MEDICAL DECISION SUPPORT SYSTEM USING AUGMENTABLE GUIDELINE ENGINE

by

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ABSTRACT

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Increasing life expectancy accompanied by existing growth of wireless infrastructure and ubiquitous computing technologies has given healthcare providers access to vital information within their healthcare networks. Medical decision support systems (MDSS) play an increasingly important role in medical practice by assisting physicians with making clinical decisions. MDSS are interactive computer programs, which are designed to assist physicians and other health professionals with decision making. Currently, the strategies for providing MDSS has failed, in part, because they have not provided a secure, timely access to information that is current, ability to

modify their knowledge base without hard coding them in their system. To eliminate some or all the problem noted above, this paper proposes a new Medical Decision Support Systems called OGU using Augmentable Guideline Engine. The guideline engine is base on the InterMed project's GLIF; InterMed project is a collaboration among medical informatics groups.

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CHAPTER 1

INTRODUCTION

Increasing life expectancy accompanied by the existing growth of ubiquitous computing technologies and wireless infrastructure has given healthcare providers access to vital information anywhere and at anytime within their healthcare networks.

The information needs of physicians and healthcare workers are complex and ever increasing in a world of rapidly expanding medical knowledge and a practice environment where they are required to know and do more with limited resources [1]. Information technology services play a crucial role in exploiting the huge size of medical data involved, to make sense of all this data a medical decision support systems (MDSS) have been promoted as one of the key features of electronic health records most likely to lead to a real transformation in our healthcare system [2]. However, there are also concerns that malfunctioning or inappropriate use of a medical decision support systems could jeopardize the well-being of the a patient; while there have been a few discussions about the ethical issues arising with the use of computer-assisted medical decision making system, there is still no consensus on the ethically appropriate use of medical decision support systems. There are many of ethical issues that needs to be addressed in the creation of medical decision support systems, for example, privacy, security, and validity of the implemented systems, a malfunctioning or misuse pose a great danger to patient safety, physicians could relinquish their own independent

medical judgment to rely solely on medical decision support systems advice, dehumanization of patient care due to the use of computer which could lead to the adverse effects on the physician-patient relationship, increase reliance on medical decision support systems could lead to a degradation of physicians' reasoning skills, and confidentiality and security of the processed patient data [3]. One of the most important issues out of the entire issues list above is the protection of patient privacy and confidentiality. Privacy is central to the doctor-patient relationship. According to the California HealthCare Foundation [31], national poll in January 1999, only a third of U.S. adults say they trust health plans and government programs to maintain confidentiality all or most of the time. One in five American adults believes that a health care provider, insurance plan, government agency, or employer has improperly disclosed personal medical information. Half of these people say it resulted in personal embarrassment or harm [31].

The protection of patient medical records is critical because of the following:

- Medical history may influence their credit ratings.
- Employment opportunities.
- Ability to get medical insurance.
- Capability to get good rates for medical coverage.
- Ability to avoid unwanted marketing.

Patient's medical information is a hot commodity, accord to *The New York Times* the whole exchange of computerized medical information is a $40-billion-dollar industry.

To get a portion of this money, significant amount of companies are targeting potential customers by buying patient's medical records collected from database houses that have purchased lists from doctors, clinics, pharmacies, hospitals, and Health Maintenance Organizations (HMOs). Companies participating in this practice are participating in a gross invasion and a breach of fundamental medical ethical issues. Before the introduction of electronic medical records it used to be that patients could consider a visit with their physician to be an extremely private encounter. They expected that anything told to the physician would not be repeated unless they gave explicit and informed consent. But the definition of informed consent is changing in a very insidious way. There have been numerous stories in the news media about unauthorized access to patient medical record, for example, a Maryland clerk was prosecuted for selling an elderly patient health records to HMO recruiters, and then contacting the patients with a sales pitches; the names, birth dates, Social Security numbers, and disability ratings in some cases of as many as 26.5 million veterans were stolen recently from the home of a Department of Veterans Affairs employee. This theft represents the biggest unauthorized disclosure of Social Security data ever. Information about patient's health and healthcare is perhaps the most sensitive and personal kind of information that is collected and shared, and it deserve the strongest protection under the United States' federal law. In order to deal with all these privacy issues the United States government pass a bill in 1996 call the Health Insurance Probability and Accountability Act (HIPAA), this bill applies to health plan, health care cleaning houses, health care providers; it requires them to maintain reasonable safeguards to ensure the integrity and

confidentiality of patient records and information, protect against threats to the security and unauthorized use or disclosure of information. In making medical decision support system more secure various computer security technologies can be use like encryption (to assure confidentiality of medical records and authentication of identify of viewer of records), authentication (passwords, digital signatures, biometric information), access control (different viewer have different privileges based on need to know), physical security (limitations of network access by laptops), administrative controls / confidentiality policies.

Medical Decision Support Systems (MDSS) play an increasingly important role in medical practice by assisting physicians with making clinical decisions; medical decision support systems (MDSS) are expected to improve the quality of medical care [3]. Medical decision support systems (MDSS) are interactive computer programs, which are designed to assist physicians and other health professionals in applying new information to patient care through the analysis of patient specific medical data in making decisions. A working definition has been proposed by Dr. Robert Hayward of the Centre for Health Evidence; "Medical Decision Support Systems (MDSS) link health observations with health knowledge to influence health choices by clinicians for improved health care" [4]. Many of these systems are used to enhance diagnostic efforts and include computer-based programs such as Dxplain™ that provide extensive differential diagnoses based on clinical information entered by the clinician [14]. Other forms of medical decision support systems, includes antibiotic management programs, anticoagulation dosing calculators, and systems seeking to prevent medical errors and

improve patient safety. Medical decision support systems vary greatly in their complexity, function and application. Although many clinical decision support systems are relatively simple, with no inherently complex internal logic systems. Among the most common forms of support systems are drug-dosing calculators, these are systems that calculate appropriate doses of medications after clinicians input key data (e.g., patient weight, indication for drug). These calculators are especially useful in managing the administration of medications. More complex systems include computerized diagnostic tools that, although labor intensive and requiring extensive patient specific data entry, are useful as an added measure when a patient has a confusing list of symptoms and an unclear diagnosis. Other systems, both simple and complex, may be integrated into the point-of-care and provide accessible reminders to physicians regarding appropriate management based on previously entered data. These systems may be most practical when coupled with electronic medical records. Finally, through their integration with practice guidelines, decision support systems may provide physicians with suggestions for appropriate care, therefore decreasing the likelihood of medical errors. For example, a guideline for the management of community-acquired pneumonia may include a system that, after the input of patient-specific data, would provide a recommendation regarding the appropriateness of patient therapy. A great variety of patient safety issues may be affected by medical decision support systems. Since the systems are typically intercalated at the point-of-care, they are likely to have their greatest effect on problems related to the individual patient. Some of the best studied applications of decision support systems are those that seek to prevent adverse

drug reactions and inappropriate drug dosing as well as those that facilitate the appropriate use of effective preventative measures, such as those for thromboembolic (Formation in a blood vessel of a clot that breaks loose and is carried by the blood stream to plug another vessel) disease [15, 16]. The functionality and effectiveness of medical decision support systems has been evaluated in a number of systematic reviews. These reviews are based on the following system types:

- MDSS in clinical settings
- MDSS that aids in the provision of outpatient preventive care
- The utility of MDSS in medication dosing
- The utility of MDSS in the implementation of practice guidelines.

All the systems were rated on a 10-point scale for quality, outcome measures, and degree of follow-up. The scale assessed the design features of the each system.

Decision support systems may also help ensure a minimum standard for quality of care as part of the implementation of practice guidelines by providing patient-specific recommendations after the input of patient information. This combination of decision support systems and guidelines may be especially effective in conjunction with the use of the electronic medical record.

The history of medical decision support systems back to the early 1950s, these systems were very primitive this is due to fact that in fifties computer architectures were very limited in their performance.

The basic components of a medical decision support systems (MDSS) include a dynamic (medical) knowledge base and an inference mechanism (usually a set of rules

derived from the experts and evidence-based medicine) [4]. It could be based on Expert systems or artificial neural networks or both (Connectionist expert systems) [4]. While the adaptation of large-scale diagnostic systems has been slower than expected, the growing ubiquitous and availability of patient's electronic records and the technical complexity of medical decision support systems (MDSS) has prompted the widespread use of computer-assisted medical decision making. Currently, most medical decision support systems (MDSS) provide decision support for particular therapeutic tasks such as interpreting pulmonary function tests or diagnostic, analyzing electrocardiograms (ECG), or managing the use of anti-infective agents [3]. Medical decision support systems may provide significant benefits in the process of care, preventing medical errors and prompting physicians to provide appropriate preventive care measures. Most studies show no major adverse effects from the use of MDSSs. Although one study demonstrated that they may increase a physician's consultation time (which means the decrease in time spent on direct patient care), others suggest that they may improve efficiency, especially in terms of data recall. The usefulness and efficiency of such systems is clearly dependent on the programmed logic, therefore Medical decision support systems must be developed with extremely high quality control standards. A system that provides erroneous information and guidance, for example, has the potential to cause broad harmful impact. Medical decision support systems (MDSS) can help physicians to organize, store, and apply the exploding amount of medical knowledge in a proper way. Table 1 shows functions of medical decision support systems developed

for the following medical purposes: alerting, reminding, critiquing, interpreting, predicting, diagnosing, assisting, and suggesting [17].

Table 1 Some functions of medical decision support systems (MDSS) [17]

Function	Example
Alerting	Highlighting out-of-range laboratory value.
Reminding	Reminding the physician to schedule a mammogram.
Critiquing	Rejecting an electronic order.
Interpreting	Interpreting the electrocardiogram.
Predicting	Predicting risk of mortality from a severity of illness score.
Diagnosing	List a differential diagnosis for a patient with chest pain.
Assisting	Tailoring the antibiotic choices for liver transplantation and renal failure.
Suggesting	Generating suggestions for adjusting the mechanical ventilator.

Medical decision support system are expected to improve the quality of care by providing more accurate, effective, and reliable diagnoses and treatments, and by avoiding pitfalls due to physicians' insufficient knowledge. Evaluation studies demonstrate that medical decision support systems (MDSS) can have a positive effect on clinician performance and patient outcomes and can decrease healthcare costs by providing a more specific and faster diagnosis [3]. Currently, the strategies for providing Medical decision support systems (MDSS) have failed, in part, because they have not provided a secure, timely and easy access to information that is, current, integrated with other information like the physician's workflow, and relevant questions that occur during the patient visit; plus, the performance of medical decision support

systems (MDSS) is subject to some important limitations for example when they are used at or beyond the border of their intended scope [1, 2]. Looking at all the currently available medical decision support systems (MDSS) none of they have a proven and adequate method to handle the privacy and security issues on accessing of patient's vital information, modification of their knowledge base without hard coding them in their system. Eliminating some or all the problem noted above, this paper proposes a Medical Decision Support Systems using Augmentable Guideline Engine. The guideline engine is base on the InterMed Project's GLIF; interMed project is a collaboration among medical informatics groups at Stanford, Harvard, McGill, and Columbia universities, supported by the National Library of Medicine, developed a representation for sharable clinical guideline. The initial version of the representation was known as the Guideline Interchange Format (GLIF), was published in 1998 and since then there has been improvement to GLIF, a model for representational language for sharable computer-interpretable guidelines. Guideline Interchange Format (GLIF) will be use in the translation of clinical practice guidelines into an electronically encoded form such that they may be modify (change rule) and shared among various clinical institutions and settings. Our guideline engine uses GLIF because its account for human communication, validation of logical consistency and completeness (not correctness) and incorporation into institutional information system environments.

The remainder of this paper is organized as follows. Section 2 gives a background and overview of historical work in the area of medical decision support system (MDSS). Section 3 formulate the problem and presents our technique called

OGU using augmentable guideline engine. Section 4 describes our analysis of the solution. Finally, Section 5 presents concluding remarks and direction for future work.

