Privacy-preservation and the Use of Data for Research: A COVID-19 Use Case in Randomly Generated Healthcare Records

Madalena Lopes E. Silva1, Maria Claudia Cavalcanti1 and Maria Luiza M. Campos2

1Instituto Militar de Engenharia, Praça General Tibúrcio 80, CEP 22290-270, Rio de Janeiro, RJ, Brazil
2Universidade Federal do Rio de Janeiro, Av. Athos da Silveira Ramos, 274 - CCMN - Ilha do Fundão, CEP 21941-90,

Keywords: Web of Data, Research Data Management, Law, Legal Compliance, COVID-19 Pandemic, Anonymous Data.

Abstract: The provision of clinical data for research purposes has become central to monitoring and understanding the COVID-19 outbreak. In such a pandemic scenario, obtaining new research results is an imperative and urgent requirement. However, nowadays, personal data are protected by different legal regulations, to which all these data must comply, especially those related to the health of individuals. Then, a tough challenge arises in the academic sphere: how to provide a large amount of detailed clinical data for research and, simultaneously, guarantee the privacy of the individuals involved? Thus, this article discusses how the biomedical community may face this challenge and it presents the main ongoing initiatives and available emergent technologies that are useful to meet such urgent demand. Moreover, it also shows, through a use case, how it is possible to deal with this challenge, presenting the applicability of privacy-preserving techniques over a randomly generated typical dataset of COVID-19 health records.

1 INTRODUCTION

There are several articles (Hutchings et al., 2020) that discuss some reasons why researchers do not share data in the health domain, such as the concern that other researchers take their results, loss of opportunities or funding, and having data misinterpreted or misused. However, the health crisis caused by the COVID-19 pandemic highlighted the urgent need to share clinical data for research purposes and to support decision-making in the definition of public policies.

On the other hand, clinical data sharing makes it possible: (i) to achieve greater transparency and confidence in research conducted in this sector; (ii) to more quickly identify the behaviour of diseases aiming at controlling actions (Smáradottir, 2018); (iii) to positively impact decisions on treatments to which patients will be submitted (Smáradottir, 2018); and (iv) to support health research and the definition of public policies.

In line with this new scenario of high demand for research data, many initiatives emerged to monitor COVID-19 outbreak evolution and general profile of patients, such as analytical panels1. More specifically, clinical data about COVID-19 patients have also been shared, such as the FAPESP COVID-19 Data Sharing/BR repository2, in Brazil.

Complementary to other descriptive metadata that support data reuse, provenance metadata about the used privacy-preserving techniques is important for researchers when it is necessary to track back aggregated and/or anonymized data to reach an original clinical data. Provenance metadata is information about entities, activities, and people involved in producing a piece of data or thing, which can be used to form assessments about its quality, reliability, or trustworthiness and can be applied in several domains.

Although there are works that discuss the legislation around the issue of privacy of health data (Carvalho et al., 2020; Ferreira, 2020; Bondel et al., 2020), they did not take into account scientific research demands for accessing original data. Therefore, the main contributions of this article are: (i) to discuss the issue of privacy guarantees, addressed by the lat-
est regulations and protection codes, in contrast to the need to make data available for scientific research in critical moments such as the pandemic of COVID-19; and (ii) to demonstrate, through a use case, that it is possible to anonymize health records for research and still track back an individual identification if necessary, with the help of provenance metadata.

The article is organized as follows: In Section 2, concepts and facts related to the preservation of privacy are presented to contextualize the reader; in Section 3 the main policies and initiatives for research data are explored; in Section 4, health systems in Brazil are addressed as well as examples of actions aimed at making clinical data available for research; in Section 5, a use case of randomly generated health records is discussed; and, finally, the last section concludes the paper.

