cantons, hospitals, …) [x2]	Approval processes for multi-cantonal projects need to be timely, harmonised and streamlined [x1]
Limitations given the content of the data/what is possible with the data [x5]	

Source: Own written and oral survey.

5. Two key recommendations to improve the situation

Summary

This chapter presents two key recommendations that emerged from the NRP 74 synthesis process to improve the situation regarding the use of routinely collected data in the provision of health care:

1. The introduction of a Unique Personal Identifier for all routinely collected health care data.
2. The establishment of a national institution or commission in charge of coordinating and preparing

   a) the approval steps for the use of routinely collected data in the health care sector for research and
   b) the technical solutions for accessing the required data (e.g. remotely, on-site, as data download).

Regarding the implementation of these recommendations, Chapter 5.3 summarises the feedback on hindering or facilitating factors provided by key stakeholders at a dialogue event in autumn 2021.

For a brighter future of health services research, two central measures have emerged in the synthesis process of NRP 74 to improve the situation regarding the use of data that are routinely collected in the process of health care provision, as outlined below.

Both measures are well established in the scientific literature, and are already in place in other countries. They are seen both by NRP 74 researchers and national stakeholders as essential pillars that can significantly strengthen health services research and thus the health care system in the future. In the following, we will briefly highlight the benefits that would accompany these measures and discuss some aspects, which should be considered when implementing them.

5.1 Recommendation 1: Introduce a Unique Personal Identifier for all routinely collected data in the health care sector

Unique Personal Identifier: Definition

Each person at birth is assigned a unique “number” (or code) which they keep throughout their lives. At each encounter with the social and health system, this unique person identifier (UPI) accompanies them. An alternative is to have a separate UPI set up only for the health system.

Benefits of a Unique Personal Identifier

If data on health care services is at first stored in separate data systems with different legal data owners, the presence of the UPI makes it technically possible to link up information for the same person from different sources of information (if the UPI is handled perfectly).

Data protection aspects

Technical solutions exist to use encrypted UPIs to link the information for a specific research project without revealing the “true” UPI to the research group. This can be done with project specific encryption

steps. This together with other well-defined rules and technical implementations regarding data access, possibly only remotely, should make it possible to use information across data sources for research projects while adhering to the applicable strict data protection in place. Other countries have already implemented such solutions. To make such an implementation successful, a central institution/ commission with the necessary resources is also needed (see second recommendation).

Various possible methods, with the SSN as the most obvious option

The Swiss social security number SSN, already existing, is the most obvious candidate for the UPI. However, this needs to be clarified with the relevant authorities and other health care partners involved (Federal Office of Public Health, Federal Statistical Office, provider organisations and relevant cantonal authorities). Adaptations to ordinances or laws may be necessary.

5.2 Recommendation 2: Establish a national institution or commission in charge of coordinating and preparing approval steps and the technical solutions for the use of health care data

Role and possible scope of a national institution/commission

This national institution/commission would be in charge of coordinating and preparing approval steps and the necessary technical solutions for the use of routinely collected health care data, be it at the level of cantonal or national agencies, hospitals, health insurance companies etc.

The institution would coordinate the various needed approvals from regional research ethics committees, data protection officers, and institutions who later would need to provide the relevant (encrypted) data. The institution might need to install a fair and competent scientific review of proposed research projects in order to limit the work to projects that are of high enough scientific merit. Given the appropriate legal basis, the institution/commission could grant certain approvals independently.

The institution/commission - possibly as an extension of the work of the SPHN data centre activities - should also advise on (or enforce) the proper implementation steps for safe-guarding data protection for approved projects.

All procedures and agreements used in this institution/commission should be jointly accredited by the research ethics committees and the federal and cantonal data protection officers.

Benefits of a nationwide approval commission

It would greatly facilitate the conduct of research projects in health services and real-world clinical research if clear and simple-to-follow steps were in place to obtain the necessary approvals (permissions etc) to access (and possibly link) existing routinely collected digital information on health-related services and patients treated. The proposed national institution or commission would help to transparently define and implement these necessary steps.

Prerequisite: Mandatory rules for data owners

If projects have received all necessary approvals to use the data (under proper data protection) the “official” data owners have a duty to provide the data according to the technical steps defined to safe-guard data protection. It is unclear whether such an obligation is already implied by the existing laws (Federal Act on Health Insurance (KVG) and others) or whether amendments to laws or ordinances are

needed. It is likely that data owners will need to be remunerated to some degree to comply with this duty.