CHAPTER 2

RELATED WORK

Medical decision support systems are increasingly being used to support clinicians' decision making, these systems are intended to improve the quality of patient care, reduce variations in quality of care, and reduce costs. In order to effectively discuss some of these systems; first, we must talk about the methodologies / technologies beside them then discuss some of the currently available systems.

2.1 Medical Decision Support Systems Technologies

Since the pre-historic time, human beings have attempted to explain natural phenomena using models. In the past four decades, a new breed of modeler, the medical informatician (people who develop and evaluate new methodologies for acquiring, representing, processing, and managing knowledge and data related to health, health care, and the biomedical sciences). As all aspects of science and society become increasingly information intensive, the need to understand, to apply, and to create new methods for modeling, managing, and acquiring information has never been greater. Medical informatics is the intersection of information science, medicine and health care. It deals with the resources, devices and methods required to optimize the acquisition, storage, retrieval and use of information in health and biomedicine. Health informatics tools include not only computers but also clinical guidelines, formal medical terminologies, and information and communication systems.

Medical informatician has developed and proliferated a new kind of model, the Medical Decision Support Systems (MDSS) [5]. The general diagnostic decisions support systems are designed to assist clinicians develop a differential diagnosis list on the basis of patient-specific signs and symptoms. They use probabilistic or rules-based inference to compare patient information with a knowledge base to generate a differential diagnosis list that is typically ranked in descending order of likelihood and some of the systems provide additional information about the suspected diseases and suggest appropriate diagnostic tests if clinicians choose to pursue these diagnoses [6]. The majority of important concepts related to current MDSS were developed and presented in the literature prior to 1976, in this literatures date back to 1979, review of approaches used by early medical decision support systems identified the following classes of MDSS [5]:

- Clinical algorithms.
- Clinical databanks (that include analytic functions)
- Mathematical pathophysiologic (the scientific study of functional changes associated with or resulting from disease or injury) models
- Pattern-recognition systems
- Bayesian statistical systems

Clinical algorithms is incorporating a method of using medical texts such as the Oxford Text Book of Medicine and hundreds of medical journal articles into a

differential diagnosis decision tree model to computer diagnose an illness through the symptom presented by a patient.

Clinical databanks are mainly use to gain information about individual patients for clinical intervention. They are also use for accumulation of carefully defined data collected in a uniform manner over a long period of time, which can be used for studies concerning the natural history of disease, prognosis, disease classification, diagnostic criteria, and cost-benefit analysis [18].

A mathematical pathophysiologic model deals the application of mathematical inference to the study of functional changes associated with disease or injury.

Pattern-recognition system is a sub-topic of machine learning which refer to a system that is capable of autonomous acquisition and integration of knowledge. Pattern-recognition systems are capacity to learn from experience, analytical observation, and other means, results in a system that can continuously self-improve and thereby offer increased efficiency and effectiveness. It is also a branch of artificial intelligence that is concern with the description of observations.

Bayesian statistical system deals with concept of explaining how to change existing knowledge in the presence of new data. It allows for the combination of new data with existing knowledge or expertise. On this system inferences are always conditional, conditioned on prior information.

Implementation of many complex algorithms involves the constant tradeoffs between memory and CPU cycles; the same is true for the development of real-world diagnostic systems, a diagnosis system involves a constant balancing of theory and

ability to build, and maintain adequate medical databases or knowledge bases, and ability to create applications that respond to users' needs and intend in acceptably time periods. In theory, we have understanding in developing applications that take into consideration the stages of symptoms, the levels of uncertainty in patients thought of physicians finding, the seriousness of each illness being consideration, and the time courses of illnesses. However, it is not yet feasible to build such broad-based applications for patient care.

To help improve their imperfect knowledge of how they solve diagnostic problems, physicians use both logic as in set theory, Boolean algebra and probabilistic reasoning as in Bayes' rules (the probability of an event happening is based on the previous event that happened). These concepts were essential components of medical reasoning, therefore, earlier medical decision support system (MDSS) project were based on either logical systems or probabilistic systems.

Logical systems are based on distinguish among mutually exclusive alternatives, and it played an important role in MDSS. Currently, such systems are applicable to narrow domains, especially those where it is fairly certain that only one disorder is present. Ideal application areas are those where detailed knowledge of the study of the biological and physical manifestations of disease as they correlate with the underlying abnormalities and physiological disturbances, or extensive data that makes it possible to identify parameters useful for separating diagnostic sets into nonintersecting subsets based on specific characteristics. The problem with logic systems is that the world of medical decision making often contains many shades of gray, rather than simple black

and white issues that can be decided through answering critical questions for example, a hospitalized patient may experience nausea and vomiting for a variety of interrelated reasons, including anxiety, underlying illnesses, and side effects of medications, so the search for a single answer in many situations may be futile [5].

The second method that physicians use to improve their imperfect knowledge of how they solve diagnostic problems is probabilistic systems, which is base on the concept of Bayes' Rule. Bayes' Rule is a subjective (applicable to the degree to which a person believes a proposition) probability, involves the use of Bayes' theorem which states that if A and B are events and P [B] (probability of event B) > 0, then

$$P [A|B] = (P [A]) (P [B|A]) / (P [B])$$

Where:

P [A|B] is probability of event A occurring given event B has occurred.

P [B|A] is probability of event B given A.

P [A] is the prior probability of A.

P [B] is the prior probability of B.

The outcome of Bayes' rule depends on the available data that is the same data can produce different results depending on available data.

The first practical Bayesian system was also the first medical decision support system project to be utilized at widespread clinical sites, it was a diagnosis system, which employed Bayesian methods for decision making in diagnostic radiology. The large amount of research surrounding current work on Bayesian belief networks for medical diagnosis systems have played and will continue to play an important role in

medical decision support system development. In medical diagnosis, it is sometimes advantageous to reason categorically (causally), and other times to reason probabilistically. The dichotomy between logical (categorical) and probabilistic (actuarial) styles of reasoning continues to be enigmatic for current system developers [5].

The third alternative to logical and probabilistic reasoning combines features of both, but retains a fundamental difference. That alternative is heuristic reasoning. Heuristic reasoning exploit the information processing structure of the reasoning system (in the case of psychological heuristics, the human mind), and the structure of the environment to produce reasonable answers when knowledge and/or computational resources for finding the perfect correct answer might not exist [19]. Heuristics reasoning is also an approach to understanding diagnostic reasoning. Although heuristics allow for faster processing of information than analytic methods, they can lead to errors because not all information is considered. The HEME program for diagnosis for hematologic (the study of blood, blood-forming organs, and blood diseases) disorders was one of the earliest, systems to employ heuristics reasoning, and also one of the first systems to use, in effect, criterion tables for diagnosis of disease states. Programs that heuristically match terminology from stored descriptions of disease states to lexical descriptions of patient cases are similar conceptually to HEME, a diagnosis program for hematologic disorders [5].

Finally, a method that has not be mention is rule-based systems. Rule-based system is also known as expert system, it is the simplest form of artificial intelligence.

Rule-based systems automate problem-solving know-how, provides a means for capturing and refining human expertise, it constitute the best currently available means for codifying the problem-solving know-how of human experts [20]. Although many different techniques have emerged for organizing collections of rules into automated experts, all rule-based system (RBSs) share certain key properties [20]:

- They incorporate practical human knowledge in conditional if-then rules,
- Their skill increases at a rate proportional to the enlargement of their knowledge bases,
- They can solve a wide range of possibly complex problems by selecting relevant rules and then combining the results in appropriate ways,
- They adaptively determine the best sequence of rules to execute, and
- They explain their conclusions by retracing their actual lines of reasoning and translating the logic of each rule employed into natural language.

Rule-base systems have their own application programming interfaces (APIs) called JESS, it was developed entirely in Sun Microsystems‘ Java language by Ernest Friedman-Hill at Sandia National Laboratories in Livermore, CA. Rule-based systems are generally used in applications such as mortgages, credit card authorization, fraud detection, e-commerce, and personalization. Because the actions of the rule-based system tend to be hidden from view, people tend not to realize just how extensively they are used.

A large number of rule-based medical decision support systems have been developed over the years, but most rule-based MDDS systems have been devoted to narrow application areas, due to the extreme complexity of maintaining rule-based systems with more than a few thousand rules, an example of a recently developed rule-based system in a focused domain is TRAUMAID [5], a system for diagnosis and treatment of penetrating injuries to the chest or abdomen. Another application of the rule based system is in medical record systems that incorporate data-driven warning and reminder systems; it uses rules to diagnose conditions that trigger the reminders. Table 2, below is a category of MDSS.

Table 2 Categories of medical decision support systems (MDSS).

Category	Description
General MDSS with Broad Application Domain	Mainly diagnosis applications like forensic diagnosis, radiologic diagnosis, psychiatric diagnosis, orthodontic diagnosis.
MDSS with Intermediate-Scope Application Domain	Analysis applications i.e. ECG (Electrocardiogram) interpretation, analysis of EEG (Electroencephalogram) tracings, analysis of gait disorders.
MDSS with Narrow Application Domain	Typical medical testing applications e.g. perimetry (visual) testing, heart attach detection, optokinetic (eye movement) testing.

2.2 Available Medical Decision Support Systems

There has been a lot of work done in medical decision support systems, the conceptual basis for MDSS construction developed during the 1950s and 1960s, leading to exploratory and innovative implementations in the 1970s. Evolutions in medical

decision support systems during the 1980s and 1990s were due to the following four factors:

- Changes in hardware platforms and user interfaces.
- Philosophical changes in the perceived role of Medical decision support systems.
- New models for diagnostic decision support.
- Through understanding of how to evaluate Medical decision support systems.

Like any other technology, the personal computer made it possible for application developers to disseminate medical decision support systems in a cost-effective manner to a large user community due to it invention, ubiquitous and evolution.

Desktop computers in the office and at home replaced limited access to mainframe computers via dial-up modems or via direct lines. The personal computer platform also encouraged development of new, sophisticated graphic user interfaces for medical decision support systems. Better evaluations from a broad-based audience allowed developers to evolve systems in response to users' feedback. Availability of standard microcomputer platforms allowed software developers to target common machines and computing environments, rather than developing exotic hardware and software prototypes on one-of-a-kind development, platforms that were less likely to appeal to health care workers in the field [5]. Medical end-users can collect a series of programs that run on a single machine, helping users to avoid having to purchase a machine just to run a single software program, no matter how useful the single package is. In order to enable data exchange among local and remote programs or machines, it

is necessary to have a method that facilitates accurate and reliable transfer of information among systems that have different internal data (format) dictionaries. Working to make this possible is the United States National Library of Medicine Unified Medical Language System project, which started in 1987; continues through the present time, represents one such effort [5]. Table 3, below are list of currently available Medical decision support systems [6].

Table 3 Currently available medical decision support systems [6].

System Name	Purpose
Clinical decision support system for detection and respiratory isolation of tuberculosis patients	To automate the detection and respiratory isolation of patients with positive cultures and chest x-rays suspicious for TB.
Columbia-Presbyterian Medical Center Natural Language Processor	To automate the identification of 6 pulmonary diseases (including pneumonia) through analysis of radiology reports.
Computer Program for Diagnosing and Teaching Geographic Medicine	To provide a differential diagnosis of infectious diseases matched to 22 clinical parameters for a patient; also to provide general information about infectious diseases, anti-infective agents, and vaccines.
DERMIS	To provide a differential diagnosis of skin lesions.

Table 3 - Continued

DXplain	A decision support system which uses a set of clinical findings (signs, symptoms, laboratory data) to produce a ranked list of diagnoses which might explain (or be associated with) the clinical manifestations. DXplain provides justification for why each of these diseases might be considered, suggests what further clinical information would be useful to collect for each disease, and lists what clinical manifestations, if any, would be unusual or atypical for each of the specific diseases.
Fuzzy logic program to predict source of bacterial infection	To use age, blood type, gender, and race to predict the cause of bacterial infections.
Global Infectious Disease and Epidemiology Network (GIDEON)	To provide differential diagnoses for patients with disease of infectious etiology. All potential bioterrorism agents as specified by CDC are included in the GIDEON knowledge base.
Iliad (and Medical HouseCall which is a system for consumers derived from Iliad)	To provide a differential diagnosis based on clinician-entered signs and symptoms. The knowledge base is focused in internal medicine and was last updated in 1997.
Neural Network for Diagnosis Tuberculosis	To predict active pulmonary TB (using clinical and radiographic information) so that patients may be appropriately isolated at the time of admission.
PNEUMON-IA	To diagnose community-acquired pneumonia from clinical; radiologic and laboratory data.