2 BACKGROUND

Advances in automation and digitization of health systems have brought agility in service, and facilitated the retrieval of information and exams, but, on the other hand, they have also made patient data more exposed to privacy violations and security breaches. It is necessary to point out that data security and privacy are two related concepts, but they should not be confused. Security refers to aspects of protecting a system from unauthorized use, including user authentication, information encryption, access control, firewall policies, and intrusion detection. Privacy refers to ensuring those entitled to control over the availability and use of their data, through data governance mechanisms.

To understand policies and initiatives to provide data security and preserve privacy, it is also necessary to know the already consolidated legislation. The Health Insurance Portability and Accountability Act (HIPAA) in USA, the General Data Protection Regulation (GDPR) in Europe, and the General Data Protection Law (Lei Geral de Proteção de Dados LGPD), in Portuguese in Brazil define many requirements and qualify possible penalties for cases of their violation. Among these requirements there are guarantees such as the right to be forgotten (data exclusion) and the need to collect user consent for the use of their data (Ferreira, 2020).

Pioneeringly, the HIPAA regulation has defined, in a comprehensive manner, which protective measures should be used to treat data related to individual clinical data. The aforementioned regulation also defines a group of 18 sensitive attributes considered identifiers, which may uniquely identify an individual. These attributes are known as Protected Health Information (PHI), such as name, date, registration numbers, IP addresses, photos, and biometric data, among other demographic information. More recently, GDPR and LGPD defined the set of personal data that can lead to the identification of a particular individual, directly or indirectly. There are also attributes that are classified as semi-identifiers (Brito and Machado, 2017), such as race, age, schooling, among others, which may indirectly identify an individual when combined with external information. Although there are already many anonymization tools available to cope with these law requirements and minimize the risks of identification, these tools still need to be improved (Carvalho et al., 2020).

On the other hand, according to GDPR Art. 9, items (h) and (i), and LGPD Art. 7, item (IV), and Art. 13, data used for health research and academic activities are exempt from consent collection. Additionally, as a result of the waiving of consent for research purposes, projects are also exempt from providing guarantees of data exclusion, since, in principle, the data used in research may remain perpetually available for reuse. Therefore, while pre-processing personal data using anonymization techniques is strongly recommended, an important requirement for the pre-processing tools is to apply anonymization in such a way that it should be possible to have access to the original data when requested by a restricted group of researchers.

Nowadays, there are different types of anonymization techniques, which are usually applied to identifier attributes. It is worth mentioning the technique known as pseudoanonymization. It consists of any process of transformation of personal data, carried out in such a way that these data cannot be associated with the individual without the use of additional data, which must be kept separately. It is a process of desidentification that removes or replaces identifying attributes such as names and identification keys (IDs) of a given dataset but keeping in a separate place the data that can directly identify the individual. In pseudoanonymization, different IDs must be used for each existing domain, such as research, administrative or medical. In this way, the possibility of re-identification of a given patient is guaranteed when necessary and by duly authorized persons.

On the other hand, for semi-identifier attributes,
the simplest anonymization strategy is data suppression, a mechanism in which defined attributes are removed from the dataset. The suppression can be applied as a filter over a certain value, to remove just a cell of data or an entire record.

Other anonymization techniques are also usually applied: generalization, masking and disturbance. Generalization consists in replacing semi-identifier attribute values by more generic ones, increasing the uncertainty regarding that data. Masking is widely used in the generation of datasets for testing or training. An example of data disturbance is the addition of noise, usually applied to numerical attributes that receive their original disturbed values by adding or multiplying by a value. In general, it preserves the statistical properties of the data although it can generate meaningless values (Brito and Machado, 2017).

The ideal point to be reached is where there is a sufficient degree of anonymity in the dataset, with a calculated and acceptable risk of re-identification, but which does not compromise the usefulness of the data. The appropriate strategy chosen should combine pseudonymization for identifying attributes and anonymization techniques for semi-identifying attributes (Sauermann et al., 2020).

