A Model-driven Privacy Compliance Decision Support for Medical Data Sharing in Europe

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Summary
Objectives: Clinical practitioners and medical researchers often have to share health data with other colleagues across Europe. Privacy compliance in this context is very important but challenging. Automated privacy guidelines are a practical way of increasing users’ awareness of privacy obligations and help eliminating unintentional breaches of privacy. In this paper we present an ontology-based approach to privacy decision support for the sharing of patient data across European platforms.

Methods: We use ontologies to model the required domain and context information about data sharing and privacy requirements. In addition, we use a set of Semantic Web Rule Language rules to reason about legal privacy requirements that are applicable to a specific context of data disclosure. We make the complete set invocable through the use of a semantic web application acting as an interactive privacy guideline system can then invoke the full model in order to provide decision support.

Results: When asked, the system will generate privacy reports applicable to a specific case of data disclosure described by the user. Also reports showing guidelines per Member State may be obtained.

Conclusion: The advantage of this approach lies in the expressiveness and extensibility of the modelling and inference languages adopted and the ability they confer to reason with complex requirements interpreted from high level regulations. However, the system cannot at this stage fully simulate the role of an ethics committee or review board.

1. Introduction

When sharing medical data between different health organizations in Europe, it is important that the different parties involved in the sharing handle the data in the way indicated by the legislation of the Member State where the data was originally collected. Privacy requirements, such as patient consent, may be subject to conflicting conditions between different national frameworks. Conflict may also arise between different legal and ethical frameworks within a single Member State. Whilst most EU Member States are now governed by similar personal data protection rules, harmonization remains more apparent than real. This is due, first, to the fact that subject to the provision of suitable safeguards the European Data Protection Directive leaves some space for Member States to lay down exemptions to some of the obligations the Directive introduces [1], such as, the obligation to notify the data subject of the processing of their data. Also for reasons of substantial public interest, Member States may lay down additional exemptions to the ban of the processing of sensitive personal data [1]. Second, as described in some studies [2], the definitions used do not lead to a uniform understanding of the key concepts underpinning the directive. Focusing on the concept of “Personal Data” for example, many Member States find it ambiguous. The UK found that in some cases data is not easily classified as personal or non-personal, and that this classification may be relative to the circumstances. Overlaps in the interpretation of “Personal Data” have also resulted in different ways of governing anonymized and pseudonymized data [2]. Consequently, the frameworks in some Member States, such as the UK [3], tend to be less favourable to the processing of personal data for medical research when compared to other Member States’ frameworks, including, for example, the Italian data protection framework. The latter seems to grant more privileges to medical researchers in allowing consent to be given in a single, one-off statement [4]. This raises ethical concerns on handling secondary use of the data [5].

These issues explain the diversity, complexity and dynamicity of the rules governing privacy protection. We believe modeling can simplify and abstract the complexity of rules from the real world to allow their automation and enforcement at the organizations’ process level as a way of privacy compliance management. In previous work presented in [6] we have demonstrated the usefulness of our privacy requirement knowledge-base in closing the gap between high level policies and operational access controls by suggesting a privacy aware access control model and archi-
In this work we use our knowledge-base to provide an automated privacy guideline and advice service to medical users to assist and protect them from everyday pitfalls in the course of necessary healthcare data disclosure. In this paper our ideas are structured as follows: in section two, we analyse a selection of privacy requirements and issues associated with the sharing of patient sensitive data across European borders. In section three, we present our technical solution to the modelling and automation of privacy requirements. Section four presents a proof of usability of the model for building decision support applications to help medical users of a healthgrid [7] to share medical data while complying with privacy obligations. Finally we conclude and hint to related work and future tasks.

2. Materials and Methods

The principal problem addressed in this work is how to encode privacy legislation and related regulatory frameworks (e.g. institutional rules on ethics) in such a way that they are amenable a) to provision of decision support for the non-expert user, b) to automation of compliance at an operational level, and c) to documentary support for compliance audit. This paper reports only on (a) decision support; [6] reports on (b) and a planned paper will cover audit.