Table 3 - Continued

Quick Medical Reference (QMR)	QMR is a diagnostic decision-support system with a knowledge base of diseases, diagnoses, findings, disease associations and lab information. With information from the primary medical literature on almost 700 diseases and more than 5,000 symptoms, signs, and labs, Iliad can suggest relevant diagnoses, give advise regarding cost-effective workup strategies, and explain relationships of findings to diseases.
SymText	To analyze radiology reports for specific clinical concepts such as identifying patients with pneumonia.
Texas Infectious Disease Diagnostic Decision Support System	To provide a weighted differential diagnosis based on manually entered patient information.
University of Chicago – Artificial Neural Network for Interstitial Disease	To help radiologists differentiate among 11 interstitial lung diseases by using clinical parameters and radiographic findings to develop a differential diagnosis.
University of Chicago – Computer Aided Diagnosis of Interstitial Lung Disease	To aid in the detection of interstitial lung disease in digitized chest radiographs.
VisualDx	Is an image-based software system that serves as a reference to support diagnosis and treatment.
TheraDoc, Inc.™	Is a medical informatics company that designs, markets and implements expert systems for clinical decision support.
HDP, the Heart Disease Program The Heart Disease Program (formerly known as the Heart Failure Program)	Is a program to assist physicians with the diagnosis of cardiovascular disease.

Table 3 - Continued

PRODIGY (Prescribing RatiOnally with Decision Support In General Practice studY)	Is a major initiative in the United Kingdom to develop and evaluate a computerised prescribing decision support system for UK General Practice. PRODIGY is based at the Sowerby Centre for Health Informatics at Newcastle (SCHIN) and is funded by the NHS Executive.
DiagnosisPro	The database now has 9,000 disease/drug terms and 16,000 attributes (symptoms, signs, lab, X - Ray findings) -- - linked with 120,000 relationships. Suggested treatment options are now included, as well.
Problem Knowledge Couplers	Problem Knowledge Couplers are data capture and clinical guidance software tools that provide decision and management support to clinicians.

All the above system contributes to the goal of medicine by preventing or treating diseases, but they all do it differently. All these systems not only contribute to the goal of medicine, but also improve the quality or efficiency of healthcare delivery [3]. Very few studies has been done to address the cost of development and implementation of medical decision support systems, because majority of these systems are computer based they require significant hardware and many of them are intergrated with electronic medical records systems which are not in universal use. The frequent updating of the system software is very expensive. The most of these systems have been around since the early 1980s, the most popular of these systems is DXplain, it provides extensive differential diagnoses based on the clinical information entered by

the clinician. DXplain was developed at the Laboratory of computer science at the Massachusetts General Hospital; it accept a set of clinical finding (signs, symptoms) as input to produce a ranked list of diagnoses, which it provides justification for why each of the diagnoses should be considered. DXplain has been around for over 18 years, development began in 1984, and the first version, with information on approximately 500 diseases was released in 1986 [21]. DXplain system uses an interactive format to collect clinical information and makes use of a modified form of Bayesian logic to derive clinical interpretations. The system has been used by tens of thousands of physicians and medical students since its original release, both as a stand-alone version (no longer supported) and over the Internet [21].

Some of the mention medical decision support systems use different type of representation format for sharable computer-interpretable clinical practice guidelines including Guideline Interchange Format (GLIF). Next, we will talk about these representations.

2.3 Guideline Interchange Format (GLIF)

Computer based approaches to the representation of clinical practice guidelines are potential tools for providing opportunity to improve both the quality and efficiency of treatment by physicians through enabling decision support at the point of care [8]. Several technologies including the internet have increased the possibilities of the distribution of clinical guideline to physicians. This widespread distribution can allow for different medical institution across the globe to share and use a common standard of clinical guideline. For this to happened, it is critical that these guideline be encoded in a

common representation language that will be share electronically, such language must be complete, that is, it must avoid ambiguity in its representation of medical concepts and procedure if it was to achieve sharability. Such language is the Guideline Interchange Format (GLIF); it is a language for the structured representation of sharable computer-interpretable guidelines. It was developed to help bring about the facilitation of sharing clinical guidelines. See figure 1 for high level view of GLIF.

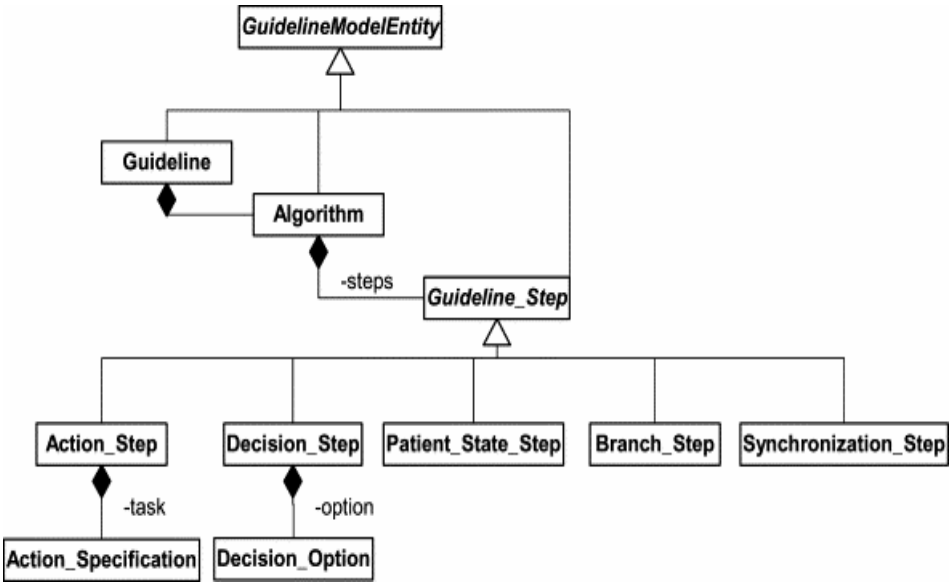


Figure 1 A high level view of the major classes in GLIF. The lines between classes denote relationships: a diamond-shape arrowhead indicates an aggregation or containment relationship, and a triangle shape indicates a generalization relationship.

There are several models to create computer-interpretable clinical guidelines that enable decision support during clinical encounter like Asbru, PROforma, PRODIGY, PRESTIGE, EON and GUIDE.

Asbru [22] is being collaboratively developed at Ben Gurion University and the Vienna University of Technology. It is a time-oriented, intention-based, skeletal-plan

specification language that is used to represent clinical protocols. Skeletal plans capture the essence of a procedure but leave room for execution-time flexibility in the achievement of particular intentions. Asbru's developers have enriched skeletal plans by characterizing plan attributes such as intentions, conditions, and effects; adding a rich set of ordering of plans; and defining temporal dimensions of states and plans. Uncertainty in temporal scope and parameters can be expressed by bounding intervals [22].

PRO*forma* [22] was developed at the Advanced Computation Laboratory of Cancer Research, UK. It combines logic programming and object-oriented modeling and is formally grounded in the R^2L Language. One aim of the PRO*forma* project is to explore the expressiveness of a deliberately minimal set of modeling constructs. PRO*forma* supports four tasks: actions, compound plans, decisions, and enquiries. All tasks share attributes describing goals, control flow, preconditions, and postconditions. The simple task ontology should make it easier to demonstrate soundness and to teach the language to encoders [22]. The PROforma model assists patient care through active decision support and workflow management by representing guidelines as constraint satisfaction graphs, where the nodes of the graph represent tasks that can include actions, decision, enquiries or complex plans [9].

PRODIGY was developed at the University of Newcastle upon Tyne. The PRODIGY on the other hand is a model that focuses on patient scenarios that drive decision-making and structures guidelines as a set of choices for the physician which have to be made between alternative actions [10]. It provides support for chronic

disease management in primary care [22]. The PRODIGY project's aim is to produce the simplest, most readily comprehensible model necessary to represent this class of guidelines [22].

The PRESTIGE uses a declarative approach to representing knowledge about the healthcare enterprise, the patient health record, and the protocol [11].

EON [22] was developed at Stanford University and provides a suite of models and software components for creating guideline-based applications. It views the guideline model as the core of an extensible set of models, such as a model for performing temporal abstractions. EON uses a task-based approach to define decision-support services that can be implemented using alternative techniques. Its guideline execution server uses formalized clinical guidelines and patient data to generate situation-specific recommendations. A temporal data mediator supports queries involving temporal abstractions and temporal relationships. A third component provides explanation services for other components [22]. The EON guideline model uses a combination of modeling primitives, such as various decision-making mechanisms, flow of control constructs, actions and activities, and a distinction between the normal case and its exceptions [12].

GUIDE [22] is part of a guideline modeling and execution framework being developed at the University of Pavia. It supports:

(1) Integrating modeled guidelines into organizational workflows.

(2) Using decision-analytical models such as decision trees and influence diagrams.

(3) Simulating guideline implementation in terms of Petri nets.

GUIDE considers issues such as patient data, the implementing facility's organizational structure, and resource allocation [22].

As mentioned earlier GLIF is a structured representation language of guideline that was created by the InterMed Collaboratory. The goal of the GLIF specification is to provide a representation for guidelines that is [13]:

- Precise and unambiguous.
- Human-readable.
- Computable, in the sense that the logic and sequence in guidelines specified in GLIF can be interpreted by computer.
- Adaptable to different clinical information standards, thus enabling guideline sharing.

The original GLIF specification was published in 1998, GLIF version 2.0 (GLIF2), it consists of two parts: the GLIF object model and the GLIF syntax. The GLIF model was published in Interface Definition Language (IDL); it allowed the specification of the guideline as a flowchart of ordered steps. These steps represented clinical decision and action steps. To model concurrency, branch and synchronization steps were used. GLIF's guideline class also specified maintenance information (author, status, modification date, and version), the intention of the guideline, eligibility criteria, and didactics [13]. A separate language was created for the GLIF guideline instance syntax; this language specified the structure of the text files that contained GLIF encoded guidelines. These files were used for sharing. GLIF2 has been the basis for

several implementations of guideline-based applications, including one in Brigham and Women's Hospital's BICS information system, and web-based applications for driving clinical consultations [13]. However, GLIF2 has certain deficiencies that limit its usability. These deficiencies include integrating GLIF2 guidelines with heterogeneous clinical systems, lack of ability to specify how to structure important attributes of guideline steps, and GLIF2's limited set of low-level constructs. Version 3.0 of GLIF (GLIF3) was introduced in order to handle these deficiencies. GLIF3 enables guideline specification at three levels: Conceptual GLIF flowchart, Computable/Parsable specification and an implementable specification, they constitute the three levels of abstraction.

Conceptual level: This level is represented as flowcharts (See Figure 2) that can be used for browsing, through guideline viewing programs.

Computable level: At this level, expression syntax, definitions of patient data items and clinical actions, and flow of the algorithm are specified. This level may be verified for logical consistency and completeness.

Implementable level: At this level, guideline is ready for incorporation into any independent institutional information system environments.

GLIF3 is intended to thoroughly support specification of guidelines that differ in their medical purposes (e.g. screening, disease management); their intended uses (patient management, education, reference); their intended uses (e.g. physician, patient); and their place of use (e.g. ICU, out of hospital).

All these guideline model has representation primitives (see table 3) that constitute the basic components of a guideline representation model; these primitives are used to represent specific clinical tasks. These primitives are categories into actions and decisions according to the type of tasks they intended to represent. Primitives are also used to represent intermediate state of a specific context during the application of clinical practice guidelines. These intermediate states could be either patient states that describe the clinical status of a patient, or execution states that describe the situation of a guideline implementation system [24].