3 INITIATIVES AND POLICIES FOR RESEARCH DATA

Within the new scenario of open science, specifically in the health domain, the reuse of data collected at the patient care level can enable transparency, credibility and reproducibility of research. Thus, initiatives have emerged to facilitate data publication and sharing, standardization of processes, establishing sets of good practices. The Resource Data Alliance (RDA6) and GO-FAIR7 are important examples of these initiatives that are detailed in the next subsections.

3.1 Resource Data Alliance (RDA)

RDA is a global initiative that brings together researchers and those interested in discussing and seeking solutions on sharing and reuse of open research data. It is structured through many subject-oriented interest groups (IG) and working groups (WG), which discuss and deliberate on good practices and recommendations in this scope.

One of those groups that focused on discussions about COVID-19 is the RDA COVID-19 Working Group which, after meetings held in 2020, released recommendations related to the sharing of COVID-19 data and preserving the privacy of individuals involved (COVID-19-Workgroup, 2020).

In the aforementioned paper, the authors classify attributes in two main groups: (i) direct identifiers and (ii) indirect identifiers. Direct identifiers should be treated with "hashing with key", i.e., using a hash function on the target value with the addition of a constant (salt). For example, one may apply the SHA-3 function on the name of an individual, using a key concatenated with a constant string “215” (salt). For the same identifier, several different pseudonyms can be produced, according to the choice of the salt. In this approach, there must be a person who is the secret key owner (usually the original data administrator). Besides the key, he also must keep track of the hash function and the "salt" used for a given anonymized dataset. This way, he will be able to identify the pseudonyms through a simple decryption process. Indirect identifiers such as gender, age, schooling, location, race/ethnicity should be treated with encrypting using a key that provides a cipher-text. The same secret key is needed for the decryption.

3.2 GO-FAIR Initiative

Proposed in (Wilkinson et al., 2016), the FAIR principles aim to guarantee some data characteristics that are often not found and that make it difficult to discover, obtain, and reuse data for research purposes. FAIR is an acronym for Findable, Accessible, Interoperable, and Reusable; each letter represents a group of characteristics. Data sharing based on these principles means that the data is standardized and described in a way that it can be easily reused by humans and machines8.

GO FAIR is an international initiative that has as its objective to disseminate and implement FAIR principles and aims to implement the vision of the European Open Science Cloud. This initiative proposes implementation network structures, which aim to establish a community to exchange information on these principles and the implementation of a FAIR infrastructure on the Internet, through the GO FAIR Implementation Networks (IN) - community-led and self-governed working groups across disciplines and countries.

The Implementation Networks involve people, institutions, and organizations. The implementation of an IN also provides gains in the preservation of privacy as it keeps metadata in public repositories.
separately from data, that can remain in institutional repositories, and the attribution of Creative Commons licensing, which restricts access to the data. The GO BUILT strand mediates communication between researchers and the institution that wishes to have greater control over their data.

Although anonymization techniques reduce but do not eliminate the risk of re-identification, how much should the guarantee of the privacy of individuals weigh against research results for the development of vaccines and medicines? Is it possible to find a balance spot where both goals are achieved? The GO-FAIR initiative attempts to address these issues by expanding alternatives to ensure privacy preservation through the use of Creative Commons licensing for published datasets for reuse in research. This type of licensing offers flexibility, allowing the institution that captures or generates the data to define in advance which data will be published open, which will have restricted access, and which researchers will have access to those data.

4 BRAZILIAN HEALTH SYSTEM AND RESEARCH DATA

In response to the pandemic, the WHO created and released the COVID-19 Clinical Platform, an anonymized data platform that enables member states of International Health Regulations (IHR)\(^9\) to share clinical data of SARS-COV-2 infection suspected or confirmed patients. To this end, the WHO provided a standard Clinical Report Form (CRF)\(^10\), defined to collect data from exams, consultations, and follow-up of these patients.

