

An Ontology for Medical Treatment Consent

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Abstract— Active duty military personnel, their families and veterans seek medical services from the Military Health Service, which partners with private care, or the Veterans Administration, respectively. Indeed, medical services for active duty personnel, who need medical services on deployment, is a readiness issue. Laws that govern the practice of medicine, licensing to practice medicine and the permission to treat a patient is based on local laws (state level) that are specific to medical sub-specialties. That provides a daunting challenge to patients who move frequently, such as active duty military and their families. As most medical providers are transforming their record keeping to Electronic Medical Record (EMR) system, it is desirable to obtain, verify and act according to the legally enforced medical consent using EMRs. We present an Ontology-based framework and a prototype system that provide end-to-end services using an open source EMR system. Providing an electronically verifiable, but compliant with locally mandated laws in one universal system can be beneficial to VA and other DoD EMR systems.

Keywords—*informed medical consent; medical consent law; workflow management system; ontology*

I. INTRODUCTION

Failure to obtain informed consent is listed as a top ten reason for medical malpractice claims [1]. The improvement in flexibility, automation and enforcement for electronic patient informed consent management are especially beneficial to patients who relocate, such as active duty military and their families. This mobility entails their medical treatment be subject to local regulations. Given that EMRs services can be centralized, cloud based or being offered remotely, having a consent management system that can provide a diverse collection of consents for every treatment would benefit EMR services generally, and especially the Military Health Service. Although some VA hospitals have implemented electronic consent process, iMedConsent [2], they do not provide enforcement mechanism and is considered mostly educational for the patients. The system we prototype can accommodate (i.e. obtain and enforce though out long chains of treatment processes), can be deployed from one location but cover multiple regions (such as states, countries) and be helpful for the military, military dependants and as well as for other mobile populace.

Informed patient consent – either express or derived -- expresses the patient's wishes, and consists of an agreement between the care providers and patient, including choice between potential treatment regimes or terminating treatment.

Part of the process of obtaining consent involves the caregiver providing a risk/benefit analysis and explaining alternative treatments in a way that the patient understands, and accurately communicates the care provider's understanding in an unbiased way [3].

State law specifies acceptable explanation. Further, consent laws obligate the caregiver to attest that the patient and/or the guardian have the capacity (including physical/mental capacity and maturity) to provide consent. Over the years, federal, state, and local governments and healthcare organizations have developed laws, regulations, and standards for obtaining and memorializing informed consent. However, consent laws and regulations are complex and sometimes ambiguous, and change often. Therefore EMR must take these changes as they are mandated. We postulate that having a consent service that is aware of the semantics of informed medical consent can satisfy the evolving and diverse nature of mandated informed treatment consents.

As a substantiation of our postulate, we provide a semantic web driven, medical workflow aware [4] control system to obtain and enforce treatment consent. The medical personnel that use our system do not see a difference between the existing EMR system and our prototype. Some highlights of our system are: A refined Workflow-based EMRs that allow the medical staff to obtain consents dynamically--i.e., if required by a procedure in a treatment workflow; and evaluating these consents automatically as a care team goes from one step to another in the treatment workflow [5]. Furthermore, our combined workflow based consent management engine ensures that treatment workflow move forward only if consents have been granted (including break-the-glass kind of emergency treatments). This enhancement improves current practice of patient informed consent management.

Following this Introduction, Section 2 describes related work; Section 3 explores ontology-based reasoning to derive the informed treatment consent; Section 4 shows architecture of our consent-based workflow control in a Workflow-based EMR system; and finally, Section 5 contains concluding comments.

II. RELATED WORKS

A. Informed Consent in Current EMRs

The American Medical Association considers the term

informed consent, first used by a California appeals court in 1957 [6], “an ethical obligation of the practice of medicine and a legal requirement per statute and case law in all 50 States” [7] y. Medical informed consent falls mainly into two categories: consent for medical information disclosure; and consent for medical treatments. Herein we mainly address the latter, with a focus on informed consent for procedure-oriented treatment regimes.

In the past decade, consent management has received considerable attention from researchers and healthcare organizations who proposed different ways to improve electronic consent management system. For example, “e-Consent: The Design and Implementation of Consumer Consent Mechanisms in an Electronic Environment” [8] provided guidelines on how to design an e-consent system. Another relevant work is by Ruan C. & Yeo S.S. [9], who used the UML Model to design an e-consent system. They first identify various parts necessary to specify the e-Consent rules about patient record protection, and then used UML to model the properties required by an e-consent system and to make the associated patient record protection rules explicit and verifiable. However, that work was theoretical; they neither designed nor implemented a system that works with EMR systems.

Rusello G. et al. proposed creating consent-based workflows for healthcare management [10] where patients can control disclosure of their medical data for inter-institutional consults. This work does not address workflows for procedure-oriented treatment regimes, treating consent contents as black boxes. Others have proposed e-consent management to be integrated with EMR or EHR systems [11-14]. Win et al. in their paper “Implementing patients consent in electronic health record systems” [15] expressed patient consent using an interface-based approach. However, those e-consent approaches focus mainly on sharing medical data, privacy, and security aspects [16-18], but not the complicated nature of treatments.