An *action* is a clinical or administrative task that is recommended to perform, maintain, or avoid during the process of guideline application, e.g., recommendation of a medication or invocation of another guideline [24]. All the guideline models mention in this paper support the representation of actions.

A *decision* is a selection from a set of alternatives based on predefined criteria in a guideline, e.g., selection of a lab test from a set of potentials. It is also a way to represent the process of medical decision making [24]. All the guideline models mention in this paper support the representation of actions.

A *patient state* in the context of a guideline is a reification of a treated individual's clinical status based on the actions that have been performed and the decisions that have been made. For example, the description of a patient who has already received the first dose of the influenza vaccine and is eligible for the second dose as in the state of "eligible for the second dose of influenza vaccine" is a patient state [24].

An *execution state* is a description of a guideline implementation system based on the stage of a task, such as the action and decision defined previously, during the process of guideline execution. For example, the description of a guideline system as ready for execution of the task "recommend the second dose of influenza vaccine" when a patient has already received the first dose of the influenza vaccine and is eligible for the second dose is an execution state [24]. Table 4 shows the representation primitives for actions, decisions, patient states, and execution states in each guideline representation models.

Table 4 Representation primitives [24].

Guideline models	Actions	Decision	Patient states	Execution states
Asbru	Plan	Condition, preference	Temporal patterns	Plan state
EON	Action, activity	Decision	Scenario, activity state	Not in the guideline representation model
GLIF	Action step	Decision step	Patient state step	Not in the guideline representation model
GUIDE	Task, wait, monitor	Decision	Implicit in Petri Net	NA
PRESTIGE	Protocol	State transition	NA	Procedure state
PRODIGY	Action, activity	Decision	Scenario	NA
PROforma	Action, enquiry	Decision	NA	Task State

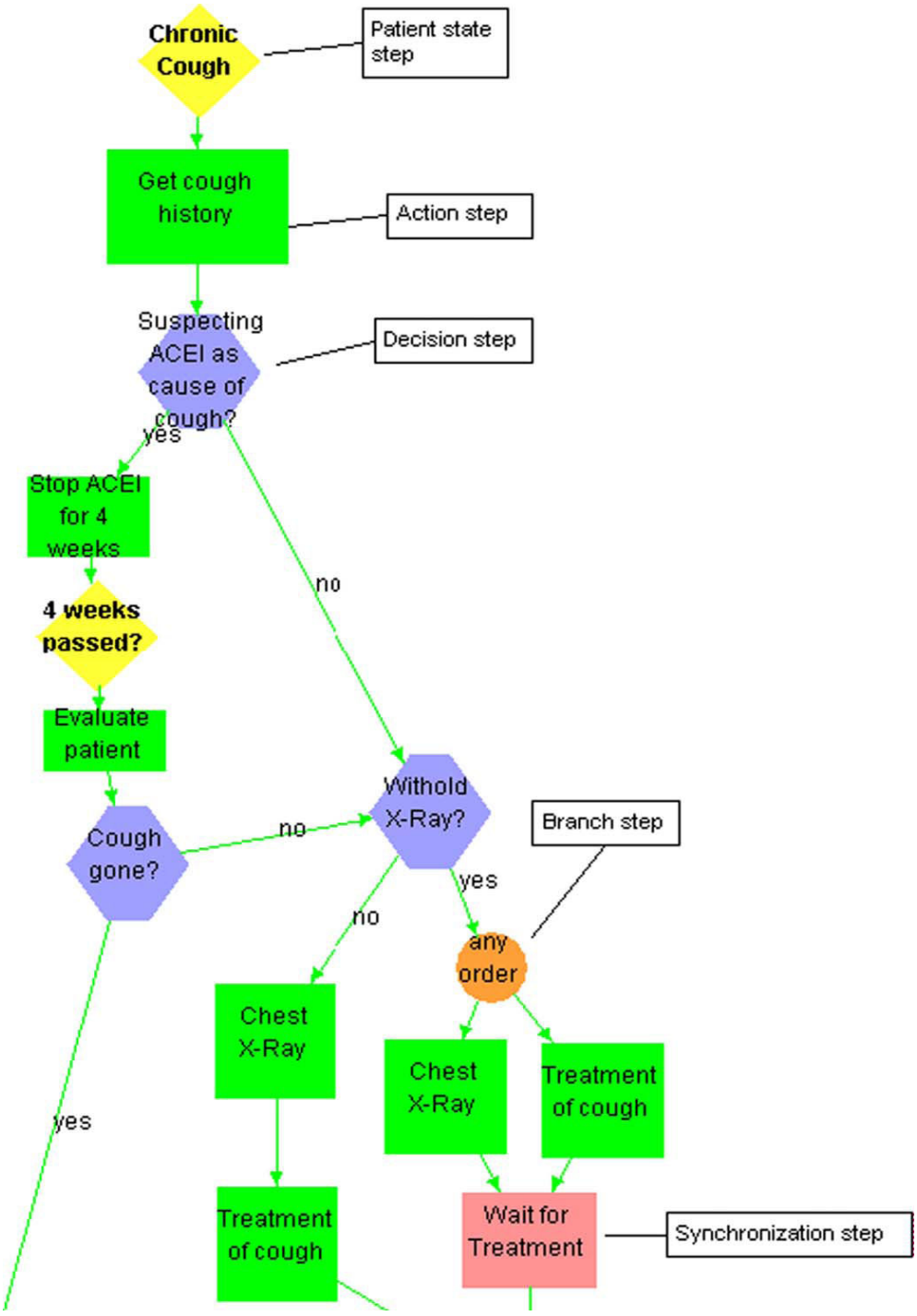


Figure 2 Conceptual flowchart specification of stable angina guideline.

CHAPTER 3

SOLUTION APPROACHES

The emerging of information technologies in health care, such as computerized patient record systems has make security of patient vital electronic record a major issue because of the lack adequate confidentiality of the individual records being managed electronically, for example, according to the *LA Times*, roughly 150 people (from doctors and nurses to technicians and billing clerks) have access to at least part of a patient's records during a hospitalization, and 600,000 payers, providers and other entities that handle providers' billing data have some access also [7]. Open network technology like the internet increases the possible of patient data interception. Privacy is not the only issues facing current medical decision support systems; lack of ability to learn from clinical trials is another problem. This paper proposes an approach to eliminate these problems. Our approach toward improving medical decision support systems is called OGU using augmentable guideline engine, see figure 3 below. This approach is explained thoroughly next.

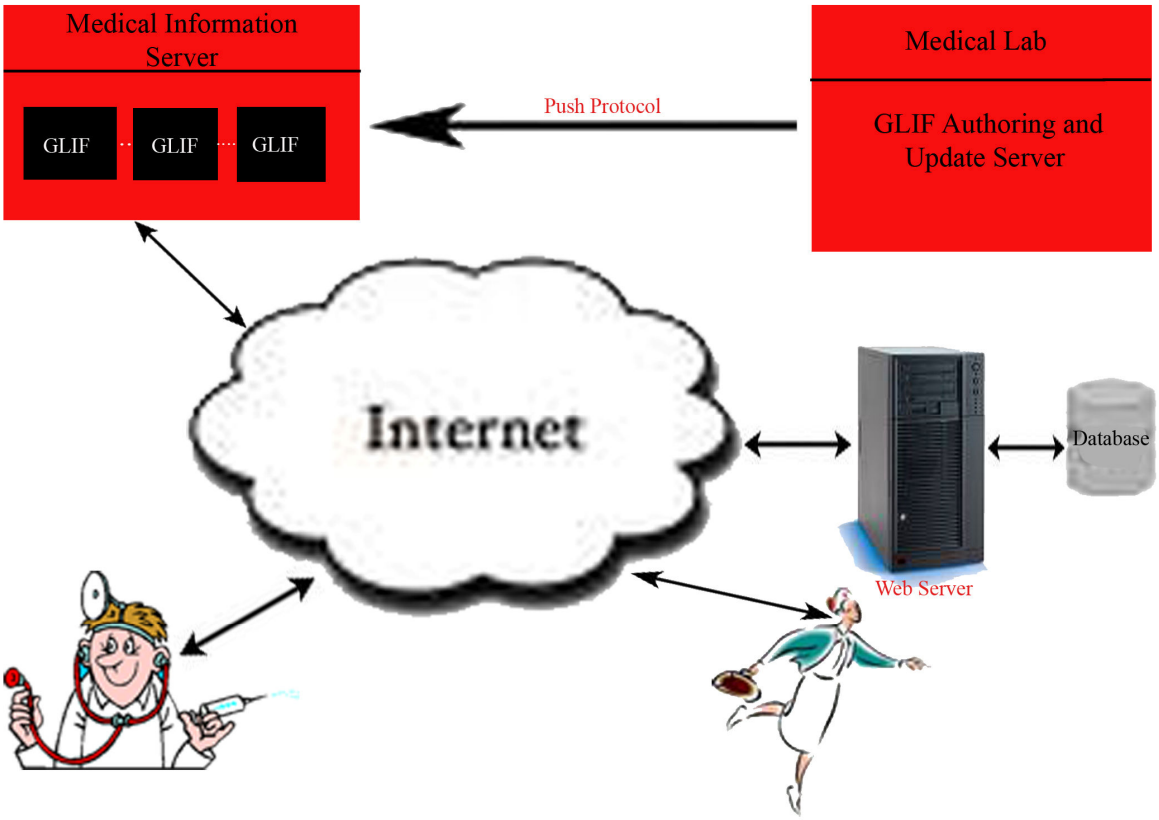
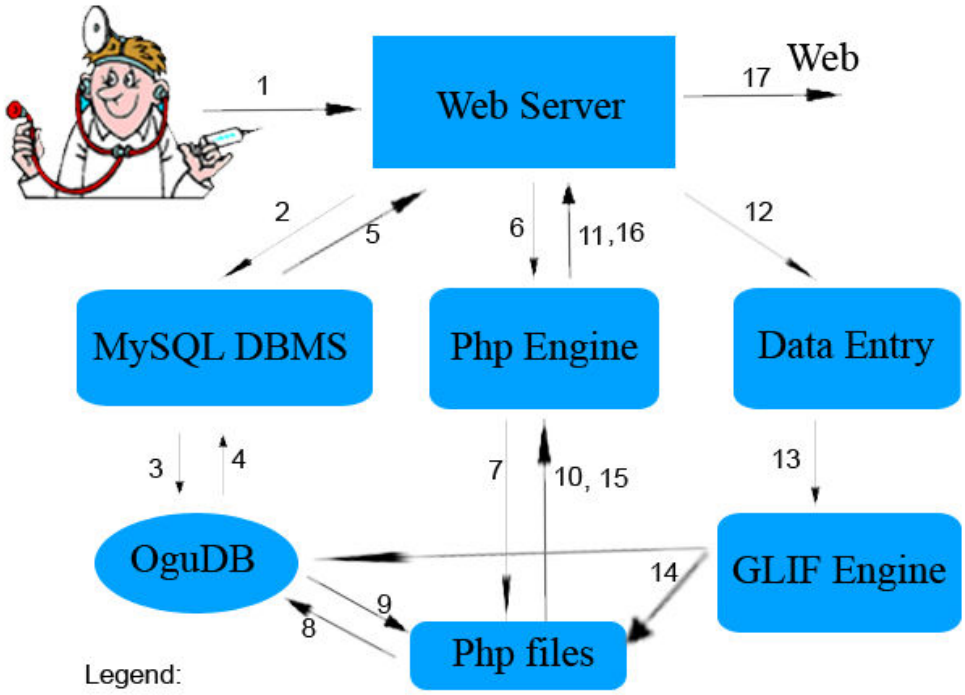


Figure 3 Overview of OGU using augmentable guideline engine.

3.1 Ogu Using Augmentable Guideline Engine

OGU using augmentable guideline engine is a medical decision support system that is designed to assist physicians and other health professionals in applying new information to patient care through the analysis of patient specific medical data in making decisions. It provides: (1) decision support assistance to physicians as a part of physician workflow, (2) decision support during patient care encounter (during diagnosis and treatment) (3) treatment based on well established clinical guideline, (4) augmentable clinical guideline, (5) drug allergic reaction monitoring, (6) monitoring of

drug to drug interactions, (7) drug dosage control based on patient age, and (8) secure access to patient's record. Figure 4 below, show the architectural layout of OGU using augmentable guideline engine.