Hospital and administrative systems in primary, secondary, and tertiary areas capture about 80Mb of clinical data per patient per day (Huesch and Mosher, 2017). Thus, to reuse as much of these data as possible, several hospital units have been making efforts to adapt data collection to the CRF format. However, this change was not possible in a short period of time, as the pandemic scenario makes it difficult for the medical staff to adapt to the evolution of the system.

The next subsections will briefly address the existing health systems in Brazil and two initiatives for the publication and sharing of clinical data collected by hospital systems that are also used for research.

4.1 Unified Health System

Universal health coverage, the goal of the member states of WHO, has been achieved in Brazil with the implementation of the Unified Health System (Sistema Único de Saúde (SUS) in Portuguese). It was created in 1991 by the Health Ministry (Ministério da Saúde (MS) in Portuguese) to coordinate the development of Health Information Systems (SIS in Portuguese) meeting the needs in this area, according to constitutional guidelines (Cunha and Vargens, 2017). The MS is also responsible for consolidating and making data supplied by municipal health secretariats available on the website of Datasus\(^11\). e-SUS epidemiological surveillance system (e-SUS-VE)\(^12\) receives notification of suspicious, probable, and confirmed cases of COVID-19, starting on March 2020, which was previously managed by the Redcap platform.

4.2 FAPESP COVID-19 Data Sharing/BR Repository

An important initiative was also undertaken by FAPESP (São Paulo research funding agency), responsible for the COVID-19 DataSharing/BR Repository, in which data were made available from patients who underwent any diagnostic exam (related or not to COVID-19), as of November 1st, 2019, even for those who did not obtain a positive result on the exam. The participating institutions that established a cooperation agreement are the Clinic Hospital of Medicine University of São Paulo, the Syrian-Lebanese Hospital, the Israeli Hospital Albert Einstein, the Fleury Institute, and Portuguese Beneficence of São Paulo, up to now, being the captors and publishers of datasets in this repository.

The guarantee of privacy preservation was defined as the responsibility of each institution and is part of the agreement with FAPESP. Anonymization algorithms have been developed that comply with the requirements demanded by the legislation that defines HIPAA. Identifying attributes such as name, Cadastro de Pessoa Física (CPF), date of birth have been deleted from the datasets. As a treatment to be able to disclose the residence area code - Código de Endereçamento Postal (CEP), the granularity of only the first five digits was adopted.

The data made available by FAPESP include a set of attributes not identical to those contained in the CRF of the WHO and a reduced quantity, due to the

\(^9\)https://bityli.com/OqwIB

\(^10\)https://bityli.com/lbPFR

\(^11\)http://plataforma.saude.gov.br/coronavirus/covid-19/

\(^12\)https://covid.saude.gov.br
anonymization techniques employed. Although with losses, the published dataset is significant and still proves useful for a considerable number of data analyzes.

4.3 A Virus Outbreak Data Network: VODAN

One of the implementation networks currently active within the GO FAIR initiative\footnote{https://www.go-fair.org/wp-content/uploads/2020/03/data\_together\_march\_2020.pdf} is the Virus Outbreak Data Network\footnote{https://www.go-fair.org/implementation-networks/overview/vodan/} (VODAN), jointly with the Committee on Data (CODATA), RDA, and World Data Systems (WDS). Dedicated to the publication and sharing of data on epidemics and pandemics, the IN initially aims at capturing data about the SARS-COV-2 virus, materialized in VODAN networks\footnote{https://www.vodan-totafrica.info/about-vodan-africa/about-vodan-africa-asia}. A second objective is to provide metadata associated with these data in FAIR Data Points (FDP\footnote{https://www.fairdatapoint.org/}), an architecture composed of repositories and services necessary for sharing, publishing, and reusing those data.

To add a higher level of preservation of privacy and security, the VODAN network proposes that the federation of FDP nodes publish and allow access to metadata, maintaining the data to be shared in their local infrastructure. To make it easier and faster to implement FDP, the VODAN initiative created and made available “VODAN in a box” (VIAB\footnote{https://docs.vodan.fairdatapoint.org/en/latest/}).