Our case study carries the additional complexity of a supra-national “directive” which has been variously interpreted in national legislation. Indeed, our thesis is that this additional layer of complexity allows us to demonstrate the power of our method better than would be the case under a single regulatory regime. As is the case with EU directives in general, the European Data Protection Directive 95/46/EC has been “transposed”, as the official jargon has it, into national legislation in the Member States. These national laws are not necessarily in complete agreement with the Directive, nor are they necessarily entirely compatible with each other. (Examples of this will be discussed below.) In any case, it is generally accepted that text law, i.e. the statutes themselves, are not ordinarily well understood and acted upon by non-experts, so that between the law and any potentially questionable action stands an interpreter of the law, a “lawyer”, who provides expert opinion or professional guidance. In our case, the need to interpret data protection legislation in the various Member States of the EU is of such importance to business that there are many immediate sources of guidance, such as, in the UK, the Information Commissioner’s Office website guidelines [8]. In our work, we have sought to codify guidelines that have been specified by legal experts from different European Member States, rather than attempt the legal text itself. A standard reference work for research in this field is that published by the Privireal project [5] and we have largely relied on this.

A relatively recent approach to harmonizing fields in which different languages or data structures are applied to a common domain is through so-called “ontologies”. An ontology is a standard method of organizing the concepts in a domain in such a way that it can map to the various linguistic or informatic practices that may occur in that domain. Inter-relationships between concepts, such as equivalence, subsumption, specialization and generalization, and so on, are also mapped. A commonly used language for ontology description is the Web Ontology Language (OWL, after the character in AA Milne’s children’s story) which forms the basis of the tool Protégé from Stanford University [9]. It is possible to reason with OWL concepts using the Semantic Web Rule Language (SWRL) and we have adopted both. Through the use of these technologies we have captured the legal requirements and modelled them as a semantic web knowledge base. This may be interpreted by a ‘reasoner’ or rule engine to work out the applicable privacy requirements for a given case of medical data sharing.

Through the use of the Protégé application programming interface (API) and the Protégé OWL API we develop a semantic web application that allows a professional user to specify facts describing a specific case of proposed data sharing in order to get as output a list of privacy requirements that sender and recipient must comply with. Also users can choose to generate a report of privacy requirements per Member State. In our practical examples, we have used the rule-based system environment Jess [10] to demonstrate such reasoning in particular use-cases. Last but not least among our tools is the eXtensible Access Control Markup Language (XACML) which allows us to interpret our high level policy rules into actionable permissions and obligations; this is important, but figures somewhat less in the work reported here than it does in subsequent work.

3. A Selection of Privacy Requirements

The governance of personal data in Europe imposes certain obligations of regulatory compliance. By ‘privacy requirements’ we mean those obligations that must be fulfilled by all parties involved in the process of sharing or processing sensitive patient data, whether for healthcare or medical research, to preserve informational aspects of the patient’s privacy. This entails understanding of conceptual information about rights, obligations and consequent actions; among these is the obligation to obtain and maintain patient consent; privacy preserving actions such as anonymization or pseudonymization and encryption; and rights, such as those of the data subject to dissent or to be notified. This ontological variety leads us naturally to an ontology-based model. Our model must be sufficiently flexible to reflect any differences and, indeed, conflicts between EU Member States in the specification of and provision for these requirements. In the following paragraphs we analyze a selection of requirements specifically taking into consideration the degree of challenge faced when trying to comply with them. A fuller analysis of such challenges has been published in joint work with partners from the SHARE project in [11].

3.1 Patient Consent

To qualify as legitimate, the processing of medical data has to be covered by one of six hypotheses listed in Article 7 of the Directive 95/46/EC (the first hypothesis being

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should be recorded, as well as the determination of practicability of consent [4].

Based on detailed analysis in [5], some Member States do not distinguish between consent and explicit consent (e.g. Poland), while in others consent must always be explicit informed consent, although this does not mean it has to be written (e.g. Estonia). The Czech Republic distinguishes between consent to the processing of personal data and consent to the processing of sensitive data which must be explicit and written. UK Law requires explicit consent when sensitive data is to be processed; this requires active communication between the relevant parties, but this may be other than written. The period of validity of consent also differs from one state to another.