Legend:

1: Login
2: Validate User
3: Checking DB for User
4: Result of DB Check
5: Pass check Result to Server (Access granted or Denied)
6: User Page based on Profile
7: Dynamic page generation
8: Get User Content
9: Receive User Content
10: Pass Content for Display
11: Pass Content to Server
12: Symptoms / Data Entry
13: Pass User Entry to GLIF Engine for Decision
14: Pass Decision
15: Dynamic page generation based on Decision
16: Pass GLIF Decision to Server
17: Dsiplay Decision on browser

Figure 4 Architectural Layout of OGU using Augmentable Guideline Engine

Our technique identifies that is it critical to have an augmentable guideline so that, the propose medical decision support system can quickly learn from clinical trials that can make a different in saving lives. GLIF version 3 was chosen as the model for our guideline because it stresses the importance of sharing guidelines among different institutions and software systems and because it tries to build on the most useful features of other guideline models and to incorporate standards that are used in health care.

The technique is divided into two parts: (1) Patient Management system, (2) Guideline Engine.

The patient management system provides two important aspect of the overall system: it facilitates user {admin, doctor, nurse} account management and maintenance of patient's virtual Medical Record (vMR). The user account management provides secure access to the entire system (see Figure 5), creation of new account for new users (see Figure 6), and also it allows each patient to have their own physician that they encounter; and it gives the following access to users:

- Admin privileges to add physicians, nurses.
- It gives the physician privileges to add nurses and patients.
- It gives the nurse privileges to add patients.

Figure 5 Login screen in the system.

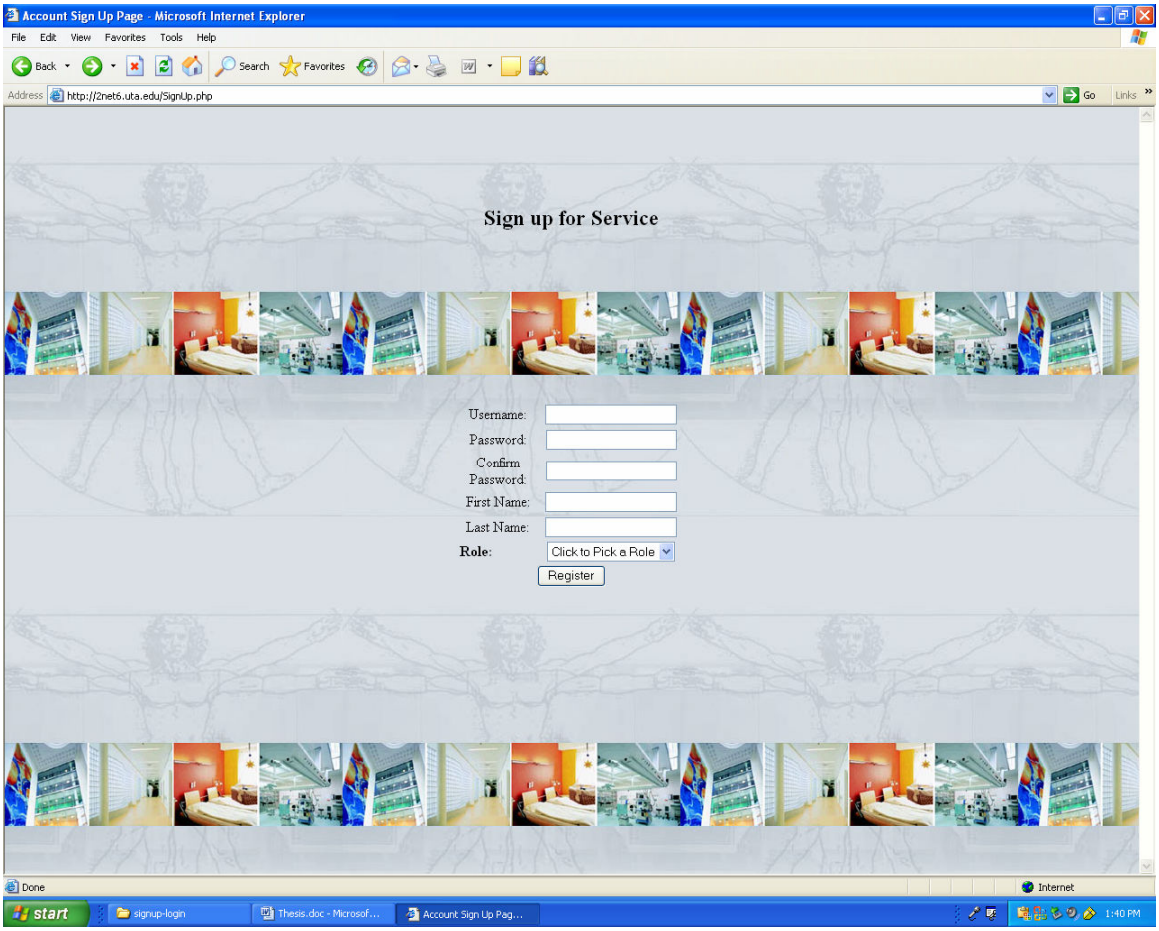


Figure 6 New account screen.

The maintenance of patient's electronic record is done using vMR; a vMR support a structured data model for representing information related to individual patients. A real patient medical record is a complex legal entity containing detailed financial, demographic, and clinical information about the patient, together with attribution and audit trail data; it is known Electronic Medical Record [23]. Virtual medical record is not a replica of Electronic Medical Record (EMR) but it only contains necessary information for modeling guideline (See Table 5), for example, an asthma guideline may require that we know whether the patient is currently taking an 'inhaled β_2 agonist'

and at what dose. Other attributes of the prescription in the EMR (e.g., number of refills, identity of prescribe) are irrelevant. vMR supports [23]:

(1) A structured data model for representing information related to individual patients.

(2) Domains for values of attributes in the data model.

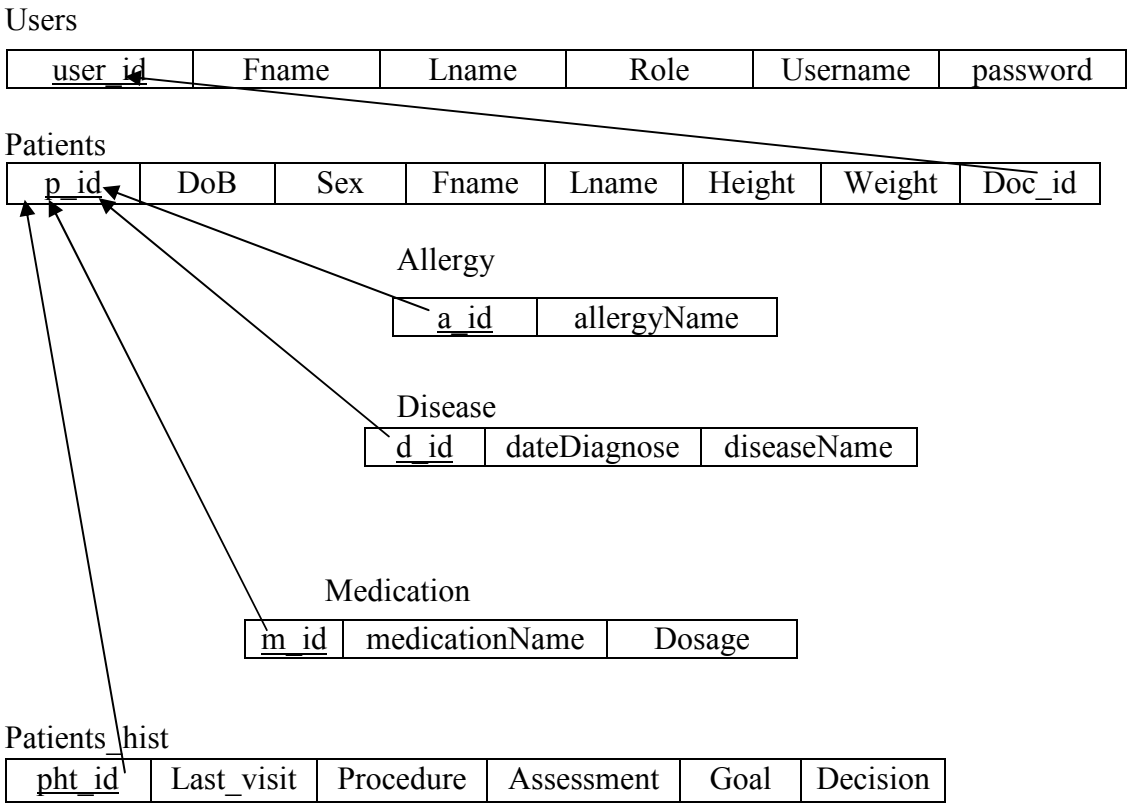
(3) Queries through which guideline decision support system can test the states of the patient.

It also allows guideline authors to encode clinical guidelines using rich and well-defined model of patient data and allows system developers to specify the requirements for guideline-specific storage, such as logging of guideline-based clinical assessments, decisions, and goals [23].

Table 5 Mapping of records types in vMR.

vMR	Content
Patient	Demographic data
Qualitative Observation	e.g., symptoms, signs
Quantifiable Observation	e.g., height 1.76m
Medical Authorization	e.g., Atenolol 100mg one a day, 28 days
Procedure (done)	e.g., Pancreatectomy
Allergy State	e.g., sensitive to penicillin
Clinical Assessment	e.g., poorly controlled hypertension
Goal	e.g., aim to BP less than 140/85
Decision	e.g., Start 2nd line therapy

The vMR is needed for easier access to patients' vital information, and for the second part of our technique. See figure 7 show how the vMR is implemented in our MySQL database. To provide increase security user's passwords are encrypted before they are stored in the users table, see below figure.



Referential Integrity:

Foreign Key (doc_id) References Users(user_id)
Foreign Key (pht_id) References Patient(p_id)
Foreign Key (a_id) References Patient(p_id)
Foreign Key (d_id) References Patient(p_id)
Foreign Key (m_id) References Patient(p_id)

Figure 7 Representation of vMR in MySQL database table.

Guideline engine is the heart of our technique; it uses the virtual medical record of a patient combined with the patient's symptoms and duration of the occurrences of the symptom to decide the step in the patient's care. The author tool that will be used in the creation of all the guideline is called PROTÉGÉ, it is a national resource for biomedical ontologies and knowledge bases supported by the National Library of Medicine. Protégé [43] is a free, open-source platform that provides a growing user community with a suite of tools to construct domain models and knowledge-based applications with ontologies. At its core, Protégé implements a rich set of knowledge-modeling structures and actions that support the creation, visualization, and manipulation of ontologies in various representation formats. Protégé can be customized to provide domain-friendly support for creating knowledge models and entering data. Further, Protégé can be extended by way of a plug-in architecture and a Java-based Application Programming Interface (API) for building knowledge-based tools and applications.

An ontology describes the concepts and relationships that are important in a particular domain, providing a vocabulary for that domain as well as a computerized specification of the meaning of terms used in the vocabulary. Ontologies range from taxonomies and classifications, database schemas, to fully axiomatized theories. In recent years, ontologies have been adopted in many business and scientific communities as a way to share, reuse and process domain knowledge. Ontologies are now central to many applications such as scientific knowledge portals, information management and integration systems, electronic commerce, and semantic web services.

The Protégé platform supports two main ways of modeling ontologies:

The **Protégé-Frames** editor enables users to build and populate ontologies that are frame-based, in accordance with the Open Knowledge Base Connectivity protocol (OKBC). In this model, an ontology consists of a set of classes organized in a subsumption hierarchy to represent a domain's salient concepts, a set of slots associated to classes to describe their properties and relationships, and a set of instances of those classes - individual exemplars of the concepts that hold specific values for their properties. Features of Protégé-Frames include:

- A wide set of user interface elements that can be customized to enable users to model knowledge and enter data in domain-friendly forms.
- A plug-in architecture that can be extended with custom-designed elements, such as graphical components (e.g., graphs and tables), media (e.g., sound, images, and video), various storage formats (e.g., RDF, XML, HTML, and database back-ends), and additional support tools (e.g., for ontology management, ontology visualization, inference and reasoning, etc.).
- A Java-based Application Programming Interface (API) that makes it possible for plug-ins and other applications to access, use, and display ontologies created with Protégé-Frames.