Long-term financing requires strategic view

The proposed national institution/commission will certainly need appropriate financial resources to operate. At this stage of the discussions, it is unclear whether such an institution/commission can be affiliated with existing institutions or needs to be created de novo. It is also unclear what the needed budget level should be. A pilot build-up might be the most sensible approach for the next steps.

5.3 Implementation aspects raised by stakeholders

On 15 September 2021, key stakeholders were invited to a dialogue meeting with the synthesis team as well as the president of the NRP 74 steering committee, its programme manager and head of knowledge transfer. The goal was to receive feedback on the synthesis team's key insights and recommendations and to discuss their feasibility for implementation. The event was attended by a variety of experts, representing the Association of Health Insurers santésuisse, the Center for General Medicine and Public Health (Unisanté) of the University of Lausanne, the Department of Health of the Canton of Zurich, the Federal Office of Public Health, the Federal Statistical Office, the Federation of Surgical Societies Switzerland, Helsana, SASIS AG, the State Secretariat for Education, Research and Innovation, the Swiss Conference of the Cantonal Ministers of Public Health, the Swiss Health Observatory OBSAN, the Swiss Institute of Bioinformatics, the Swiss Medical Association FMH, the Swiss National Accident Insurance Fund SUVA, and the Swiss Personalized Health Network.

Stakeholders broadly agreed on the need for both a UPI and more clearly defined rules and processes for data access, sharing and linkage. Regarding the UPI, some stakeholders emphasised that not only patients, but also institutions (e.g., hospitals) and health care providers need a unique identifier, so that data can be reliably linked. To facilitate approvals and processes (including linkage), the establishment of a nationwide "approval commission" (or institution) was discussed.

Various challenges were also identified. Most prominently, the need for resources dedicated to the proposed activities was emphasised, not only for the "institution" that would eventually implement these new processes, but also for data providers. Several stakeholders also mentioned the importance of data privacy issues, particularly if the SSN was to be used as a UPI.

Stakeholders felt that the biggest "facilitators" might be ongoing initiatives, especially at the FSO, e.g. the pilot project "Spitalstationäre Gesundheitsversorgung" (SpiGes). Building on what is already planned and works was considered to have great potential (see also [11]).

Stakeholders disagreed on the roles and responsibilities of the proposed "institution", i.e., whether it should only be an information centre providing information and advice, or play a broader role (e.g. in coordinating approvals), or even have some decision-making power (i.e. granting approvals). It was also discussed where this new institution could be established. Some stakeholders suggested that it could be incorporated into the FSO, since the FSO is arguably a transparent and politically neutral institution recognized as a data specialist (and thus well positioned to coordinate the collection and use of data). Moreover, the FSO is well established in the proper handling of highly protectable data (i.e., it maintains best practice on data protection and data security).

At the meta level, the importance of clear definitions when talking about "routine data", "health care data", "health services research" etc., was emphasised, as well as the extension of the subject to monitoring (as opposed to research). Other issues that were discussed were the importance of standardisation and

harmonisation (with stakeholders pointing to the SPHN as a major driver in this field), and closely related, the importance of “high quality” data. A minimal quality standard, especially for data to be linked, was suggested. Another point emphasised was the importance of the digitalisation of health care data, also in the ambulatory setting. While focusing on ongoing initiatives may allow for quick wins, the ambulatory setting should not be forgotten.

Annex I – Recent parliamentary requests (motions and postulates) aiming at improving the health care data framework (selection) as of 1.4.2022