Many healthcare organizations attempted to have electronic consent management in their EMRs. Veterans Administration Medical Centers use iMedConsent™ [2] that supports electronic access, completion, signing, and storage of informed consent forms and advance directives. iMedConsent has two parts: software application and clinical content library. It generates consents on each procedure without workflows. Nonetheless, the system neither dynamically gains informed consents at the point of providing treatments nor enforces consents on medical procedures.

B. Ontologies in the Healthcare Domain

Ontologies have been used to represent actionable knowledge in biomedicine [19–23], decision support [24], information integration, etc. Some examples are: BioPAX, an ontology for the exchange and interoperability of biological pathway (cellular processes) data [25]; CCO and GexKB, Application Ontologies (APO) that integrate diverse types of knowledge with the Cell Cycle Ontology (CCO) and the Gene Expression Knowledge Base (GexKB) [26]; Disease Ontology, designed to facilitate the mapping of diseases and associated conditions to particular medical codes [27]; Linkbase, a formal

representation of the biomedical domain, founded upon Basic Formal Ontology [28]; NCBO Bioportal, biological and biomedical ontologies and associated tools to search, browse and visualize [29]; NIFSTD Ontologies from the Neuroscience Information Framework: a modular set of ontologies for the neuroscience domain [30]; SNOMED CT (Systematized Nomenclature of Medicine -- Clinical Terms) [31]; OBO Foundry, a suite of interoperable reference ontologies in biology and biomedicine [32]; OBO-Edit, an ontology browser for most of the Open Biological and Biomedical Ontologies [33]; PRO, the Protein Ontology of the Protein Information Resource from Georgetown University [34], and so on. Yet, no works have efficiently leveraged a technique for informed treatment consent in EMRs. In this paper, we provide a methodology to address this gap.

III. USING ONTOLOGY-BASED REASONING TO DERIEVE INFORMED TREATMENT CONSENTS

A. Entities of Medical Treatment Consent Ontology

To create our ontology for medical treatment consents, we studied several medical treatments in actual medical facilities, obtained their consent forms and studied state law governing medical consents. We combined information obtained from interviews with the various paper-based documents used to record events and data that are associated with the workflows. We found there are common entities used in the informed treatment consents, such as patients (may or may not be an *Informed consent giver*), treatments (usually, consisting of several treatment procedures – so called tasks in the treatment workflow specifications), treatment performance locations (some treatments may be not be permitted in some states) and informed consents (where some procedures within a treatment regime may not require consent). Based on our observations, we created the following classes, attributes and rules on the ontologies.

B. Classes, Properties Created in Ontology

➤ Classes

1. *Patient*: (one requiring medical assistance) with attributes such as age, name and active status used to evaluate maturity.

2. *Treatment*: Methods used to manage ameliorate, or prevent a disease, disorder, or injury. Each Treatment has a name (such as eye surgery, dialysis etc.).

3. *Procedures*: generally, every treatment consisted of a set of predefined procedures. Each procedure has a procedure’s name.

4. *Consent*: legal documents expressing the willingness for the patient to be subjected to treatments and encompassing procedures (referred to as TreatmentConsent) or providing the authority share medical information (SharingConsent).

5. *TreatmentConsent*: A subclass of Consent, modeling the agreement to receive treatment. Its nature is determined by state law, federal law or medical sub-discipline. Thus, the attributes are the state, treatment name, treatment type. An example, *anesthesiaConsent*

1) *MandatoryConsent*: a sub-class of *TreatmentConsent* with attributes active (or passive). An example is *anesthesiaConsent* for Suegray.

2) *OptionalConsent*: is a sub-class of *TreatmentConsent*, but its omission does not affect performing the procedures. An example is anesthesia consent for giving birth. Most states do not mandate this consent.

6. *AdultPatient*: is the patient's maturity status. Competent adult patients may give their own treatment consents.

7. *MinorPatient*: is a patient's maturity status. Without exception, such as during an emergency, minor patients cannot provide treatment consent.

8. *PerformInState*: is a State in which the treatment is to be performed. They associate with Treatment.