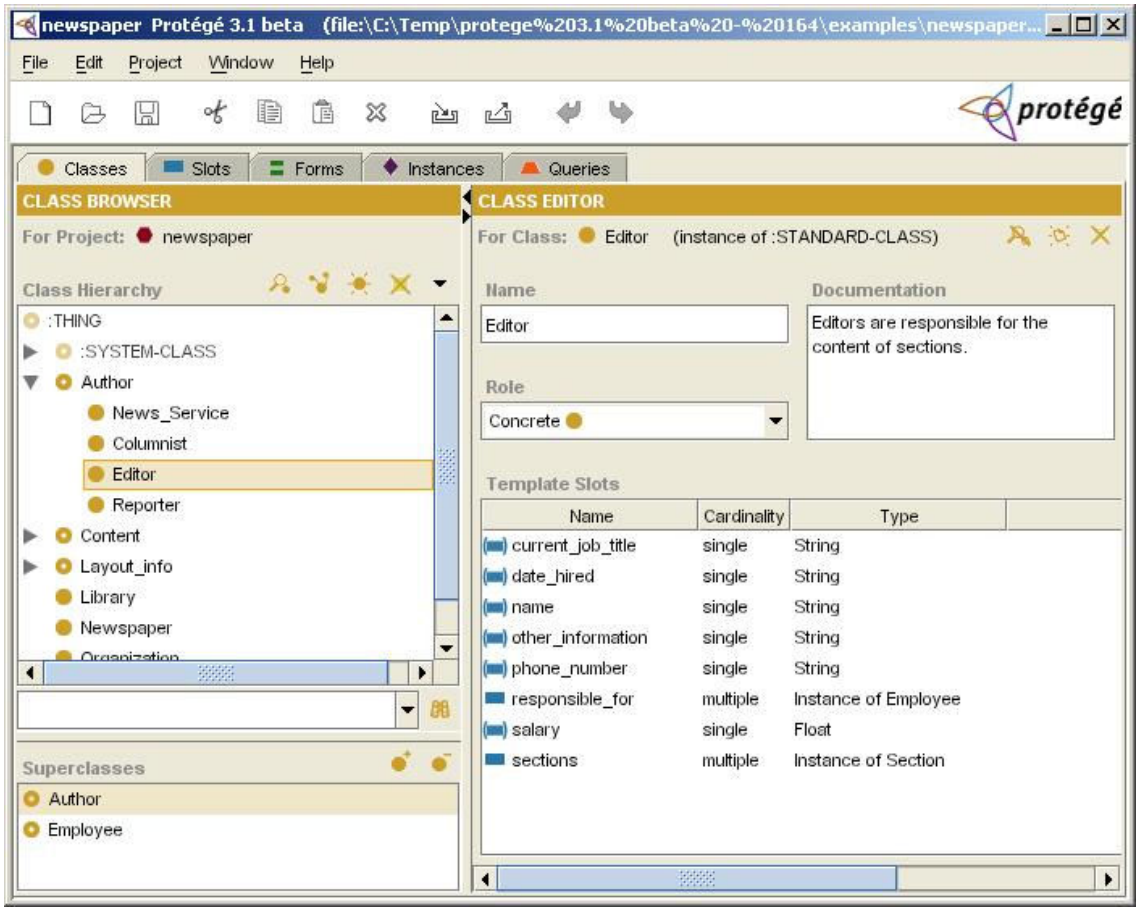


Figure 8 Protégé's class ontology editor [43]

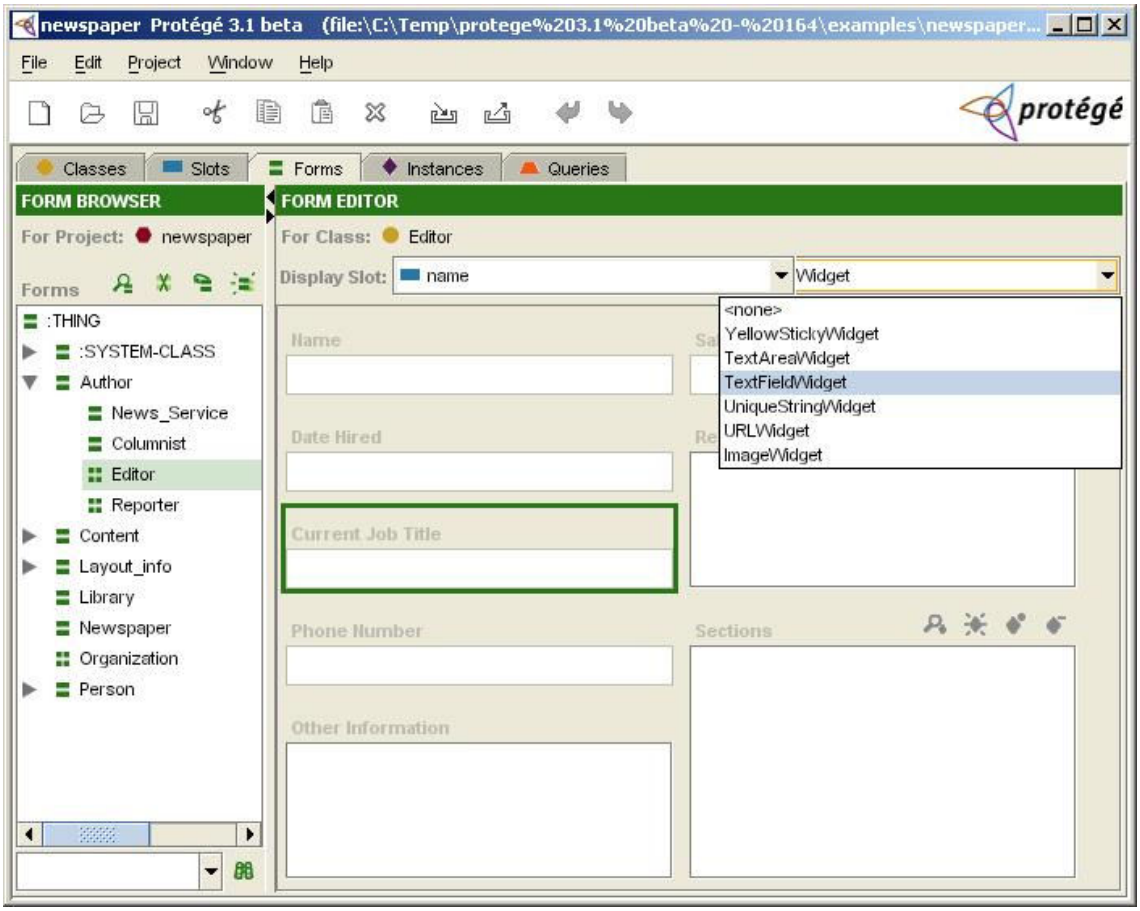


Figure 9 Protégé's forms ontology editor [43]

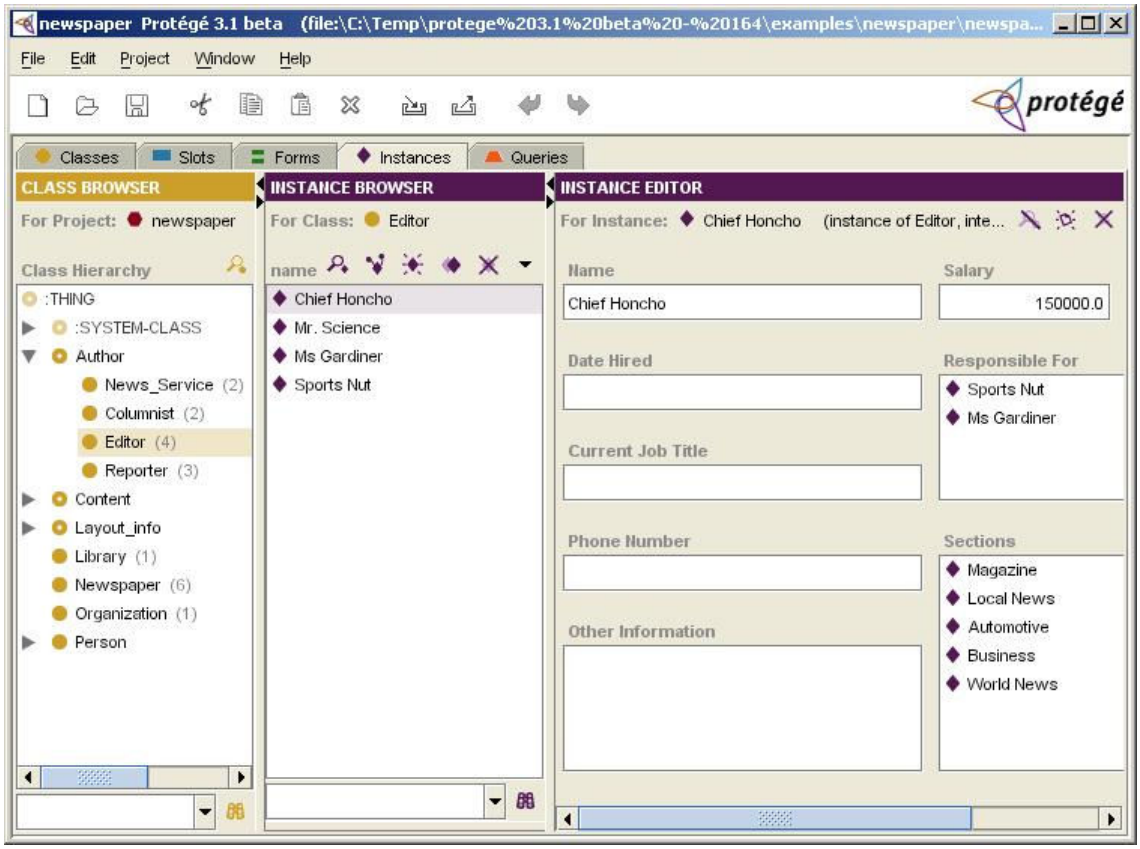


Figure 10 Protégé's instance ontology editor [43]

The **Protégé-OWL** editor enables users to build ontologies for the *Semantic Web*, in particular in the W3C's Web Ontology Language (OWL). "An OWL ontology may include descriptions of classes, properties and their instances. Given such an ontology, the OWL formal semantics specifies how to derive its logical consequences, i.e. facts not literally present in the ontology, but entailed by the semantics. These entailments may be based on a single document or multiple distributed documents that have been combined using defined OWL mechanisms". The Protégé-OWL editor enables users to:

- Load and save OWL and RDF ontologies.

- Edit and visualize classes, properties and SWRL rules.
- Define logical class characteristics as OWL expressions.
- Execute reasoners such as description logic classifiers.
- Edit OWL individuals for Semantic Web markup.