The SHARE Project [11] investigated different European and national legal frameworks on consent for the processing of patient data and found that some general themes are repeated in most of these:

- necessity of consent to the processing of the data;
- explicit (or express) patient consent;
- specificity of consent (specific or general);
- way in which consent must be collected (verbal, written);
- who may contact the data subject to get his consent;
- how consent should be documented (electronic, printed); legal competence of the data subject;
- who may give consent instead of the data subject (next of kin, proxy or legal representative);
- lifetime of consent validity;
- practicability of consent (practicable, impracticable); and
- miscellaneous others of narrower scope.

The vocabularies of most national frameworks, whether legal or ethical, include most of these topics. However, harmonization of these requirements is not complete, not only because some Member States have omitted certain requirements, but also because of the diversity of definitions and interpretations. Hence, we consider that consent requirements in Europe should be classified under a standard taxonomy where the local description or definition of each entity in the taxonomy is allowed to differ from one Member State to another.

3.2 Personal Data Anonymization

Data protection legislation in Europe is mainly designed to govern and control the processing of personal data. While in most instances such legislation bans the processing of personal data, it also often allows conditional lawful processing of such data in certain circumstances. If the conditions or circumstances do not allow, the only way to process personal data is by de-personalizing them first. We are interested in patients’ medical data which is normally classified as “sensitive” in data protection law. Research involving anonymous data does not require patient consent, provided data controller and processor commit to special safeguards to ensure complete anonymity. However, if anonymized data can still be considered indirectly nominative (e.g. through correlation with other data), consent is generally required and further safeguards must be adopted to protect the privacy and confidentiality of individuals [12]. De-personalization of data can take one of two forms, anonymization, where all data that can potentially identify the data subject (the patient) are masked or eliminated, and pseudonymization, where the identifying data are reversibly mapped onto and replaced by non-identifying codes appropriate to the circumstances. The degree of required anonymity varies from one Member State to another, not least because of differences in the definition of “personal data” within the different legal frameworks. Further possible conflicts of interpretation also arise between Member States; these are discussed in [5].

3.3 Specific Purposes of Processing

According to Article 6-1.b of the Directive 95/46/EC, data may be “collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes. Further processing of data for historical, statistical or scientific purposes shall not be considered as in-
compatible provided that Member States provide appropriate safeguards”.

Therefore, there is an assumption of compatibility between the original (collection) purpose and further scientific purposes. However, according to Article 11-1 of the directive, data subjects must be informed of the secondary use of their data, in particular, of the identity of the controller and the purpose of the processing. This duty to inform may be lifted only if the provision of this information is impossible or would involve a disproportionate effort. In these cases Member States shall provide appropriate safeguards (Article 11-2).

The Directive considers the disclosure of personal data to third parties as a processing operation, and thus subject to usual legal provisos. Transfer of data, as a particular form of disclosure, will only be allowed if the data subject has given his explicit consent to the processing of those data or when processing is necessary for certain special purposes, such as protection of the vital interests of the subject or of the security of the state, or where the subject has manifestly already made that data public.

In the light of the Data Protection Directive, if healthgrids are to be used for risk detection, disease monitoring and preventive care, legal guidelines should be established that clarify the circumstances in which professionals can make further use of personal data related to health in the interests of public health [11]. Such guidelines should allow for secondary uses even where such uses could not have been foreseen at the time of data collection.

4. Modelling Privacy Requirements: OWL plus Rules

The diversity, complexity and dynamicity of the rules governing privacy protection in Europe explains the need for a modelling approach that is able to abstract this complexity and facilitate its automation and enforcement at the process level. We shall use the term “privacy requirements” to mean all those obligations that must be fulfilled by all parties involved in the process of sharing and processing sensitive patient data for medical purposes (by which we embrace both healthcare and medical research) to preserve the patient’s privacy. This term therefore encompasses patient consent, anonymization or pseudonymization, the rights of the data subject including his right to dissent and to be notified. Our approach deals only with the requirements that could be enforced using a policy-based approach and does not include the cases where the intervention of ethical committees is essential. Our model should rather reflect similarity and possible conflicts between the EU Member States in the specification and the provision of these requirements. In the following paragraphs we present our attempt to model and to automate privacy requirements in the context of medical data disclosure in Europe.