➤ Properties (express the relationship of two classes) in Ontology

TABLE 1 PROPERTIES TABLE

Property Name	Domain	Range
<i>asksMandatoryConsentByPatient</i>	Patient class	MandatoryConsent
<i>asksOptionalConsentByPatient</i>	Patient class	OptionalConsent class
<i>has</i>	Treatment class	Procedures class
<i>isPatient</i>	AdultPatient class or MinorPatient class	Patient class
<i>isState</i>	PerformInState class	State class
<i>needsMandatoryConsent</i>	Procedures class	MandatoryConsent class
<i>needsOptionalConsent</i>	Procedures class	OptionalConsent class
<i>performedIn</i>	Treatment class	State class
<i>requiresMandatoryConsent</i>	Procedures class	Consent class
<i>requiresOptionalConsent</i>	Procedures class	Consent class

Table 1 shown relationship between two classes. Properties may have a domain and a range specified. For example, row1 in above table indicates:

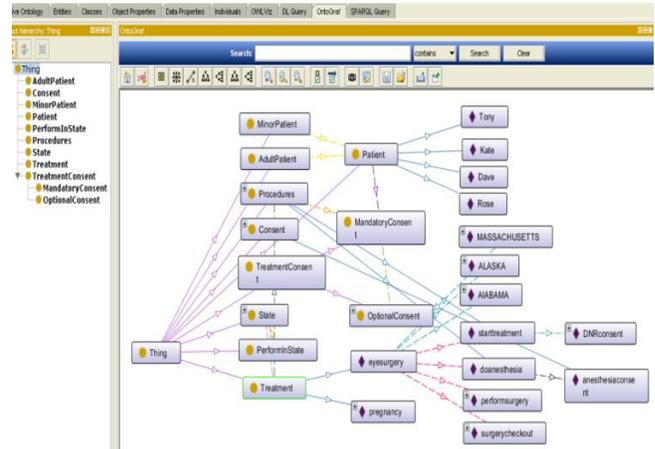
asksMandatoryConsentByPatient: it links individuals belonging to the class Patient to individuals belonging to the class MandatoryConsent.

A view of the entities of treatment consent ontology developed in Protégé 4.3. shown in Fig.1.

C. Rules for Enforcing Informed Treatment Consent

We now show how to use the ontological syntax and create rules that specify treatment consent. As stated, these rules formalize contents taken from the many natural language documents consisting of state laws and sub-disciplines regulations that govern specific institutional practices [35]. These rules specify in the consent components:

Fig. 1. Entities of treatment consent ontology



Rule (1) Information Disclosure Standard: Obligates the care provider to disclose and discuss information relevant to the proposed treatment, their risks and benefits and the available alternatives with their risks and benefits [36]. These come in two main standards: The normal person's standard and the professional standard. 25 states mandate the use of the patient standard, while 23 have mandated the professional standard. The laws in the remaining two states, Colorado and Georgia, are not easily classifiable as one or the other [37]. Nonetheless, the scope of required information to be disclosed is still being debated. Two states, Minnesota and New Mexico, require the care provider to explain using both these standards.

Rule (2) Decisional Capability: Evaluation of patient's competence to understand the information and providing rational and voluntary decisions about the healthcare treatment. In [38], authors described four psycho-legal standards, communicating a choice, factual understanding, appreciation of the situation, and rational manipulation of information, all used to evaluate a patient's competence in giving consent. However, to date this lacks a widely accepted standard. Hence, we do not codify this aspect.

Rule (3) Competency: Validation of patient's maturity to grant informed consent. For the informed treatment consents, an essential component of the conception of autonomy is allowing competent adult persons and emancipated children to make their own health care decisions. Our examinations have led to categorizing the consents as follows:

1. *Informed consent giver (governed by Rule (3) - competence):* the person with the legal right to make health care decisions, such as parents or legal guardians of minors, healthcare proxies, healthcare providers or third parties.
2. *Treatment information (governed by Rule (1) - information or disclosure):* at a minimum, includes treatment name, procedures for this treatment, treatment preformed location.
3. *Patient's decision of the treatment (governed by Rule (2) - decisional capability):* includes the decision

(deny or accept) by providing all required conditions such as patient’s and other attributes such as signatures, date, etc.

Consequently, formalization of informed consent should base its consents on all the above-mentioned attributes. Assuming that consent rules and patient information is available in an EMR, we show how to generate the consent decisions. Auto-generation of the appropriate forms to be signed by the consent giver will be described elsewhere.

The following example shows the complicated nature of decisions made by our consent service. Most states set the age at 18 years, but Alabama allows health care consent to be made by minors 19 years of age and older [39]. So, can an 18 year-old resident of Virginia requiring dialysis treatment during a visit to Alabama give consent for the treatment? Answering this question will determine the adult status of the VA resident, but that too depends on the treatment sought as described below.

- Depending on the treatment type, the age of the minors who may consent may differ.

Example: In CA, for General Medical Treatments, Cal. Fam. Code § 6500, states a minor 18 years of age or older may give his/her own treatment consent. However, for Pregnancy (not include sterilization and abortion), CAL. FAM. CODE § 6925 (2012) states that *a minor may consent to medical care related to the prevention or treatment of pregnancy, but this law does not authorize a minor: (1) To be sterilized without the consent of the minor’s parent or guardian. (2) To receive an abortion without the consent of a parent or guardian other than as provided in Section 123450 of the Health and Safety Code.*

- Even if the patients are minors, for certain treatment with some minor active status such minors are allowed to give their own treatment consent.