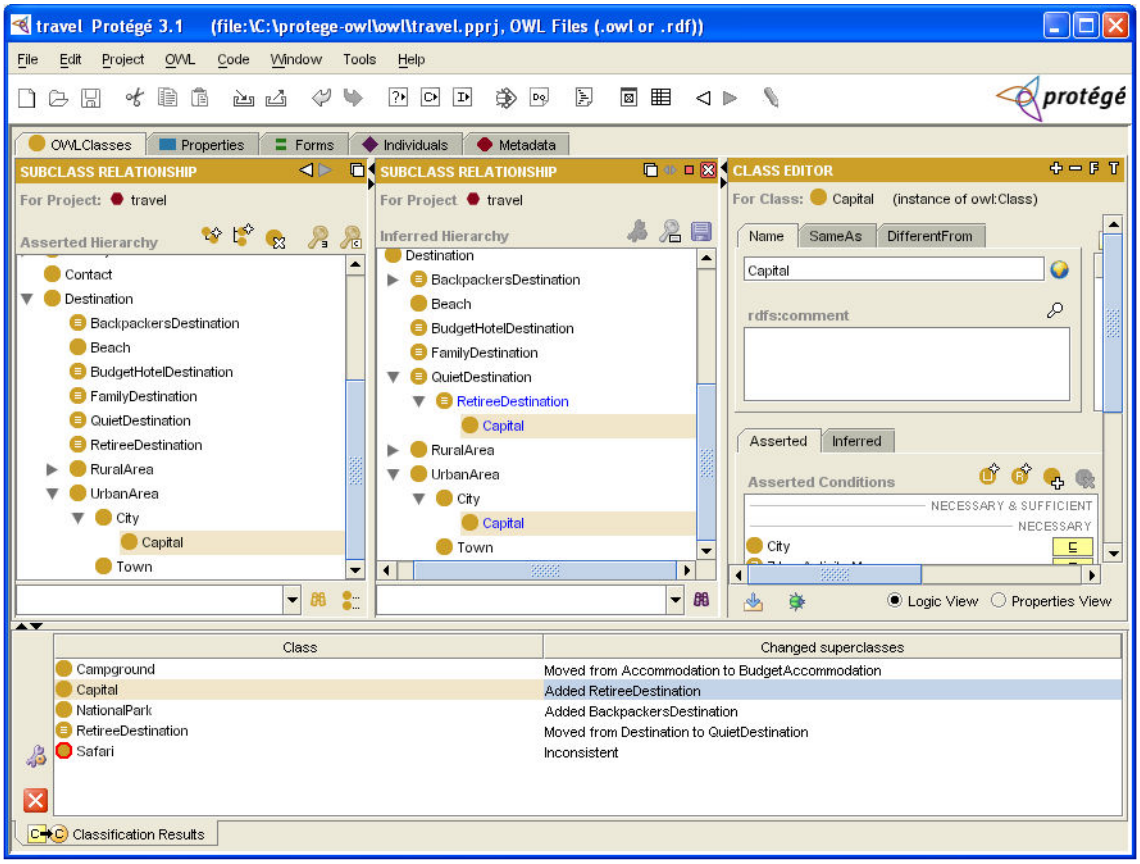


Figure 11 Protégé OWLClasses View [43]

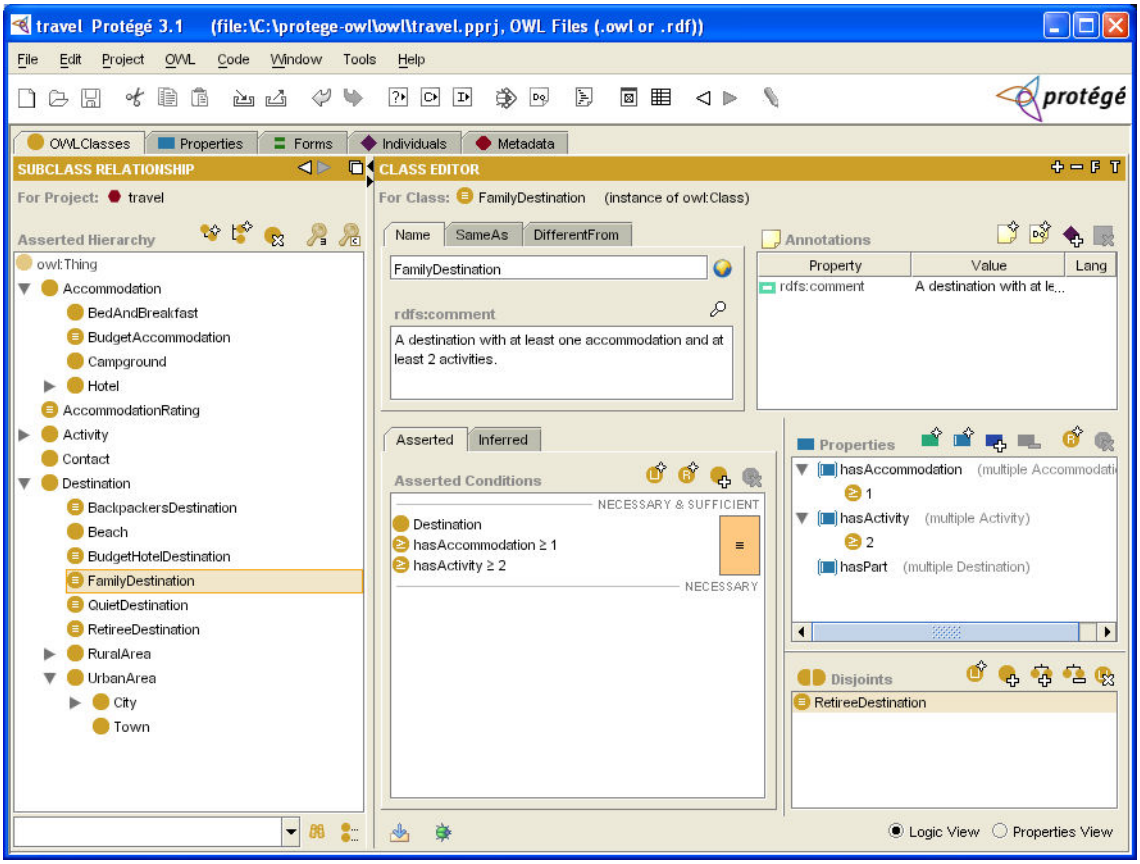


Figure 12 Protégé OWLClasses classification [43]

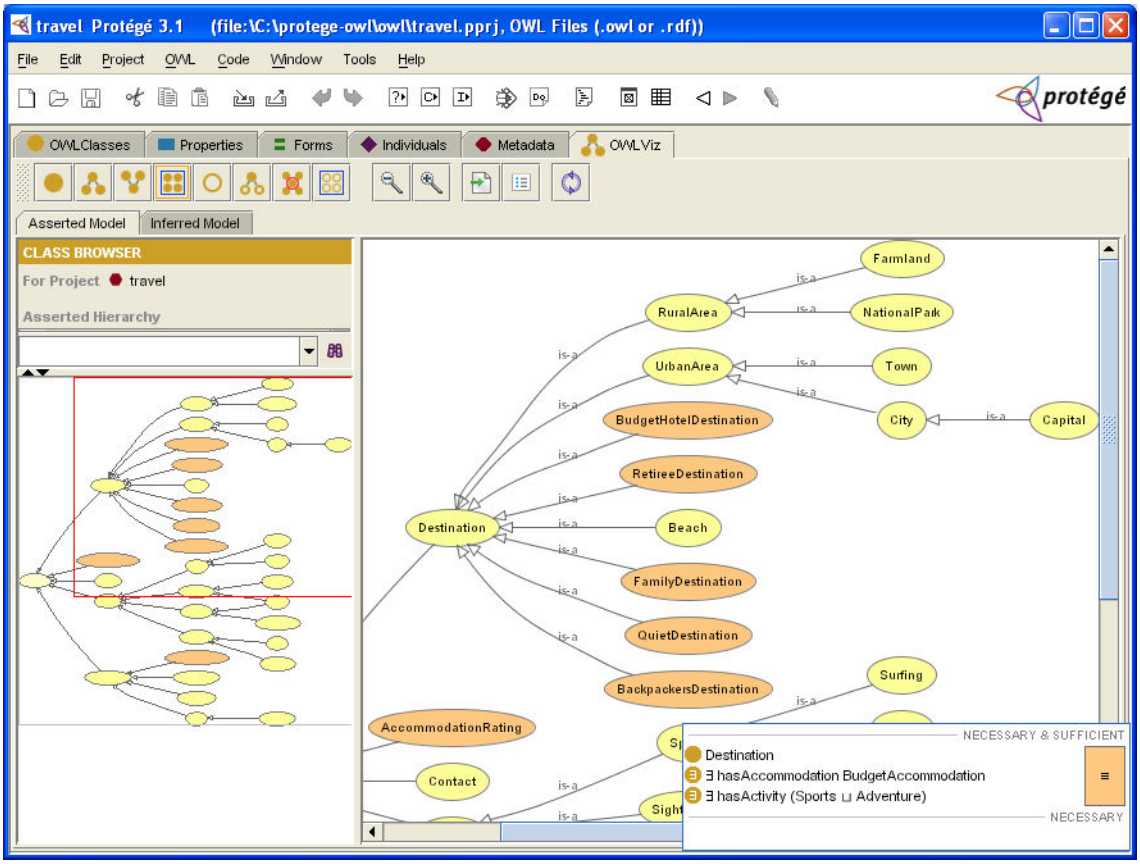
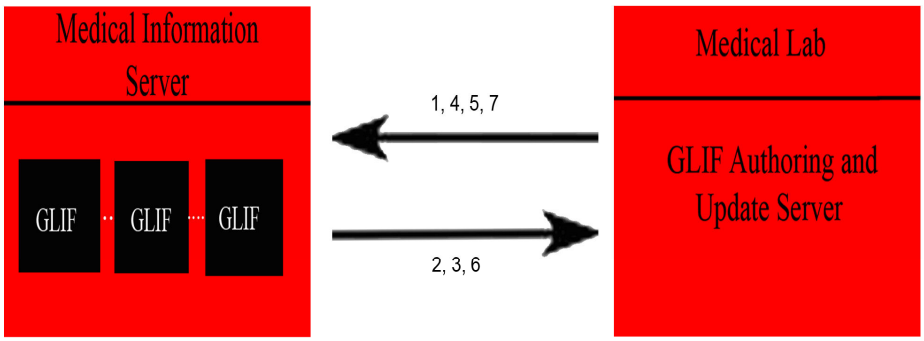


Figure 13 Protégé OWLViz ontology [43]

Whenever a new clinical trial is available an update is made to the current clinical guideline using PROTÉGÉ, therefore the medical decision support system will use the current clinical guideline in it next step decision.



Legend:

1: Medical Lab sends hello to Medical Information Server.

2: Medical Information Server sends hello to Medical Lab.

3: Medical Information Server sends its digital certificate to Medical Lab.

4: Medical Lab computes a preliminary secret Key, and encrypts it using Medical Information Server's public key sent in the Medical Information Server's certificate, then sends the encryted secret key to Medical Information Server.

5: Medical Lab computes some additional keys and encryptions initialization information to be used in the conversation, and sends a "finished" message to Medical Information Server.

6: The Medical Information Server also compute additional keys and initialization information, and sends a "finished" message to Medical Lab.

7: Medical Lab sends the new clinical trial Guideline to Medical Information Server.

Figure 14 Updating of GLIF Guideline.

For the rule update, see figure 14; when the newly create GLIF guideline with the new clinical trial is available, it is stored in a Medical lab GLIF Update Server using a push protocol the GLIF update server will authenticate itself for security reason to the Medical Information server where all the old guideline reside; once the authentication process is complete, the medical information server will be updated with current guideline with new clinical trial to replace the old guidelines.

In a push protocol the server initiates data transfer and controls the flow of data. For example, Real-time Transport Protocol (RTP) is a push protocol used for streaming media. Similarly, the SGI MediaBase protocol is a push protocol used for video-on-demand (VOD). The authentication process between GLIF update server and the medical information server is very crucial for security reasons. Authentication is the method of identifying an individual process or entity that is attempting to login or gain access to a secure domain. The authentication process confirms the GLIF update server's identification to the medical information server that it is attempting to gain access to the medical information server for file transfer of the new guideline with new clinical trial. To provide this type of authentication, the mechanisms supported, including Secure Socket Layer/Transport Layer Security (SSL/TLS).