In the Brazilian scenario, VODAN BR is conducting efforts to perform de-identification experiments. Also, hospitals are already applying specific de-identification techniques according to each institution implementation decision. Section 5 presents an use case that illustrates a typical de-identification process that may be used in those hospitals. Furthermore, it also illustrates that re-identification of patients may eventually be necessary, and that with the help of reserved provenance data, this becomes possible.

5 USE CASE IN EHR

To highlight how anonymization techniques may be applied in Electronic Health Record (EHR) and make it possible to reidentify individuals, we discuss a use case based on randomly generated EHR. For the purpose of making this use case, we used a sample of randomly generated data (Table 1), extracted from the dataset named COVID-DS1, since this avoids exposing real data. This dataset has as identifier attributes person_id and name, and as semi-identifiers gender, birth_date, address and phone. In this use case there are also sensitive personal data (that are attributes that have meaning for researchers) named temperature, apdiastolic (diastolic arterial pressure) and apsystolic (systolic arterial pressure). It is worth to mention that from a variety of available anonymization techniques (Fung et al., 2011), some of them have been arbitrarily chosen for this use case, since it is not in the scope of this paper to compare them.

For the pseudoanonymization process, as was published by RDA (Sauermann et al., 2020), it is necessary to apply different privacy-preserving techniques according to the privacy category of the attribute. As one can see in the anonymized dataset in Table 2, firstly it was applied a “SHA-3 hash 256” algorithm over person_id with different keys for each domain to access the data, such as Health, Research and Admin. On the name attribute a suppression technique was applied, where all names were removed. The gender attribute was maintained for analytical purposes. Birth_date was transformed in age_range, containing only a reference to the age range, featuring a generalization. In the case of the address attribute, part of it was deleted, remaining only the ZIP Code. The phone attribute was also removed. The other sensitive attributes, temperature, apdiastolic and apsystolic were maintained to be further used also for analytical purposes.

As highlighted before, provenance metadata plays an important role on these processes, specially when it is necessary to reidentify individuals for further investigation. To illustrate such a situation, consider the pandemic scenario. Analytical panels of the pandemic usually show aggregated numbers, i.e., they do not show individual data. This is due to the anonymity requirement for sensitive data, but also because panels are used to provide a broad view of the pandemic behavior. However, while analyzing such behavior, in order to understand the reasons why a certain region has more cases than others, or why it has a worse death rate than others, it is necessary to look more closely, and reach patient detailed clinical data. In order to obtain such data it is necessary to trace back the transformations applied so far, one by one. The metadata that supports patient reidentification is reserved and available only for data curators. It is necessary to request special permission to obtain them.

Therefore, to make reidentification possible, provenance metadata should be captured, up to the attribute level of the original dataset. A metadata
structure, inspired on workflow ontologies (Rautenberg et al., 2015; de Mendonça, 2016), was used in this use case. This metadata structure is presented in Table 3, where: (i) attribute_id represents the unique identification keys of attributes, (ii) dataset_id represents the unique identification keys of datasets in which attributes are linked, (iii) attribute_cat_id represents the suggested attribute privacy category keys of each one of the attributes (e.g. 1-Identifier, 2-Quasi-identifier, 3-Sensible, etc.) (iv) step_id represents the keys of the executed steps in the workflow (e.g. 3-Anonymization), (v) execution_seq represents the unique keys of the steps execution sequence, (vi) pprtechique_id represents the unique keys of the privacy preservation technique used in step execution (e.g. 1-Hash Function, 2-Hash Function + Salt, etc.), (vii) domain_id represents the unique keys of domains involved in anonymization process (e.g. 1-Health, 2-Research, 3-Admin, etc.), (viii) hash_key and salt represent the hash and salt used in the anonymization process for that specific attribute, (ix) label shows an attribute processed name in the workflow execution, and (x) type represents the type of involved attributes (e.g. string, date, number, etc.). More details can be found in the GitHub repository.