Additional Table 5: Recent parliamentary requests

Name	Submitted on	Submitted by	status of deliberations
Motion 22.3163: «Stärkung der digitalen Kompetenzen von Gesundheitsfachpersonen»	16.03.2022	A. Silberschmidt	Not yet discussed in the Council
Motion 22.3016: «Implementierung einer nachhaltigen Data-Literacy-Strategie in der digitalen Transformation des Gesundheitswesens»	04.02.2022	Social Security and Health Committee	Not yet discussed in the Council
Motion 22.3015: «Elektronisches Patientendossier. Praxistauglich gestalten und finanziell sichern»	04.02.2022	Social Security and Health Committee	Not yet discussed in the Council
Motion 21.4374: «Einführung einer digitalen Patientenadministration»	02/12/2021	A. Silberschmidt	Motion to 2nd Council
Motion 21.4373: «Einführung eines eindeutigen Patientenidentifikators»	02/12/2021	A. Silberschmidt	Motion to 2nd Council
Motion 21.3957: «Digitale Transformation im Gesundheitswesen. Rückstand endlich aufholen!»	18/06/2021	E. Erlich	Accepted
Motion 21.3779: «Die Krankenversicherer sollen dem BAG genau, vollständig und kostenlos Daten liefern»	17/06/2021	V. Maitre	Not yet discussed in the Council
Motion 21.3925: «Elektronisches Patientendossier als Kommunikationsinfrastruktur nutzen und Zugriffsrechte vereinfachen»	18/06/2021	R. Humbel	Not yet discussed in the Council
Motion 21.3021: «Mehrwert für Forschung und Gesellschaft durch datenbasierte Ökosysteme im Gesundheitswesen»	18/02/2021	Science, Education and Culture Committee	Motion to 2nd Council
Motion 20.4672: «Verbindlicher Zeitplan für die digitale Transformation im Gesundheitswesen»	18/12/2020	R. Humbel	Not yet discussed in the Council
Motion 20.4717: «Bürgerinnen und Bürger müssen die digitale Hoheit über ihre Gesundheitsdaten erhalten»	18/12/2020	B. Flach	Not yet discussed in the Council
Motion 20.3923: «Besseres Datenmanagement im Gesundheitsbereich»	10/08/2020	Social Security and Health Committee	Accepted
Postulat 20.3700: «Nutzung anonymisierter persönlicher Daten im öffentlichen Interesse.	17/06/2020	J. Bellaîche	Not yet discussed in the Council

Name	Submitted on	Submitted by	status of deliberations
Prüfung der Machbarkeit einer freiwilligen Datenspende»			
Postulat 20.3352: «Je besser die Daten, desto besser die Politik»	06/05/2020	A. Gerhard	Accepted
Motion 18.4203: «Schaffung einer modernen Dateninfrastruktur mit strukturierten Patientendaten zur Förderung der Humanforschung»	12/12/2018	Ch. Eymann	Completed/rejected
Postulat 18.4102: «Kohärente Datenstrategie für das Gesundheitswesen»	06/11/2018	Social Security and Health Committee	Accepted
Motionen 18.3432 & 18.3433: «Unbestrittene Statistiken von einem unabhängigen Organ erstellen lassen. Eine unerlässliche Voraussetzung für die Steuerung des Gesundheitssystems»	31/05/2018	O. Feller/ A. Thorens Goumaz	Completed/rejected
Motion 16.4011: «Digitalisierung. Keine Doppelspurigkeiten bei der Datenerhebung»	14/12/2016	FDP, the liberal group	Accepted
Postulat 17.3434: «Potenzial und Rahmenbedingungen für die digitale Nachhaltigkeit im Gesundheitswesen»	13/06/2017	E. Graf-Litscher	Depreciated
Postulat 15.4225: «Bessere Nutzung von Gesundheitsdaten für eine qualitativ hochstehende und effiziente Gesundheitsversorgung»	18/12/2015	R. Humbel	Accepted

Annex II – NRP 74 principal investigators/research projects consulted on the topics of this Working Paper

The researchers of the following projects shared their expertise at the 2020 NRP 74 Programme Conference and in a dedicated survey, as summarised in chapter 5.2:

NRP Project No. 2: Promoting participatory medicine in colorectal cancer screening (Prof. Dr. med. Reto Auer, Berner Institut für Hausarztmedizin BIHAM, Universität Bern)

NRP Project No. 3: What factors affect the performance of elective interventions in Switzerland? (Prof. Dr. med. Drahomir Aujesky, Universität Bern)

NRP Project No. 4: Social inequalities in the provision of in-patient healthcare in Switzerland (Dr. sc. nat. Lucy Bayer-Oglesby, Fachhochschule Nordwestschweiz)

NRP Project No. 6: Interprofessional quality circles improve medication in nursing homes (Prof. Dr. Olivier Bugnon, Université de Lausanne)

NRP Project No. 7: Routine data from primary care practices serve to improve the healthcare system in Switzerland (PD Dr. Corinne Chmiel, UniversitätsSpital Zürich, Institut für Hausarztmedizin der Universität Zürich)

NRP Project No. 9: Automatic detection of adverse drug events in the geriatric care (Prof. Dr. Chantal Csajka, Université de Genève, Université de Lauanne)

NRP Project No. 10: Promoting the merging of health data in Switzerland (Prof. Dr. Bernice Simone Elger, Universität Basel)