Example: (1) Cal. Fam. Code § 7050 provides that *an emancipated minor may consent for medical, dental, or psychiatric care, without parental consent, knowledge, or liability;* (2) Cal. Fam. Code § 6922 provides that *a minor, 15 years of age or older, is living separate and apart from the minor’s parents or guardian, whether with or without the consent of a parent or guardian and regardless of the duration of the separate residence; and the minor is managing the minor’s own financial affairs, regardless of the source of the minor’s income can give consent for medical treatments.*

- Some consent rules are not found in specific provision explicitly, but can be retrieved from combining laws.

Example: Cal. Fam. Code § 7002 provides *a minor who has married is emancipated;* according to another rule (Cal. Fam. Code § 7050 provides that *an emancipated minor may consent for medical, dental, or psychiatric care, without parental consent, knowledge, or liability.* The combination implies a

married minor may consent for medical, dental, or psychiatric care, without parental consent, knowledge, or liability.

We create patient maturity evaluation rules for each state based on its consent laws. Table 2 shows a part of the summary of 50 states’ patient maturity evaluation rules.

TABLE 2 PATIENT MATURITY EVALUATION RULES (50 STATES)

State	State Abbreviation	General Medical Treatment	Pregnancy
ALABAMA	AL	19 years of age or older (Ala. Code § 26-1-1) 1. Minor age equal or greater than 18, less than 19, and minor has an emancipation order (Ala. Code §§ 26-13-1 and 26-13-5); 2. Minor age 14 or old, has graduated from high school (Ala. Code § 22-8-4); 3. Minor is married (Ala. Code § 22-8-4; Ala. Code § 22-8-5); 4. Minor having been married and divorced (Ala. Code § 22-8-4; Ala. Code § 22-8-5); 5. Minor is pregnant (Ala. Code § 22-8-4); 6. Minor has child(ren) (Ala. Code § 22-8-5);	1. Any minor (Ala. Code § 22-8-6);

CALIFORNIA	CA	18 years of age or older (Cal. Fam. Code § 6500) 1. Minor is an emancipation minor (Cal. Fam. Code § 7050); 2. Minor is 15 years of age or older, who is living separate and apart from the minor’s parents or guardian and managing the minor’s own financial affairs (Cal. Fam. Code § 6922); 3. Married Minor is an emancipation minor (Cal. Fam. Code § 7002); 4. Minor is 16 years of age or older, who serves in the armed forces of the United States or has court order is an emancipated minor (CAL. FAM. CODE § 6950 (2012));	1. An unemancipated minor (Cal. Fam. Code § 6925);

WYOMING	WY	18 years of age or older (Wyo. Stat. Ann. § 14-1-101(a)) 1. Minor is or was legally married – minor is married, widow (Wyo. Stat. Ann. § 14-1-101(b)); 2. Minor is or was legally married – minor is divorced (Wyo. Stat. Ann. § 14-1-101(b)); 3. Minor who is in active military service of the United States may consent for healthcare treatment (Wyo. Stat. Ann. § 14-1-101(b)); 4. Minor who is living apart from his parents or guardian and managing his/her own affairs may consent for healthcare treatment (Wyo. Stat. Ann. § 14-1-101(b)); 5. Minor is an emancipated minor (Wyo. Stat. Ann. § 14-1-101(b)).	1. No explicit law

D. Deriving Informed Treatment Consents

We use the patient maturity rules of California (CA) as an example to explain Semantic Web Rule Language (SWRL) rules:

- For General Treatment (we consider eye surgery belongs to general treatment)
 1. Minor is an emancipation minor may consent for medical, dental, or psychiatric care, without parental consent, knowledge, or liability. (Cal. Fam. Code § 7050);
 2. Minor is 15 years of age or older, who is living separate and apart from the minor’s parents or guardian and managing the minor’s own financial affairs (Cal. Fam. Code § 6922) is an emancipation minor;
 3. Married Minor is an emancipation minor (Cal. Fam. Code § 7002);
 4. Minor is 16 years of age or older, who serve in the armed forces of the United States or has court order (Cal. Fam. Code § 6950);
- For Pregnancy Treatment (exclude to be Sterilization and to receive Abortion)
 1. An un-emancipated minor may consent for medical care related to the prevention or treatment of pregnancy (Cal. Fam. Code § 6925);

Let S be a SWRL knowledge base, where $\{t, p, s\}$ is a set of OWL class names. In here, $\{t, p, s\}$ refers to {Treatment, Patient, and State} coordinately. *performedIn* is an OWL property name to show the relationship between Treatment and State, and $\{“eyesurgery”, “CA”, age, fi, ls, m, iem, iaf, hco, tpi\}$ is a set of OWL constants and SWRL variables. In here,

age refers to patient's age; *fi* refers to patient's financial status; *ls* refers to patient's resident status; *m* refers to patient's marital status; *iem* refers to patient maturity level; *iaf* refers to patient's career status; *hco* refers to a legal issue related to patient, *tpi* refers to patient seeking treatment which is an attribute of Patient. Some SWRL rules have the form:

