Anonymously Analyzing Clinical Datasets

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Abstract. This paper takes on the problem of automatically identifying clinically-relevant patterns in medical datasets without compromising patient privacy. To achieve this goal, we treat datasets as a \textit{black box} for both internal and external users of data that lets us handle clinical data queries directly and far more efficiently. The novelty of the approach lies in avoiding the data \textit{de-identification} process often used as a means of preserving patient privacy. The implemented toolkit combines software engineering technologies such as Java EE and RESTful web services, to allow exchanging medical data in an unidentifiable XML format as well as restricting users to the \textit{need-to-know} principle. Our technique also inhibits retrospective processing of data, such as attacks by an adversary on a medical dataset using advanced computational methods to reveal Protected Health Information (PHI). The approach is validated on an endoscopic reporting application based on openEHR and MST standards. From the usability perspective, the approach can be used to query datasets by clinical researchers, governmental or non-governmental organizations in monitoring health care services to improve quality of care.

1 Introduction

Patients’ Electronic Health Records (EHRs) are stored, processed, and transmitted across several healthcare platforms and among clinical researchers for on-line diagnostic services and other clinical research. This data dissemination serves as a basis for prevention and diagnosis of a disease and other secondary purposes such as health system planning, public health surveillance, and generation of anonymized data for testing. However, exchanging data across organizations is a non-trivial task because of the embodied potential for privacy intrusion. Medical organizations tend to have confidential agreements with patients, which strictly forbid them to disclose any identifiable information of the patients. Health Insurance Portability and Accountability Act (HIPAA) explicitly states the confidentiality protection on health information that any sharable EHRs system must legally comply with. To abide by these strict regulations, data custodians...
generally use de-identification\(^4\) techniques \(^{21}\)\(^{11}\)\(^{20}\) so that any identifiable information on patient’s EHR can be suppressed or generalized.

However, in reality, research \(^{19}\) indicates that 87% of the population of U.S. can be distinguished by sex, date of birth and zip code. We can define quasi-identifiers as the background information about one or more people in the dataset. If an adversary has knowledge of these quasi-identifiers, it can possibly recognize an individual and take advantage of his clinical data. On the other hand, we can find out most of these quasi-identifiers have statistical meanings in clinical research. There exists a paradox between reducing the likelihood of disclosure risk and retaining the data quality. For instance, if information related to patients’ residence was excluded from the EHR, it would disable related clinical partners to catch the spread of a disease. Thus, strictly filtered data may lead to failure in operations. Conversely, releasing data including patients’ entire information including residence, sex and date of birth would bring a higher disclosure risk.

In this paper we address the emerging problem of de-identification techniques, namely, the problem of offering de-identified dataset for a secondary purpose that makes it possible for a prospective user to perform retrospective processing of medical data endangering patient privacy. Figure 1 overviews the proposed technique, and the standard data request process. Our approach differs from the traditional techniques in the sense that it employs software engineering principles to isolate and develop key requirements of data custodians and requesters. We apply Service-Oriented Architecture (SOA) that provides an effective solution for connecting business functions across the web—both between and within enterprises \(^8\).

We also present a prototype of our evolving toolset, implemented using web services to handle data queries. The results are retrieved in an XML data format that excludes all personal information of patients. The basic model used here follows the principles of RESTful web services by combining three elements: a URLs repository for identifying resources uniquely corresponding to clinical data queries, service consumers requesting data, and service producers as custodians of clinical data. The idea of combining web services with SQL queries is although not new, but it tends to provide a technological approach to avoid medical data re-identification risks. The implemented toolkit uses Java EE that offers an easy way to develop applications using EJBs. Needless to mention that Java EE is widespread and is largely used by community.

Our proof-of-concept implementation uses GastrOS, an openEHR \(^7\) database\(^5\) describing an endoscopic application. The underlying technique provides the ability to construct or use stored queries on a clinical dataset. Employing this clinical toy data warehouse of the GastrOS prototype is a useful way to demon-

\(^4\) De-identification process is defined as a technology to delete or remove the identifiable information such as name, and SSN from the released information, and suppress or generalize quasi-identifiers, such as zip code date of birth, to ensure that medical data is not re-identifiable (the reverse process of de-identification.)