NRP Project No. 11: End of life: more quality and less suffering through better planning and coordination? (Prof. Dr. med. Steffen Eychmüller, Universität Bern)

NRP Project No. 15: Provision of care for children with developmental disorders in the canton of Zurich (Prof. Dr. med. Oskar Gian Jenni, Universität Zürich)

NRP Project No. 20: The spiritual dimension of pain therapy (Prof. Dr. Simon Peng-Keller, Universität Zürich)

NRP Project No. 21: Standardised assessment and reporting system for functioning information supports quality reports and individual rehabilitation (Prof. Dr. Gerold Stucki, Schweizer Paraplegiker-Forschung)

NRP Project No. 24: Spitex uses its data to optimise client satisfaction and quality of care (Prof. Dr. med. Julia Dratva, Zürcher Hochschule für Angewandte Wissenschaften ZHAW)

NRP Project No. 26: Impact of scientific evidence on regional differences in medical services provision is smaller than expected (Prof. Dr. Matthias Schwenkglenks, Universität Zürich)

NRP Project No. 31: Development of caring communities for long-term care at home (Dr. Heidi Kaspar, Berner Fachhochschule)

NRP Project No. 32: How to improve care coordination for people with chronic conditions in Switzerland? Project "COCONUTS"(Prof. Dr. Joachim Marti, Institut Universitaire de Médecine Sociale et Préventive - IUMSP CHUV et Université de Lausanne)

NRP Project No. 34: Safer medication management for home-dwelling older adults (Dr. Henk Verloo, HES-SO Valais-Wallis)

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Glossary

Electronic patient dossier (EPD): A patient's personal collection of all treatment-related documents. Contrary to other countries, the implementation has not yet been completed in Switzerland.

Health data / health care data: Health data is a very general term that relates to any data related to health conditions (incl. events such as hospitalizations, births, deaths) of individuals or entire populations. In the provision of health care, health data are collected (in structured or unstructured form) when individuals interact with the health care system. This data typically includes a record of services received (including type and results of diagnostic procedures), conditions of those services, and clinical outcomes. Additionally, health care data includes information on the structures in place for delivering health care (e.g. location and infrastructure of a hospital as well as the staff of a hospital), and the costs and billings of those delivering care. In recent years health related data are also collected by persons/patients themselves via the use of mobile devices. This report does not discuss this data. Its focus is on digitally available routinely collected structured health data and health care data.

Health services research / health care research: A multidisciplinary field of inquiry, both basic and applied, that examines the use, costs, quality, accessibility, delivery, organisation, financing, and outcomes of health care services to increase knowledge and understanding of the structure, processes and effects of health services for individuals and populations.
Definition taken from: Feasley JC, Tranquada RE, Field MJ. Health services research: work force and educational issues: National Academies Press; 1995

"Once-only principle": Individuals and companies should have to report certain information to the authorities (such as the FSO) only once

Swiss social security number (SSN, German: «Alters- und Hinterlassenenversicherung» AHV): A 13-digit number that is used as a social security number and as a person identifier in other areas of administrative work (taxes, health insurance, …). It is anonymous and given only once.

Unique Personal Identifier (UPI): An individual code for each person living in Switzerland, with which all health care providers make data in relation to this person uniquely assignable to him or her

Real world data: Data relating to patients' health status or the delivery of health care that are routinely collected from a variety of sources, including electronic health records, insurance claims, and disease registries. In contrast to clinical trials, which are conducted under controlled conditions, real-world data reflect actual care and therefore have the potential to generate "real-world evidence".

Swiss Human Research Act (HRA, German: "Humanforschungsgesetz" HFG): Federal law which aims to protect the health, dignity and personality of human subjects in research. Regulates the use of health data in biomedical research, including the secondary use of health care data for research, together with its ordinance the *Human Research Ordinance* (HRO, German: "Humanforschungsverordnung" HFV).

Federal Act on Data Protection (FADP, German: "Bundesgesetz über den Datenschutz" (DSG): Aims to protect the privacy and the fundamental rights of persons when their data are processed. Regarding biomedical research, the FADP is only subsidiary to the HRA.

Abbreviations and acronyms

EPD – Electronic Patient Dossier

FADP – Federal Act on Data Protection

FOPH – Federal Office of Public Health

FSO – Federal Statistical Office

HRA – (Swiss) Human Research Act

HRO – Human Research Ordinance

SPHN – The Swiss Personalized Health Network

SpiGes – (Pilot project) Spitalstationäre Gesundheitsversorgung

SSN – (Swiss) Social Security Number