Example 1: (CA consent Laws for General Medical Treatment: rule2 shown in Table 2)

- (1) $\left\{ \begin{array}{l} \text{patientRequiresTreatment}(?p, \text{"eyesurgery"}), \\ \text{hasAge}(?p, ?age), \\ \text{patientFinancialIndependent}(?p, ?fi), \\ \text{patientLivesSeparately}(?p, ?ls), \end{array} \right.$
- (2) $\left\{ \begin{array}{l} \text{hasTreatmentName}(?t, \text{"eyesurgery"}), \\ \text{patientTreatmentPerformedIn}(?p, ?tpi), \\ \text{hasStateName}(?s, ?tpi), \text{performedIn}(?t, ?s), \\ \text{containsIgnoreCase}(\text{"AL || AK || CA || MA"}, ?tpi), \end{array} \right.$
- (3) $\left\{ \begin{array}{l} \text{containsIgnoreCase}(\text{"T"}, ?fi), \\ \text{containsIgnoreCase}(\text{"T"}, ?ls), \end{array} \right.$
- (4) $\text{lessThan}(?age, 16),$
 $\text{greaterThanOrEqual}(?age, 15)$
- (5) $\rightarrow \text{AdultPatient}(?p)$

Example 2: (CA consent Laws for General Medical Treatment: rule1 ~ rule4 shown in Table 1)

- (1) $\left\{ \begin{array}{l} \text{patientRequiresTreatment}(?p, \text{"eyesurgery"}), \\ \text{hasAge}(?p, ?age), \\ \text{patientFinancialIndependent}(?p, ?fi), \\ \text{patientLivesSeparately}(?p, ?ls), \\ \text{patientMarried}(?p, ?m), \\ \text{patientIsEmancipatedMinor}(?p, ?iem), \\ \text{patientIsArmedForce}(?p, ?iaf), \\ \text{patientHasCourtOrder}(?p, ?hco), \\ \text{patientIsEmancipatedMinor}(?p, ?iem), \end{array} \right.$
- (2) $\left\{ \begin{array}{l} \text{hasTreatmentName}(?t, \text{"eyesurgery"}), \\ \text{patientTreatmentPerformedIn}(?p, ?tpi), \\ \text{hasStateName}(?s, ?tpi), \text{performedIn}(?t, ?s), \\ \text{containsIgnoreCase}(\text{"AL || AK || CA || MA"}, ?tpi), \end{array} \right.$
- (3) $\left\{ \begin{array}{l} \text{stringConcat}(?v, ?fi, ?ls), \\ \text{containsIgnoreCase}(\text{"FF-FT-TF"}, ?v), \\ \text{containsIgnoreCase}(?iem, \text{"F"}), \\ \text{containsIgnoreCase}(\text{"F"}, ?m), \\ \text{containsIgnoreCase}(\text{"T-F"}, ?iaf), \\ \text{containsIgnoreCase}(\text{"T-F"}, ?hco), \end{array} \right.$
- (4) $\text{lessThan}(?age, 16),$
 $\text{greaterThanOrEqual}(?age, 15)$
- (5) $\rightarrow \text{MinorPatient}(?p)$

In Part (1) we defined a set of OWL constants and SWRL variables of a specific patient; and the information we can retrieve from EMRs. Part (2) checked whether the treatment that patients seek may be performed in the state where patient does the treatment; and which treatment can be performed in which states is known information. Part (3) established rules.

Part (4) provided constrains. Part (5) implied the consequent ((5)) from the antecedent ((1) ~ (4)).

Table 3 shows the part of summary of the syntax of consent laws of patient's maturity in 50 states.