Our approach uses the Web Ontology language (OWL) [13] to represent privacy obligations in the context of medical data disclosure. We first start with a conceptual generic model of the core concepts described in European Directive of data protection. The model is as presented in Figure 1.

The different concepts described in the rectangular shapes of the diagram are defined in details [6]. The diagram specifies also the relationships between the different concepts. For generalizability, it is worth noting that these generic concepts are also the core concepts of many international frameworks on data protection, such as the Ontario’s Freedom of Information and Protection of Privacy Act (FIPPA) [26]. With the use of OWL we specialize the gen-

![Diagram](image-url)
eric model of privacy concept and also extend it with additional concepts. This makes the model more applicable to our ultimate purpose, which is the automation of legal privacy guidelines and the process of reasoning about them. For example the OWL “Data Sharing” concept described in Figure 2 is a specialization of the generic “Data Processing” concept described in Figure 1. Another example is “consent necessity” that is normally a special type on “Consent Requirement” which is, in its turn, a specialization of the generic concept “Regulatory Requirements of Privacy” described in Figure 1.

OWL allows us to model the conceptual domain of “data sharing” or “data disclosure” and its components as hierarchies of classes/subclasses and of properties to represent the relationships between them. As shown in Figure 1, privacy requirements (e.g. Consent) may be modelled as OWL classes and assigned to the “Data Sharing” resource as object properties.

Moreover, OWL provides additional features to allow overlapping models of a concept to be merged, even when different naming conventions have been used for the same resource; for example, Explicit Consent may be termed Express Consent in another model but both concepts have the same meaning.

In complex legal domains, we need to model relationships that cannot be expressed in OWL, whose logic for describing properties is not rich enough. Legal rules are usually expressed as if – then-like rules. For example, we want to model a rule stating that if the data belongs to the UK then patient consent is necessary for any processing. Expressing this kind of rule requires the use of a semantic web rule language to allow sets of rules to be built up in terms of the different concepts of the sharing process (as described in the ontology) and properties of those concepts. This allows us to reason with the relevant set of rules and ontology classes in order to infer privacy requirements for different possible instances of sharing from the real world.

The Semantic Web Rule Language (SWRL) [14] satisfies our criteria for this task. The following example is a SWRL representation of the rule stating that patient consent is necessary for the sharing of a UK medical data item that is anonymized.

```
dataSharing(?x)∧hasSender(?x, ?s)∧locatedIn(?s, UK)∧hasStatus(?d, Anonymized)→hasConsentNecessity(?x, Necessary)
```

4.1 Additional Examples of SWRL Rules for Reasoning about Privacy Requirements in Europe

In this section we present a collection of SWRL rules that shows an attempt to formalize different legal requirements of privacy as per the privacy framework of Member States including: the UK, Italy and France. The addressed requirements include 1) the need for additional anonymization and 2) the possibility of accessing the data relating to a de-
ceased person by a legal representative (example a relative of the deceased person).

The following set of rules dictate whether a more advanced data anonymization is required for data that has previously been anonymized by an external body to the organization that is manipulating the data. In some cases, an ethical committee may still consider that even after anonymization, the data could potentially be linked with other data and lead to the identification of individuals. Further anonymization is therefore required.