\(^5\) \url{http://gastros.codeplex.com}
Fig. 1. (a): shows a traditional lifecycle of medical datasets. Custodians can be hospitals, agents may be entities working on their behalf, and recipients are individuals, or organizations such as a pharmaceutical company [5]; (b) depicts the proposed approach that links external entities to data centers using a web interface. The approach excludes all direct data accesses on a dataset.

strate queries on medical data for secondary use. The proposed technique avoids compromising patients’ personal information without utilizing de-identification framework tools. For instance, the following query can be posed to GastrOS database using our toolkit:

- Find the number of patients who are still susceptible to developing a Hepatitis B infection even after full compliance to the Hepatitis B vaccination schedule—i.e. the baseline and second detection dates for the HBsAg and Anti-HBs tests both show negative results.

The set of clinical data queries described in the paper have been crafted with the help of clinical researchers at Vanderbilt University. Supporting such complex queries required developing a set of tools, to which this paper provides the first attempt. In contrast to recent developments on big data, this paper does not focus on the management challenges of medical dataset repositories, but rather focuses on software engineering solutions to deal with the challenges of querying medical data endangering patient privacy. Our approach mainly contributes to the development of privacy preserving techniques on patient data by treating datasets as blackbox. In this way, disclosure risks associated with patient data are minimized. One of the key constraints before accomplishing this goal requires keeping the computability with data custodians. Relocating datasets is not only unsafe but leads to data re-identification attempts. To ensure that legitimate
users access and execute clinical data queries, we implement an authentication and authorization mechanism using role-based access control (RBAC). RBAC offers a flexible architecture that manages users from different organizations by assigning roles and their corresponding permissions.

The paper proceeds as follows: Section 2 describes the related work; Section 3 states an application example; Section 4 presents the technical details of our approach; Section 5 overviews the clinical data queries corresponding to the GastrOS dataset; Section 6 discusses the authentication and authorization mechanism connecting users to clinical datasets; Section 7 summarizes the work and details some future research directions.

2 Related Work

In contrast to some of the existing techniques [12] [2] [10] [13] [15], our approach relies on advanced software engineering principles and technologies for analyzing clinical datasets. For example, caGrid 1.0 [12] (now caGrid 2.0), released in 2006, is an approach that discusses a complex technical infrastructure for biomedical research through an interconnected network. It aims provide support for discovery, characterization, integrated access, and management of diverse and disparate collections of information sources, analysis methods, and applications in biomedical research. caGrid 1.0 has been initially designed only for cancer research, caGrid combines Grid computing technologies and the Web Services Resource Framework (WSRF) standards to provide a set of core services, toolkits for the development and deployment of new community provided services, and APIs for building client applications. However, caGrid does not focus on an explicit query mechanism to infer details from medical datasets, as the one proposed here. Similar work in [2] discusses a combined interpretation of biological data from various sources. This work, however, considers the problem of continuous updates of both the structure and content of a database and proposes the novel database SYSTOMONAS for SYSTems biology of pseudOMONAS. Interestingly, this technique combines a data warehouse concept with web services. The data warehouse is supported by traditional ETL (extract, transform, and load) processes and is available at \( \text{http://www.systomonas.de} \).

De-identification techniques for medical data have been studied and developed by statisticians dealing with integrity and confidentiality issues of statistical data. The major techniques used for data de-identification are (i) CAT (Cornell Anonymization Kit) [21], (ii) \( \mu \)-Argus [11], and (iii) sdcMicro [20]. CAT anonymizes data using generalization, which is proposed [3] as a method that specifically replaces values of quasi-identifiers into value ranges. \( \mu \)-Argus is an acronym for Anti-Re-identification General Utility System and is based on a view of safe and unsafe microdata that is used at Statistics Netherlands, which means the rules it applies to protect data comes from practice rather than the precise form of rules. Developed by Statistics Austria, sdcMicro is an extensive system for statistical computing. Like \( \mu \)-Argus, this tool implements several anonymization methods considering different types of variables. We have re-
ported [9] a comparison on the efficacy of these numerical methods that are used to anonymize quasi-identifiers in order to avoid disclosing individual’s sensitive information. The Privacy Analytics Risk Assessment Tool (PARAT) [6] is the only commercial product available so far for de-identifying medical data. Our quantitative analysis [9] of de-identification tools shows that de-identifying data provides no guarantee of anonymity [15]. A study [1] also shows that organizations using data de-identification are vulnerable to re-identification at different rates.