TABLE 3 THE SYNTAX OF CONSENT RULES OF PATIENT MATURITY IN 50 STATES

State	State Abbreviation	SWRL rule	
		General Medical Treatment	Pregnancy
ALABAMA	AL	hasTreatmentName(?t, "eyesurgery"), patientRequiresTreatment(?p, "eyesurgery"), hasAge(?p, ?age), patientTreatmentPerformedIn(?p, ?tpi), hasStateName(?s, ?tpi), performedIn(?t, ?s), containsIgnoreCase("AL", ?tpi), greaterThanOrEqual(?age, 19) -> AdultPatient(?p)	hasTreatmentName(?t, "pregnancy"), patientRequiresTreatment(?p, "pregnancy"), patientMarried(?p, ?m), patientTreatmentPerformedIn(?p, ?tpi), hasStateName(?s, ?tpi), performedIn(?t, ?s), containsIgnoreCase("AL", ?tpi) -> AdultPatient(?p)
		hasTreatmentName(?t, "eyesurgery"), patientRequiresTreatment(?p, "eyesurgery"), hasAge(?p, ?age), patientDivorced(?p, ?d), patientIsPregnant(?p, ?p), patientMarried(?p, ?m), patientHasChild(?p, ?hc), stringConcat(?v, ?m, ?d, ?p, ?hc), containsIgnoreCase(?v, "T"), patientTreatmentPerformedIn(?p, ?tpi), hasStateName(?s, ?tpi), performedIn(?t, ?s), containsIgnoreCase("AL", ?tpi), lessThan(?age, 19) -> AdultPatient(?p)	
.....			
CALIFORNIA	CA	hasTreatmentName(?t, "eyesurgery"), patientRequiresTreatment(?p, "eyesurgery"), hasAge(?p, ?age), patientTreatmentPerformedIn(?p, ?tpi), hasStateName(?s, ?tpi), performedIn(?t, ?s), containsIgnoreCase("CA", ?tpi), greaterThanOrEqual(?age, 18) -> AdultPatient(?p)	hasTreatmentName(?t, "pregnancy"), patientRequiresTreatment(?p, "pregnancy"), patientIsArmedForce(?p, ?iaf), patientHasCourtOrder(?p, ?hco), containsIgnoreCase("F", ?hco), patientIsEmancipatedMinor(?p, ?iem), stringConcat(?v, ?fi, ?ls), containsIgnoreCase("FF-FT-TF", ?v), stringConcat(?v, ?iaf, ?hco), containsIgnoreCase("FF-FT-TT", ?v), containsIgnoreCase("em, F"), containsIgnoreCase("m, F"), patientTreatmentPerformedIn(?p, ?tpi), hasStateName(?s, ?tpi), performedIn(?t, ?s), containsIgnoreCase("CA", ?tpi), lessThan(?age, 16), greaterThanOrEqual(?age, 15) -> MinorPatient(?p)
		hasTreatmentName(?t, "eyesurgery"), patientRequiresTreatment(?p, "eyesurgery"), hasAge(?p, ?age), patientFinancialIndependent(?p, ?fi), patientLivesSeparately(?p, ?ls), patientMarried(?p, ?m), patientIsEmancipatedMinor(?p, ?iem), patientIsArmedForce(?p, ?iaf), patientHasCourtOrder(?p, ?hco), containsIgnoreCase("FF-FT-TF", ?v), stringConcat(?v, ?fi, ?ls), containsIgnoreCase("FF-FT-TT", ?v), containsIgnoreCase("em, F"), containsIgnoreCase("m, F"), patientTreatmentPerformedIn(?p, ?tpi), hasStateName(?s, ?tpi), performedIn(?t, ?s), containsIgnoreCase("CA", ?tpi), lessThan(?age, 16), greaterThanOrEqual(?age, 15) -> MinorPatient(?p)	hasTreatmentName(?t, "pregnancy"), patientRequiresTreatment(?p, "pregnancy"), patientTreatmentPerformedIn(?p, ?tpi), hasStateName(?s, ?tpi), performedIn(?t, ?s), containsIgnoreCase("CA", ?tpi) -> AdultPatient(?p)
.....			
WYOMING	WY	hasTreatmentName(?t, "eyesurgery"), patientRequiresTreatment(?p, "eyesurgery"), hasAge(?p, ?age), patientMarried(?p, ?m), patientDivorced(?p, ?d), patientIsArmedForce(?p, ?iaf), patientIsEmancipatedMinor(?p, ?iem), stringConcat(?v, ?m, ?d, ?iaf, ?iem), containsIgnoreCase(?v, "T"), patientTreatmentPerformedIn(?p, ?tpi), hasStateName(?s, ?tpi), performedIn(?t, ?s), containsIgnoreCase("WY", ?tpi), lessThan(?age, 18) -> AdultPatient(?p)	1. No explicit law

E. Evaluation

Here, we show consequences of our rule base that comply with state consent laws and sub-disciplines regulations. The scenario of a use case is a 15 year-old patient named Kate seeking eye surgery in California. She is not married nor has she done an emancipated minor evaluation. She also does not have a court order of giving medical consent nor is serving in the U.S. Armed Forces. However, she does not live with her parents and manages her own financial affairs. In this situation, what kind of informed consents should be obtained by her care providers? May she provide these consents herself? We derive that Kate is an adult patient according to CA consent laws of patient's maturity. Therefore, she is able to consent by herself, even if her age is under CA's required maturity age.

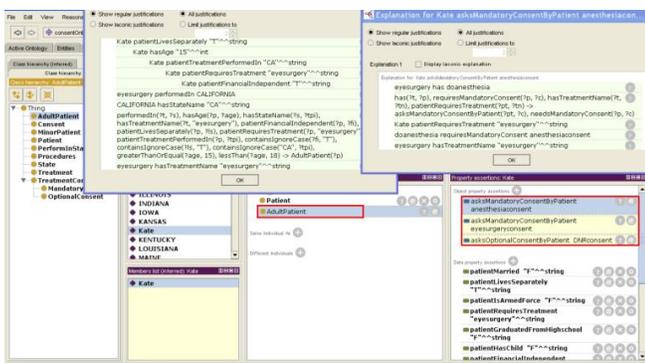
We now show how Pellet generates data properties of an individual of class Patient, here Kate, and object properties of this individual, reasoned with rules to infer the head of rule (see example 1).