Thus, in the UK:

\[
\text{dataSharing}(\text{x}) \\
\land \text{concerning}(\text{x}, \text{?data}) \\
\land \text{belongsTo}(\text{data, UK}) \\
\land \text{hasController}(\text{data, ?c}) \\
\land \text{isNonIdentifying}(\text{?d}) \\
\land \text{isLinkable}(\text{?d}) \\
\rightarrow \text{hasFurtherAnonymizationNecessity}(\text{x, Unnecessary})
\]

In Italy:

\[
\text{dataSharing}(\text{x}) \\
\land \text{concerning}(\text{x}, \text{?data}) \\
\land \text{belongsTo}(\text{data, Italy}) \\
\land \text{hasDataSubject}(\text{data, ?patient}) \\
\land \text{isDeceased}(\text{?patient}) \\
\land \text{hasLegalRepresentative}(\text{?p, ?rep}) \\
\rightarrow \text{canAccess}(\text{?rep, ?data})
\]

And in France:

\[
\text{dataSharing}(\text{x}) \\
\land \text{concerning}(\text{x}, \text{?data}) \\
\land \text{belongsTo}(\text{data, France}) \\
\land \text{hasDataSubject}(\text{data, ?patient}) \\
\land \text{isDeceased}(\text{?patient}) \\
\land \text{hasLegalRepresentative}(\text{?p, ?rep}) \\
\rightarrow \text{canAccess}(\text{?rep, ?data})
\]

In the next section we describe how the OWL ontology we have created and the semantic rules we have defined can be used to provide decision support for medical users to help them share patient data on a healthgrid in a privacy-aware manner.

5. Decision Support for Clinicians to Enhance Privacy Compliance

Our system has to reason on the privacy requirements model and knowledge base, described in the previous section, to generate protocols for medical users to guide them through the different processing tasks. For this purpose, we have developed a semantic web application that allows users to specify details of the different entities that constitute a sharing process and receive, as output, appropriate privacy management guidelines. This includes, for example, requirements regarding patient consent, such as establishing the necessity of consent and the required type of consent. The work we did in the previous section using the Protégé toolkit would be useful for ontology developers, e.g. to test and verify the usability of their models in decision making tasks, but it cannot be used by non-technical users such as clinicians. Our application allows clinicians and other medical users to enter a description of the data processing they would like to undertake in a standard fashion. A graphical user interface has been provided to allow non-technical users to enter descriptions in a standard way. Our application then pro-
cesses the data under consideration in the order portrayed graphically in Figure 3.

With the OWL and SWRL model ready to receive concrete data (cf. (1) in Figure 3), the user enters data and these are matched (2) to individuals stored in the knowledge base. The application then creates an instance of a SWRL rule engine (3, 4). As with the Protégé toolkit, we have chosen Jess as a rule engine. Jess is usually accessed through the SWRL rule engine bridge. When working programmatically, we have first to create a SWRL rule engine bridge. In our case we need to explicitly set the rule engine name to Jess. This is because the bridge is specialized for each rule engine implementation. However, interaction with the bridge should be the same irrespective of the underlying rule engine implementation.

An implementation for the Jess rule engine is supplied with the standard Protégé-OWL distribution in a Java archive (JAR) called swrl-jess-bridge.jar. A class in this repository called SWRLJessBridge contains the Jess implementation. The constructor for this class takes an instance of the OWLModel class, representing the OWL knowledge base with its associated SWRL rules, and an instance of a Jess Rete object, which represents an instantiation of the Jess rule engine. The following code snippet shows the creation of a Jess bridge. It assumes that the user knows how to create an instance of an OWL model using the Protégé-OWL API.

```java
OWLModel owlModel = ... // Create using normal Protege-OWL mechanisms.
SWRLRuleEngineBridge bridge = BridgeFactory.createBridge("SWRLJessBridge", owlModel);
```

A SWRLRuleEngineBridgeException will be thrown if any errors occur during the bridge creation. Once the Jess bridge is created, the public methods it inherits from the SWRLRuleEngineBridge class can be used to interact with it.

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Once an instance of a Jess SWRL bridge is created we invoke the infer() method (a method of the class SWRLRuleEngine) in order to load the facts and rules into the rule engine, do all the necessary transformations before and after running the rule engine and record the newly inferred axioms into the ontology [5]. Finally the decision support application extracts the newly inferred axioms [6] and uses them to generate the required output to the user.