Another approach [10] describes a special query tool developed for the Indianapolis/Regenstrief Shared Pathology Informatics Network (SPIN) and integrated into the Indiana Network for Patient care (INPC). This tool allows retrieving de-identified data sets using complex logic and auto-coded final diagnoses, and it supports multiple types of statistical analyses. However, much of the technical details have not been published; for example, the use of complex logic. This and other similar efforts [14] are mostly database-centric. A slightly similar work to this paper has been developed at Massachusetts General Hospital (QPID Inc. [7]), offering solutions at a commercial level, but no prototype is available to experiment with. A Web-based approach for enriching the capabilities of the data-querying system is also developed [13] that considers three important aspects including the interface design used for query formulation, the representation of query results, and the models employed for formulating query criteria. The notion of differential privacy [4] aims to provide means to maximize the accuracy of queries from statistical databases while minimizing the chances of identifying its records.

Our analysis shows that the effort to secure medical datasets is mainly two-faceted: 1) most research endeavors have explored the design and development of de-identification tools, and, 2) some work, mostly led by medical doctors, has tried to address the construction of clinical queries, but they do not provide technical details on the construction of their toolsets. Our approach that treats medical datasets as blackbox mainly considers the automation of services expected from a data custodian in order to minimize data disclosure risks and making clinical datasets easily accessible for internal and external users.

3 GastrOS: An Example Application

GastrOS[8] an openEHR database describing an endoscopic application, is used as a case-study of electronic medical data. This application formed part of the research done at University of Auckland by Koray Atlag in 2010 that investigated software maintainability and interoperability. For this, the domain knowledge model of Archetypes and Templates of openEHR has driven the generation of its graphical user interface. Moreover, the data content depicting the employed terminology, record structure and semantics were based on the Minimal Standard

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[6] http://www.privacyanalytics.ca/software/
[7] http://www.qpidhealth.com
[8] http://gastros.codeplex.com
Terminology for Digestive Endoscopy (MST) specified by the World Organization of Digestive Endoscopy (OMED) as its official standard.

Employing the clinical toy data warehouse of the GastrOS prototype is a useful way to demonstrate clinical research based queries on medical data for secondary use without compromising patients’ personal information by using the approach proposed here. The queries shown here focus on endoscopic findings that provide valuable anonymized information to clinicians. The implemented queries are to be mainly used by medical practitioners and health decision-makers alike to help them in their clinical management of patients at the point-of-care and in formulating appropriate health policies, respectively. For example, the following queries are obtained through brainstorming with medical doctors to illustrate our approach.

- Total number of dialysis endoscopic examination from January 1, 2010 to December 31, 2010.
- Top 5 diagnoses for those patients who received endoscopic examination and the number of cases for each diagnosis from January 1, 2010 to December 31, 2010.
- Age profile of endoscopic patients from January 1, 2010 to December 31, 2010 i.e. number of dialysis patients belonging to each of the age bracket [below 18; 18 to below 40; 40 to below 60; 60 and above.
- Number of patients who are still susceptible to developing a Hepatitis B infection even after full compliance to the Hepatitis B vaccination schedule? i.e., the baseline and second detection dates for the HBsAg and Anti-HBs tests both show negative results.

The queries given above are only a subset of original queries. The database structure of GastrOS application is described below.

3.1 GastrOS data structure

Figure 2 describes the data structure of the GastrOS database. GastrOS database contains the following tables: the clinical detection (doctor detection records), patient (patient information), and examination (examination records) tables are stored in the database.

The patient table has two relations: one patient may have more than one clinical detection record or examination record by doctor(s), so the patient id is added as a foreign key in tables ClinicalDetection and Examination. GastrOS is a toy database example with insufficient amount of data available. The original database contains less than 20 rows in each table that makes is not useful for our SQL queries. Therefore, we automatically generated virtual data of 10,000 entries (note that any real data on patients also cannot be published.) An example of the generated data is given in Figure 3. Table 1 provides the up-to-date information on the number of entries in each column of the GastrOS database.
The proposed approach implements a three-tier application and is devoid of releasing medical datasets, as opposed to traditional techniques. The major purpose and characteristic of the technique extends relatively new software technologies for supporting clinical data queries. In order to support clinical queries under consideration, we develop an integrated application using SOA and Java EE (Enterprise Edition), to extract data from GastrOS database. There are a plenty of other commercial containers such as JBOSS (Redhat), Websphere (IBM), Weblogic and Glassfish (Oracle), which could be used for our purpose.
However, our prototype tool combines Java EE based on JSF Primeface, EJB, and Java Persistence Architecture API (JPA). JPA is a Java specification for accessing, persisting, and managing data between Java objects / classes and a relational database. REST architecture, underlying RESTful web services, treats everything as a resource and is identified by an URI. Resources are handled using POST, GET, PUT, DELETE operations that are identical to Create, Read, Update and Delete (CRUD) operations. Note that in our toolkit it is suffice to implement Read operations for handling the described queries. Every request from a client is handled independently, and it must contain all the required information to interpret the request.