Analyzing the first row of Table 3, for example, the captured values mean that this record refers to the anonymization process applied to the person_id attribute (attribute_id = 000001) of COVID-19 scenario is a typical case where this kind of balancing is required for a detailed understanding of the pandemic. Also, the GO FAIR initiative has brought an important contribution through the use of license attribution, establishing access control levels and allowed data usage.

This work sought to present the initiatives and technologies available to meet this challenge. Initially, it presented an overview of related initiatives in the current international and domestic scenarios, in the direction of anonymized clinical data sharing for research purposes. It also presented concepts about privacy, sensitive data, and data protection, as well as a summary of recent and relevant legislation. Besides, this work presented a use case that illustrates a typical scenario, evidencing the use of privacy preserving techniques while making possible individual reidentification, through provenance metadata capture.

As future work, we are already performing new experiments on real data, applying different techniques, specially on scenarios where reidentification is needed. The idea is to compare such techniques and verify their effectiveness on anonymization and deanonymization tasks. Moreover, it is also interesting to explore the combined use of license and anonymization, similarly to what is proposed by the Data Use Ontology (DUO) (Delgado and Llorente, 2020) and by an extension of the UsablePrivacy Project (Pandit et al., 2018). Finally, another ongoing study is on the combination of existing ontologies to enrich provenance metadata for the reidentification of individuals.

6 FINAL CONSIDERATIONS

Although there are many initiatives to provide data for reuse and research, there is still a lack of use of anonymity techniques incorporated into the publishing processes of these data. In the literature as well, there are few papers that are concerned with the balance between the preservation of privacy and the demand for rich clinical data for analysis. The COVID-19 scenario is a typical case where this kind of balance is required for a detailed understanding of the pandemic. Also, the GO FAIR initiative has brought an important contribution through the use of license attribution, establishing access control levels and allowed data usage.

ACKNOWLEDGEMENTS

Special thanks to Programa INOVA UNIRIO PROPGPI/DIT 2020 who partially supported the VODAN BR project.
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### Table 1: Original Data (Dataset COVID-DS1)

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<thead>
<tr>
<th>personid</th>
<th>name</th>
<th>gender</th>
<th>birthdate</th>
<th>address</th>
<th>phone</th>
<th>temp</th>
<th>apdiast</th>
<th>apsyst</th>
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<td>ea5d0c10-d816-4981-ab34-92d61ea5ac1a</td>
<td>Ellynn Philcock</td>
<td>Male</td>
<td>15/08/1925</td>
<td>Mayfield Junction</td>
<td>+86 (685) 614-1409</td>
<td>35</td>
<td>10.2</td>
<td>19.7</td>
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<td>00fc771f-29aa-45d0-8942-1375c1d0f5cb</td>
<td>Teodoro Filipchikov</td>
<td>Female</td>
<td>06/08/2016</td>
<td>Norway Maple Crossing</td>
<td>+66 (837) 896-5022</td>
<td>35.6</td>
<td>11.8</td>
<td>19.7</td>
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<tr>
<td>e2c5f2dd-69b9-4deb-bc16-31bdad1aa73b</td>
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<td>Male</td>
<td>30/06/2007</td>
<td>Crest Line Plaza</td>
<td>+34 (881) 908-5963</td>
<td>39.1</td>
<td>9.6</td>
<td>20.8</td>
</tr>
<tr>
<td>326f7609-60a0-4d32-80a4-df20459f7822</td>
<td>Molly Lownes</td>
<td>Male</td>
<td>02/12/1982</td>
<td>Bartelt Drive</td>
<td>+62 (916) 666-7495</td>
<td>36.9</td>
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<tr>
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<td>29/09/1990</td>
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### Table 2: Anonymized Data (Dataset COVID-DS1)

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### Table 3: Attribute Metadata

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