### 6. Case-Study and Results

In this section, we explain how privacy requirements are integrated within some real world workflows in medical data sharing. We focus on a real world grid scenario, the MammoGrid project [15], whose aim was to standardize scanned mammograms for use in epidemiological studies, quality control for breast cancer screening, comparative diagnosis and validation of computer aided detection algorithms for mammographic images. For this case study, we focus mainly on the requirement of patient consent for two critical phases of the data lifecycle: a) uploading the data from local resources to the grid, and b) sharing the data on the grid. Data sharing for this project involves organizations from two EU Member states, UK and Italy. With a substantial grid node at CERN to support communication, we suppose that France is a grid party as well.
6.1 Uploading Data on the Grid

When a user requests to upload data from the hospital database to the federated grid database, the system must first generate the set of privacy obligations that the user needs to comply with before the data is uploaded to the grid. These requirements are generic and do not depend on the geographic location of the entities that would have access to it or share it in the future. In other terms, the national legal and ethical framework would be the primary reference for identifying privacy requirements for this task. Requirements may include anonymization, pseudonymization, de-identification, possibly including image scrambling, consent for storing the data in the grid and obligations related to the quality of the data including data provenance, accuracy and relevance. To achieve this goal, a local version of the framework must be deployed as part of the local resources at each hospital or medical research centre participating in the grid.

The data that is subject to processing for this project are patient mammograms along with other potentially identifying data such as age, age at menarche and menopause, data concerning children, as well certain body metrics of the patient. Data depersonalization was not a viable option for protecting patient identity as the data that should be hidden forms important clinical variables for comparative diagnosis. Although this data does not directly identify the patient, it could reveal the patient’s identity if linked with other data. For this reason, the justification to the processing of patient data was patient consent or ethical approval or both, depending on the Member State. For the UK, patient consent is necessary even when ethical approval has been granted. However, ethical approval is a sufficient condition for Italy. When a technician at one of the grid nodes tries to upload some local data to the shared grid database, our system will automatically generate a set of privacy guidelines to assist her through her data uploading task. For example, the following rule will be inferred in order to indicate to a radiologist at a French hospital that an express and specific patient consent is required in order to share data on the grid:

\[
\text{dataSharing}(\text{x}) \rightarrow \\
\quad \text{hasSender}(\text{x}, \text{s}) \\
\quad \text{locatedIn}(\text{s}, \text{France}) \\
\quad \text{concerns}(\text{x}, \text{d}) \\
\quad \text{belongsTo}(\text{d}, \text{France}) \\
\rightarrow \\
\quad \text{consentNecessity}(\text{x}, \text{Necessary}) \\
\quad \text{consentExplicitness}(\text{x}, \text{Express}) \\
\quad \text{consentSpecificity}(\text{x}, \text{Specific Consent})
\]

Similarly indicating to an Italian technician that patient consent is not necessary for uploading medical data to the grid will be based on firing up the following rule:

\[
\text{dataSharing}(\text{x}) \\
\quad \text{hasSender}(\text{x}, \text{s}) \\
\quad \text{locatedIn}(\text{s}, \text{Italy}) \\
\quad \text{concerns}(\text{x}, \text{d}) \\
\quad \text{belongsTo}(\text{d}, \text{Italy}) \\
\rightarrow \\
\quad \text{consentNecessity}(\text{x}, \text{Unnecessary}) \\
\quad \text{consentExplicitness}(\text{x}, \text{Any}) \\
\quad \text{consentSpecificity}(\text{x}, \text{Broad Consent})
\]

6.1.1 Use Case: Generating Legal Requirements for Uploading Patient Data into the Grid Database

This use case describes the interaction of a medical user with our system. The user would like to upload some patient mammograms to the shared grid database in order to be used for research. The user is keen to adopt good practice for privacy preservation while sharing patient data with colleagues from other European Member States via the grid. For this purpose, they choose to consult our system in order to learn about the legal requirements they need to comply with before sharing the data. First, the system asks the user to select the type of the data they wish to share. The user chooses the type of data as: “mammogram” and selects the consent requirement category from the list of legal requirements offered by the system. The system also allows the user to choose whether they want to learn only about the legal framework in their Member State or to learn about the legal requirements in different Member States. The following schema; in Table 1 demonstrates the kind of output the user gets when they choose the Member States whose legal frameworks they wish to know about as the UK, Italy and France and selects generate report.