Fig. 4. The list of authorized roles for the Organization A

# Code for the Restful-based web service.
@Path("queryone")
public class QueryOne {
    @Context
    private UriInfo context;
    @EJB
    QueryBean bean;
    @GET
    @Produces("application/xml")
    public String getHtml() {
        // TODO return proper representation object

        String sql = "select Country, COUNT(Report_ID ) AS" +
                     "TotalNum " +
                     "FROM examination, patient " +
                     "WHERE examination.Patient_ID = " +
    }
"patient.PID " +
"AND Endoscopy_Date " +
"BETWEEN \"2010-1-1\" " +
"AND \"2010-12-30\" " +
"GROUP BY Country " +
"Order By TotalNum desc ";
    String f = bean.query(sql);
    return f;
}
\}For the method query:
public String query(String sql)
{
    String result = "";
    Query query = emf.createEntityManager().
            createNativeQuery(sql);
    @SuppressWarnings("unchecked")
    List<Object[]> list = query.getResultList();
    .....
using URL in browser or a session bean, the SQL can be executed and return result by query method which invokes the entity manager of JPA. Below, we list some sample clinical queries as well as their output in an XML format.

Number of patients for each gender who are still susceptible to developing a Hepatitis B infection even after full compliance to the Hepatitis B vaccination schedule -- i.e. the baseline and second detection dates for the HBsAg and Anti-HBs tests both show negative results.

```xml
<dataset>
<item>
  <element>F</element>
  <element>184</element>
</item>
<item>
  <element>M</element>
  <element>192</element>
</item>
</dataset>
```

Top 5 diagnoses for those patients who received dialysis treatment and the number of cases for each diagnosis from January 1, 2010 to December 31, 2010.

```xml
<?xml version="1.0" encoding="utf-8"?>
<dataset>
<item>
  <element>Diagnoses_Text Colon: Primary malignant tumor, Quiescent Crohn’s disease</element>
  <element>421</element>
</item>
<item>
  <element>Diagnoses_Text Esophagus: Normal, Ectopic gastric mucosa</element>
  <element>394</element>
</item>
<item>
  <element>Esophagus: Reflux esophagitis</element>
  <element>414</element>
</item>
<item>
  <element>Esophagus: Varices certain</element>
</item>
</dataset>
```
5.1 Enabling dynamic clinical queries

The construction and execution of clinical queries on a given dataset are implemented through a web-interface of the tool. The interface allows a user to dynamically construct a clinical query on a dataset. Thus, it adds a greater flexibility to the query mechanism in developing user-oriented analysis of a dataset. For instance, Fig. 5 demonstrates how to execute a query such as "Total number of dialysis endoscopic examination of a country starting and ending on a particular date, respectively.", followed by the output in Fig 6.

These queries show that all specific details on patients are avoided when executing a query, which also means that it disables all direct accesses to patient records. It is actually realized by providing a more aggregated form of data on patients instead of conventional techniques that provide medical datasets to infer such details. Note that the toolkit does not allow any query that provides specific information on patients, such as "Provide details of all patients with a certain age". These queries are directly irrelevant to researchers since they are mainly interested in collective analysis on a dataset. The idea of combining web services with SQL queries is although not new, but it tends to provide a technological solution to a technological problem avoiding medical data re-identification risks. The rationale Using Java EE stems from the fact that it provides an easy way to develop applications, for example, EJB are convenient to use by adding only
one annotation. Java EE is also widespread being largely used both in academia and industry.

6 Authentication and Authorization Process

Our toolset implements the Role-based Access Control (RBAC) \[6] \[16] \[17]. RBAC provides a suitable mechanism to restrict user’s access on resources, such as to perform operations including insert, delete, append, and update on a medical dataset. The data model of RBAC is based on five data types: users, roles, objects, permissions and executable operations by users on objects. A sixth data type, session, is used to associate roles temporarily to users. A role is considered a permanent position in an organization whereas a given user can be switched with another user for that role. Thus, rights are offered to roles instead of users. Roles are assigned to permissions that can later be exercised by users playing these roles. Modeled objects in RBAC are potential resources to protect. Operations are viewed as application-specific user functions. For example, Fig. 7 shows a list of queries provided to an administrator role.