Using Pellet, the informed treatment consents retrieved easily and appropriately. The outcome of the proof of patient maturity and explanation is shown in Fig. 2. In this illustration, the left red box exposed that the outcome matches our presuming result. For more details of how Pellet reasons, see the following explanation provided by Protégé.

Explanation for: Kate Type AdultPatient

1. Kate has Age "15"^^ int
2. Kate patientRequiresTreatment "eyesurgery"^^string
3. Kate patientTreatmentPerformedIn "CA"^^string
4. Kate patientFinancialIndependent "T"^^string
5. Kate patientLivesSeparately "T"^^ string
6. eyesurgery hasTreatmentName "eyesurgery"^^string
7. CALIFORNIA hasStateName "CA"^^ string
8. eyesurger performedIn CALIFORNIA
9. performedIn(?t, ?s), hasAge(?p, ?age), hasStateName(?s, ?tpi), hasTreatmentName(?t, "eyesurgery"), patientFinancialIndependent(?p, ?fi), patientLivesSeparately(?p, ?ls), patientRequiresTreatment(?p, "eyesurgery"), patientTreatmentPerformedIn(?p, ?tpi), containsIgnoreCase(?fi, "T"), containsIgnoreCase(?ls, "T"), containsIgnoreCase("CA", ?tpi), greaterThanOrEqual(?age, 15), lessThan(?age, 18)

Fig. 2. Outcome of the proof of patient maturity using Pellet reasoner



In sub-section D above, we reviewed these rules, see Example 1. The input facts of individual patient, Kate, are shown in line 1 ~ line 6 from Kate's data prosperities; line 9 is the rule that used by Pellet to infer the new fact, in other words Kate belongs to adult patient base on her active status based on this particular rule.

Our goals are proposing a novel approach, named Workflow-based EMRs with a consent management component to allow gaining informed treatment consents required by a procedure in a treatment workflow dynamically, and reasoning these consents automatically by using ontologies to ensure those consents comply with consent laws and regulations.

IV. WORKFLOW-BASED EMRS WITH CONSENT MANAGEMENT

To achieve our goals, we proposed a prototype, shown in Fig. 1. We develop a consent management component incepted Workflow-based EMRs which refers back to our previous works.

The existing EMRs lack a mechanism for dynamically obtaining appropriate informed treatment consents and lack a standard way for specifying, updating and checking compliance with governmental consent laws and sub-discipline regulations. Our goal here is to build a novel EMRs by adopting a variety of technologies to address this gap.

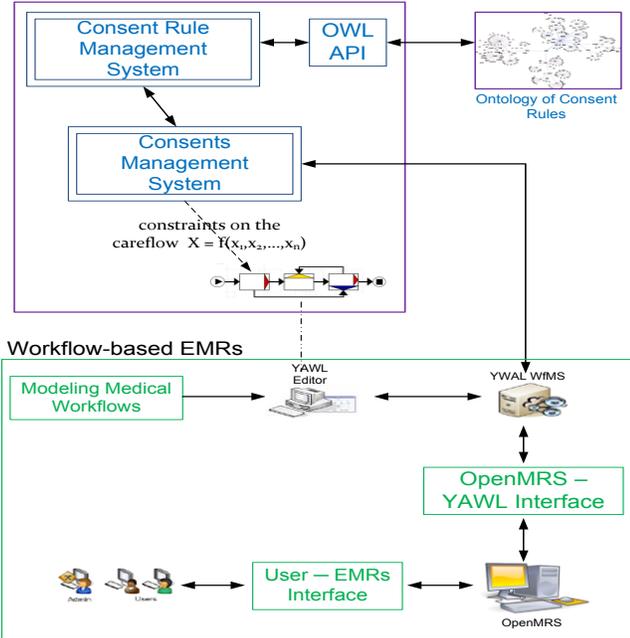
We developed a prototype consent management system on a Workflow-based EMR system. In our system, consents are issued electronically using the EMR interface and enforced using the workflow runtime. Furthermore, those consents can be used to control corresponding medical procedures dynamically. In addition, we use ontology-based knowledge representation and reasoning mechanisms to obtain required informed consents based on each patient's situation and ensure compliance with governmental consent laws and sub-disciplines regulations.

Our consent enforcement system, shown in Fig. 1 consists of (1) User Interface (UI) for EMR Operations; (2) EMR's Runtime System; (3) Workflow Management System -- a runtime system that enforces medical treatment workflow and checks for consents before enabling a workflow; (4) A Consent Management System that ascertains which consents, if any, are missing and must be issued; (5) A Consent Rule Management System -- a system connects to an ontology application and the Consent Service to obtain the appropriate informed consent automatically; and (6) Related Databases. See, the high-level architecture shown in Fig. 3.