6.2 Downloading Data from the Grid

In our application, the grid system is not fully open and data may be shared only on request. When a user within Member State A requests to access data belonging to another Member State B, the system should generate the relevant set of requirements which are just the additional safeguards

<table>
<thead>
<tr>
<th>Sharing Subject</th>
<th>Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sharing Data Type:</strong> mammogram</td>
<td>Member State: all</td>
</tr>
<tr>
<td><strong>UK</strong></td>
<td>Necessary</td>
</tr>
<tr>
<td>Necessity</td>
<td>Specific</td>
</tr>
<tr>
<td>Specificity</td>
<td>Any</td>
</tr>
<tr>
<td>Explicitness</td>
<td>GP only</td>
</tr>
<tr>
<td>Who can contact</td>
<td></td>
</tr>
<tr>
<td><strong>Italy</strong></td>
<td>Unnecessary</td>
</tr>
<tr>
<td>Necessity</td>
<td>Broad</td>
</tr>
<tr>
<td>Specificity</td>
<td>Any</td>
</tr>
<tr>
<td>Explicitness</td>
<td>Research team</td>
</tr>
<tr>
<td>Who can contact</td>
<td></td>
</tr>
<tr>
<td><strong>France</strong></td>
<td>Necessary</td>
</tr>
<tr>
<td>Necessity</td>
<td>Specific</td>
</tr>
<tr>
<td>Specificity</td>
<td>Express</td>
</tr>
<tr>
<td>Explicitness</td>
<td>Research team</td>
</tr>
<tr>
<td>Who can contact</td>
<td></td>
</tr>
</tbody>
</table>
that Member State B would usually ask users in Member State A to guarantee before sharing medical data with them. Allowing access to the data would be subject to additional security policies that are part of our focus and also to the privacy assurance the user provides when requesting the access. In order to control data disclosure when downloading data from the grid, a distributed version of the framework is required. As shown in Figure 5, this application will be deployed as a component of a general privacy compliance framework. This enables the coordination and appropriate management of sharing requests from all nodes participating in the grid.

The data now is uploaded to the grid and ready to process for the specific medical purposes of the MammoGrid project. It is very likely that patients’ mammograms would be shared with clinicians across European borders. In many cases researchers will require the data to be downloaded to their personal storage devices. At this stage, we are more concerned with the future secondary use of the data. A British organization might insist that when their data is to be processed by an Italian grid user, either the new processing purpose should be compatible with the purpose the patient has consented to or patient consent must be collected for the new purpose. The following rules determine who can contact the patient in order to collect consent, first for the UK:

### Table 2

<table>
<thead>
<tr>
<th>Sharing Data Type: mammogram_1</th>
<th>Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sharing Purpose Type: Secondary Purpose</td>
<td>Member State: all</td>
</tr>
<tr>
<td>UK Who can contact patient to get consent?</td>
<td>GP only</td>
</tr>
<tr>
<td>Italy Who can contact patient to get consent?</td>
<td>Research team</td>
</tr>
<tr>
<td>France Who can contact patient to get consent?</td>
<td>Research team</td>
</tr>
</tbody>
</table>

### 6.2.1 Use Case: Generating Legal Requirements for Secondary Sharing of Data that has not Been Collected from the Patient

This use case describes the interaction of a medical user with our system. The user in this case would like to learn about the legal requirements for the sharing of data for a secondary medical research purpose. The data in this case is being used for a purpose that is different from the primary or initial the data was collected for. The user is keen to adopt good practice for privacy preservation while sharing patient data with colleagues from other European member states via the grid. We suppose that the user already knows about the necessity of obtaining patient consent in order to comply with the European legislation. In addition the user needs to know who is allowed to contact the patient and ask for their consent. For this purpose, they choose to consult our system in order to learn about this specific legal requirement. First, the system asks the user to select the type of the data they wish to share. The user chooses the type of data as: “mammogram” and selects the Consent Point of Contact requirement category from the list of legal requirement offered by the system. The user is also asked to specify the type of the purpose for data sharing. The user specifies the purpose type as Secondary Purpose. The following schema; in Table 2 demonstrates the kind of output the user gets when they choose, for Member States the UK, Italy and France and select generate report.