To maintain a set of permissions on GastrOS database, we use the constructs from RBAC maintain, and enlist entries in corresponding tables users, roles, text$fr$querytroles, quenl$list$, and url$for$webservice. The database tables include user, role, quenl$list$, quenl$torole$, and url$webservice$. We create a user account in

<?xml version="1.0"?>
<dataset>
  <item>
    <element>Bulgaria</element>
  </item>
  <item>
    <element>Nicaragua</element>
  </item>
  <item>
    <element>Kiribati</element>
  </item>
  <item>
    <element>Holy See (Vatican City State)</element>
  </item>
  <item>
    <element>Heard Island and McDonald Islands</element>
  </item>
  <item>
    <element>Libya</element>
  </item>
  <item>
    <element>Azerbaijan</element>
  </item>
</dataset>
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Fig. 7. Query list for role of administrator

| User | ID INT(11) | username VARCHAR(20) | password VARCHAR(20) |
|------|------------|----------------------|---------------------|
| Role | ID INT(11) | name VARCHAR(100)    |                     |

Fig. 8. E-R diagram

user table with the assigned role. Here, all the roles are defined in role table. Users privileges and a list of queries are defined in tables querytorole and querylist, respectively. URLs are stored in the urlwebservice table. For example, logging in as administrator provides five SQL queries shown in Figure 7, whereas logging in as organization A allows a restricted set of SQL queries as given in Figure 8. Security management is supervised by an administrator who can do deletion, addition of roles as required. Using RBAC allows users to take multiple roles, for example, the user X could act as researcher that belongs to organization A, but can be assigned another role from the set of roles. Similarly, a permission can be associated to many roles depending on the RBAC policy. The multi-to-multi relation between roles and queries that is given in the querytorole table.
6.1 Avoiding SQL injections and sensitive information release

Web application security vulnerabilities occur in cases when an attacker or an authorized user tries to submit and execute a database SQL command on a web application, and thus, a back-end database is exposed to an adversary. These SQL injections can be avoided if queries are validated and filtered before their execution, and are checked against input data or any encoding made by a user. To prevent similar security issue in our web application we first authenticate the user input against a set of defined rules given below:

\[
\begin{align*}
\text{BlockList} &= \{\text{name}, \text{age}, \text{address}, \text{zipcode}\} \\
\text{Anti-injectionList} &= \{',', \text{etc.}\}
\end{align*}
\]

Note that the special characters given in a block list helps to avoid SQL injections. The set BlockList disables all possible access to attributes in a table such as name, age, address, and zip code to keep the fetched data completely anonymized. Set members in injectionList filters out three possible vulnerable inputs, i.e., „ etc. so that any similar attempts could be restricted. Here are the filters that check inputs against BlockList, injectionList. Before running a web service, these two atomic services are always invoked to avoid identifying the actual patients and SQL injections.

- Service one: Checks input string for characters in BlockList.

```java
bool CheckDeIdentification(String s) {
    Check Input string s, 
    if it contain character in BlockList,
    return false. Otherwise true.
}
```

- Service two: Checks input string for characters in Anti-injectionList.

```java
bool CheckInjection(String s) {
    Check Input string s,
    if it contain character in Anti-injectionList,
    return false. Otherwise true.
}
```

7 Conclusions and Future Perspectives

We presented a technique for automatic identification of clinically-relevant patterns in medical data. The main contribution of this paper is in defining and presenting an alternative approach to the data de-identification techniques commonly employed for anonymizing clinical datasets. Our technique treats datasets as \textit{blackbox} and allows data custodians to handle clinical data queries directly.
Relocating a dataset not only endangers anonymity of patients, it allows adversaries to apply advanced computational methods for retrospective processing of data. As clinical data is frequently updated, our approach enables data custodians to provide up-to-date resources to their users. We integrate RESTful web services and Java EE with a backend clinical database exchanging anonymous XML data, enabling them to be language and technology independent. Java EE, due to equipped with EJBs, is easy to use for developing applications.

In circumstances related to sharing of patients’ data, complex administrative regulations are placed at different levels of management that sometimes unnecessarily complicate the data acquisition process. Providing a tool support for linking data custodians and data requesters using software engineering techniques could pave the way to query clinical datasets more transparently and systematically. We explored new ways of anonymously analyzing clinical datasets. Our future work includes expanding the approach to more complex databases and supporting an enriched interface for analyzing bigger data repositories. We are currently dealing with the challenge of replacing de-identification techniques in use for de-identifying specific attributes in a database table, for example, patient id, and a doctor needing to find patients who had an increase of systolic blood pressure within a specific period, or patients with steady states of diastolic blood pressure for more than a week. Our future work considers incorporating such queries into the toolset, including implementing ETL processes such as in data warehouses to support clinical data analyses on large-scale integrated databases.

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