Our implementation uses an open source EMR system, OpenMRS [40], and a workflow system YAWL [41]. In our implementation, the EMR user community interacts with the EMR using the well-designed OpenMRS user interfaces. All patient data is stored in OpenMRS' databases. Whenever a treatment procedure (a task to the WfMS) requires a patient's informed consent to move to the next stage, WfMS will call the consent service to retrieve or obtain related consents as a prerequisite to proceeding with the treatment. Patient consents are stored in the OpenMRS' databases as part of their medical records. Consent Management Service is plugged in YAWL as a custom service.

As stated, we enforce medical workflows upon the OpenMRS EMRs by using the YAWL workflow management system. We did so because, first, YAWL workflow system has been used to implement many workflows in industry and academia [42]. Second, YAWL uses a domain independent syntax to specify workflows, and provides an editor and a runtime engine that can enforce workflows specified in YAWL syntax for any applications. Therefore, our models can be audited and verified by third-parties for workflow accuracy. Third, YAWL is open source software. Last, many research projects have recently used YAWL as a workflow-modeling tool. Our medical workflow system is implemented as a loadable module in OpenMRS and incorporates the knowledge of the treatment processes as a YAWL specification. The YAWL workflow engine uses these specifications to provide the caregivers the ability to step through the tasks. In addition, the workflow engine logs every incident into a database creating the audit-able record of the work process provided by

Fig. 3. High level view of workflow based EMRs with consent management



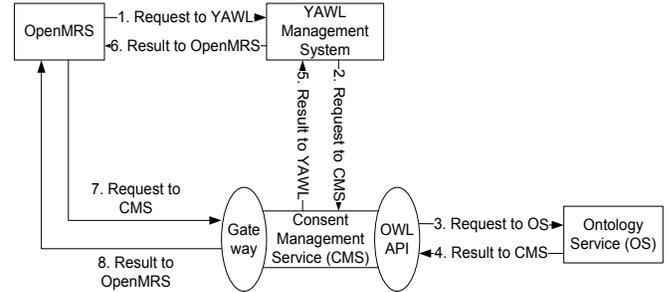
the medical organizations. In another hand, the Consent Management System acts as a customized workflow service in YAWL.

1. *OpenMRS -> YAWL: (Step 1)* - When a caregiver starts a medical treatment procedure in OpenMRS, a “launch case” event request with workflow specification id or name is sent to YAWL engine; YAWL engine enables some work item(s); *If the enabled work item(s) does not request Consent Service, Then (Step 6)* - OpenMRS checks out the enabled work item(s) and executes them.
2. YAWL enables other appropriate work items based on control flow defined in the workflow specification, sends notification to OpenMRS. Then the interactions between YAWL and OpenMRS are repeated. Otherwise,
3. *YAWL -> Consent Management Service (CMS): (Step2)* – If a task needs to check patient’s informed consent, the consent management service is triggered.
4. *CMS -> Ontology Service (OS) (Step 3)*: CMS uses OWL API to connect to the OS with patient’s information and other required consent information. An individual has be created and can be used Pellet to reason appropriate outcomes.
5. *OS -> CMS (Step 4)*: OS returns the results reasoned based on the SWRL rules to CMS.
6. *CMS -> YAWL (Step 5)*: CMS passed results to YAWL, if valid consents have been hold, obtaining consent from patients medical recodes; otherwise, asks OpenMRS (*Step 6*) retrieve appropriate consent forms based on specific treatment task requirements.
7. *OpenMRS -> CMS (Step 7)*: This is additional step

existing only required CMS. Asking what kind of consents should be issued.

8. *OpenMRS -> CMS (Step 8)*: Same as the previous step, this is additional step existing only required CMS. CMS return the answers to OpenMRS. The WfMS decides whether the treatment should continue or be aborted based on the treatment specification and on the patient’s treatment decision.

Fig. 4. Interactions between the system components



Finally, we pay attention to the privacy and security issues, which are important considerations for any EMRs.

Access Control: The medical team as a whole provides the required services to a patient who visits the medical center, from acceptance of a patient to the end of the treatment at the facility. Each team member plays a designated role in providing care with a set of assigned duties that are choreographed with each other, forming workflows. The team together provides the care planned for the patient. We used a role-based access control model to provide confidentiality. Furthermore, enforced informed consent is an access control with more complex rules.

Accountability: To monitor quality of care and consistent with continuous improvement, an EMR system must have auditing capabilities. In our workflow-enforced EMR system with consent management, the quality care team can review both procedures and outcomes from workflow logs and consent logs, which provide an audit trail that satisfies accountability requirements.

V. CONCLUSIONS

Enforcing diverse consent laws in an EMR system is useful for any and all EMR systems, but especially for EMR systems that treat mobile populations, such as military personnel and dependents. We have described an architecture and a prototype system that is based on an open source EMR system, a generic workflow engine and an Ontological rule system. Our system enforces consents for medical treatments, which when deployed will reduce medical malpractice, potential medical treatment errors caused by missing informed consents, and improve the patient-caregiver relationship. The processes of obtaining the consent and including exception processes are also be recorded in the workflow management system, thus becoming available for quality of care audits and reviews.

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