### 7. Related Work

There has been some other work involving a legal decision support mechanism in sharing biomedical data. Notable in the literature is the work of the caBIG project [16]. caBIG, funded and led by the National Cancer Institute’s Center for Bioinformatics, has as its goal the delivery of innovative approaches for the prevention and treatment of cancer. Its vision is the implementation of infrastructure and tools with broad utility and reusability within and outside the cancer community. These tools are designed to support the sharing and
reuse of large volumes of research data created by high throughput genomics and proteomics technologies. The legal, regulatory and security requirements for data sharing were studied [17] and specialized tools are being developed in order to address these challenges. Among the tools adopted by cаБIG infrastructure is the Data Sharing and Security Framework (DSSF) [18]. The cаБIG DSSF can be used as a decision support tool to facilitate data sharing by determining which data can be shared and under which type of access, data security and regulatory controls. This requires the user to assess the sensitivity of the data by using the Framework’s Privacy, Confidentiality and Security Considerations element [19]. For example, the framework asks the user to select the category of sensitivity that best describes the data he wants to share. The user can choose from three categories: a) Low Sensitivity (i.e. de-identified or anonymized data set), b) Medium (coded or limited data set), or c) High Sensitivity (identifiable data). By doing so the framework can answer legal questions related to Privacy and Security, such as the sample question: Do federal or state laws or your institution’s policies prohibit or restrict disclosure?

This framework, if automated and adopted, would certainly have a key impact on enhancing the task of data sharing while complying with diverse legislation. The ambiguity around legal issues of privacy would be better clarified by providing specialized answers to users’ concerns. However, we note the concern that leaving the responsibility to individual medical users to assess the sensitivity of data presents a risk of inconsistent assessments and diverse judgements for the same data, possibly because of lack of experience or expertise in the privacy domain. We also note that the Data Sharing and Intellectual Capital Knowledge Center [20] has provided a web-based tool for DSSF decision support, but full automation and information about methodology, architecture and techniques adopted are not yet available.

Several other research projects have addressed the problem of privacy management for sharing identifiable data across European borders including PRIME [21] and PRIME-Life [22]. However, they have tackled this problem as only a system process through designing a system and access controls that are privacy aware. We have similarly addressed these issues in [23]. In contrast, the work in this paper stresses the importance of considering privacy management and compliance as a human process through more effective teaching and explaining of privacy policies and by providing users with automated support to help minimize unintentional breaches of privacy principles. With regards to the general topic of privacy and confidentiality, the work in [24] highlighted the importance of characterizing the workforce in the health domain and its training needs, including those related to understanding privacy and confidentiality issues, in order to effectively implement health information technologies (HIT). The work in [25] presents an approach to allow access and share health data while adhering to high level privacy and security policies. We have presented a different approach to a similar problem in [6].

8. Conclusion and Future Work

Privacy requirements for the sharing of medical data between European Member States can be described within a semantic model. Once it is rich enough, the model can form a knowledge base for an inference engine to reason about the duties of medical users as imposed by different European and national legislation in order to preserve patient privacy. The new inferred knowledge generated by the inference engine can provide guidelines and protocols to help clinicians and other medical users across Europe to share medical data while complying with relevant regulatory frameworks. Our work has mainly focused on the requirement of patient consent, but we believe other requirements could be modelled in the same way, including anonymization, role-roaming, etc.

In future work, we will extend our semantic model of privacy requirements by classifying privacy requirements rules under two main categories allowing the users to differentiate between legal and ethical guidelines. It would also be valuable to adduce a measure of confidence in any given decision, using, for example, different authoritative rankings of statutes and rules to weight alternative decisions. We are also actively exploring ways of empirically validating our approach. Plans are underway for our prototype application to be extended and “gridified” (form part of a healthgrid project architecture so as to allow medical grid partners and clinical users to test it and comment on its usefulness.

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References


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