SSL, or Secure Sockets Layer, is a protocol developed by Netscape for securely transmitting confidential information like credit card numbers across the Internet, between a web browser and web server, by means of public key encryption technology. It provides assurance that transmitted data remains private and unmodified, thanks to the encryption of traffic. It also provides a way for the sender to verify the server's identity and determine that the server, to which the data is sent, is authorized to have the data. This is achieved by allowing the user to view the certificate information for the server (certificates are digital "documents" containing identifying information verified by a trusted third party). A key part of an SSL, communication session is the SSL handshake, in which the server authenticates itself to the client, the client and server

agree on an encryption algorithm and encryption keys to use for the rest of the conversation, and the client authenticates itself to the server**.** SSL typically uses a 9-message handshake process, including an optional cipher selection, but it's often simplified and described as a 6-step handshake:

1. Client sends hello to server
2. Server sends hello to client
3. Server sends its digital certificate to client
4. Client computes a preliminary secret key, and encrypts it using the server's public key sent in the server's certificate, then sends the encrypted secret key to the server
5. The client computes some additional keys and encryption initialization information to be used in the conversation, and sends a "finished" message to the server.
6. The server also computes additional keys and initialization information, and sends a "finished" message to the client

TLS, or Transport Layer Security, is a transport layer protocol based on SSL and is considered to be a more flexible successor to it. Although, TLS isn't compatible with the latest version of SSL (SSL v3.0), it is very similar, and the TLS protocol does contain provisions for a TLS connection to back down to SSL v3.0 functionality if required. Like SSL, it supports a wide variety of encryption options, and can use digital certificates for authentication. Unlike SSL, it is application-independent, and can be used to provide a secure channel for protocols other than HTTP, such as SMTP. When

a connection is made, the TLS Record Protocol first calls the TLS Handshake Protocol (similar to SSL handshake), which enables both sides of a communication to authenticate themselves to each other, negotiate an encryption algorithm supported by both sides, and exchange key information. After that, the TLS Record Protocol uses the agreed upon encryption algorithm for data exchange, and the agreed upon hashing algorithm to ensure that the message was not altered during transport.
To use SSL and TLS, you need to generate a digital certificate or obtain one from a certificate authority.

Privacy and security is a big issue for our technique, for this reasons we decide to build our server running Red Hat Linux Enterprise Workstation update 4, Apache web server with Php engine enable, MySql database version 14.7 Distribution 4.1.20, for Readhat. We decided to go with Linux operating system because of it proven security measures and track records. MySql also have a good track record, it has been used in big projects and it is also freely available to use.

Below are the use cases for our medical decision support system using augmentable guideline engine.

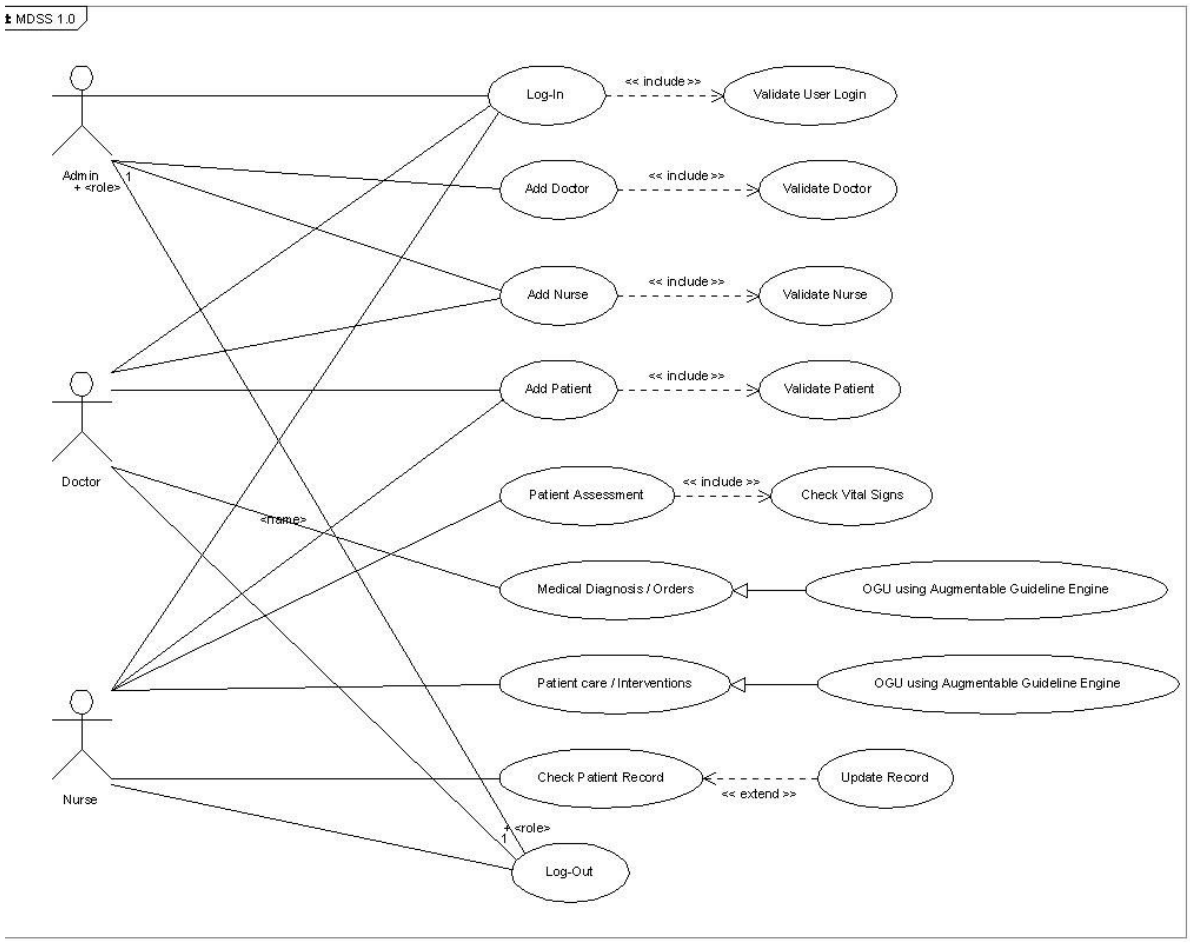


Figure 15 Use Cases of MDSS using Augmentable Guideline Engine

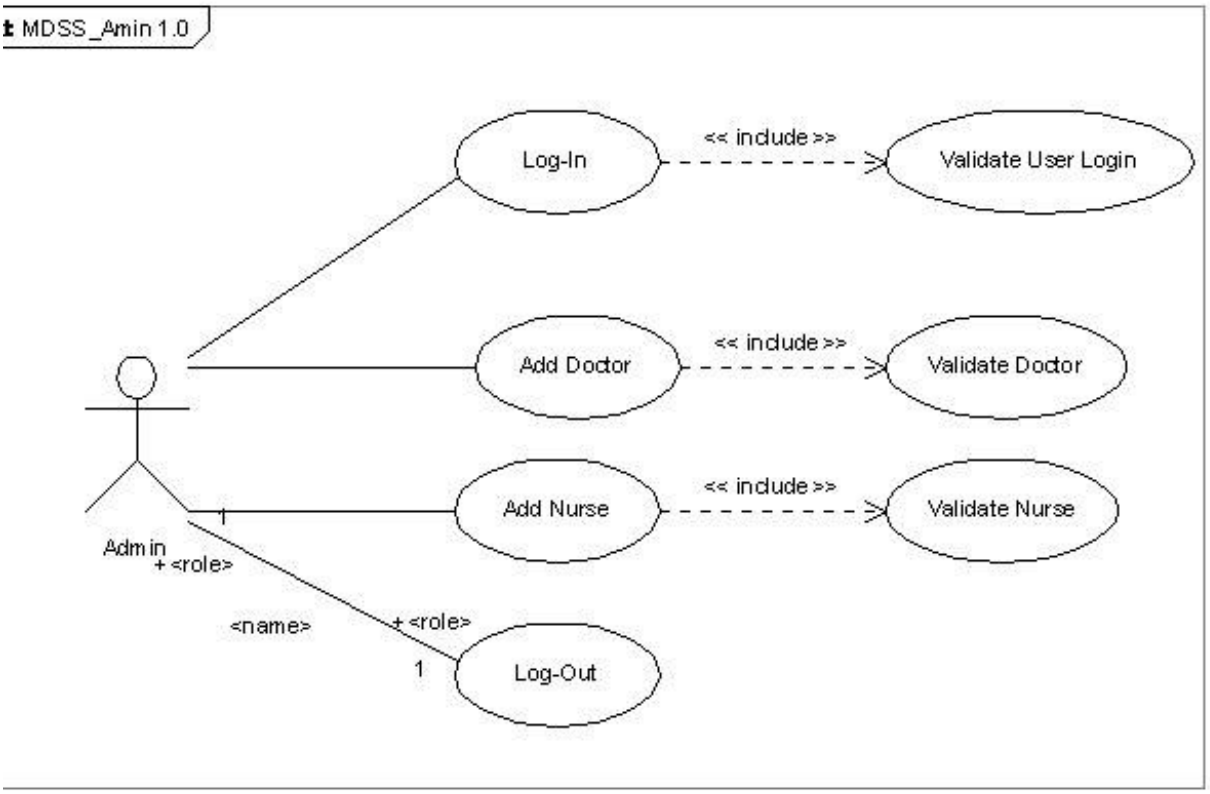


Figure 16 Use Cases for Admin

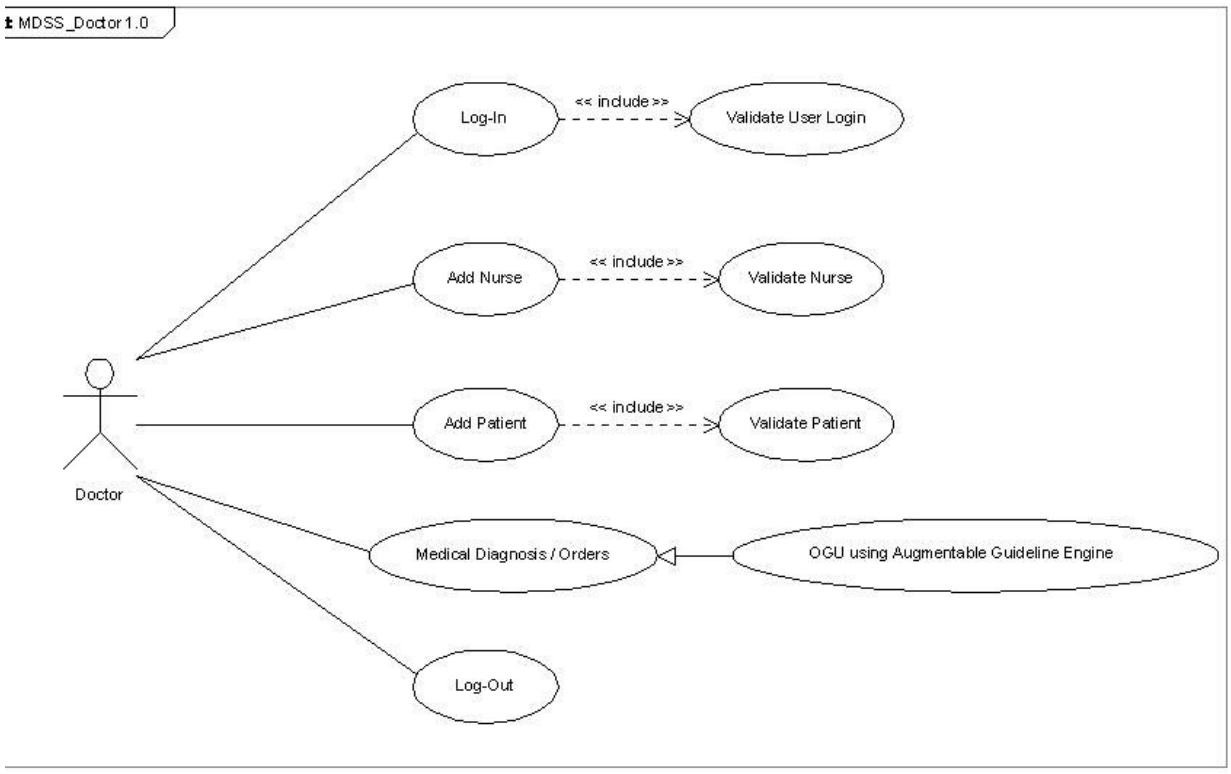


Figure 17 Use Cases for Doctor

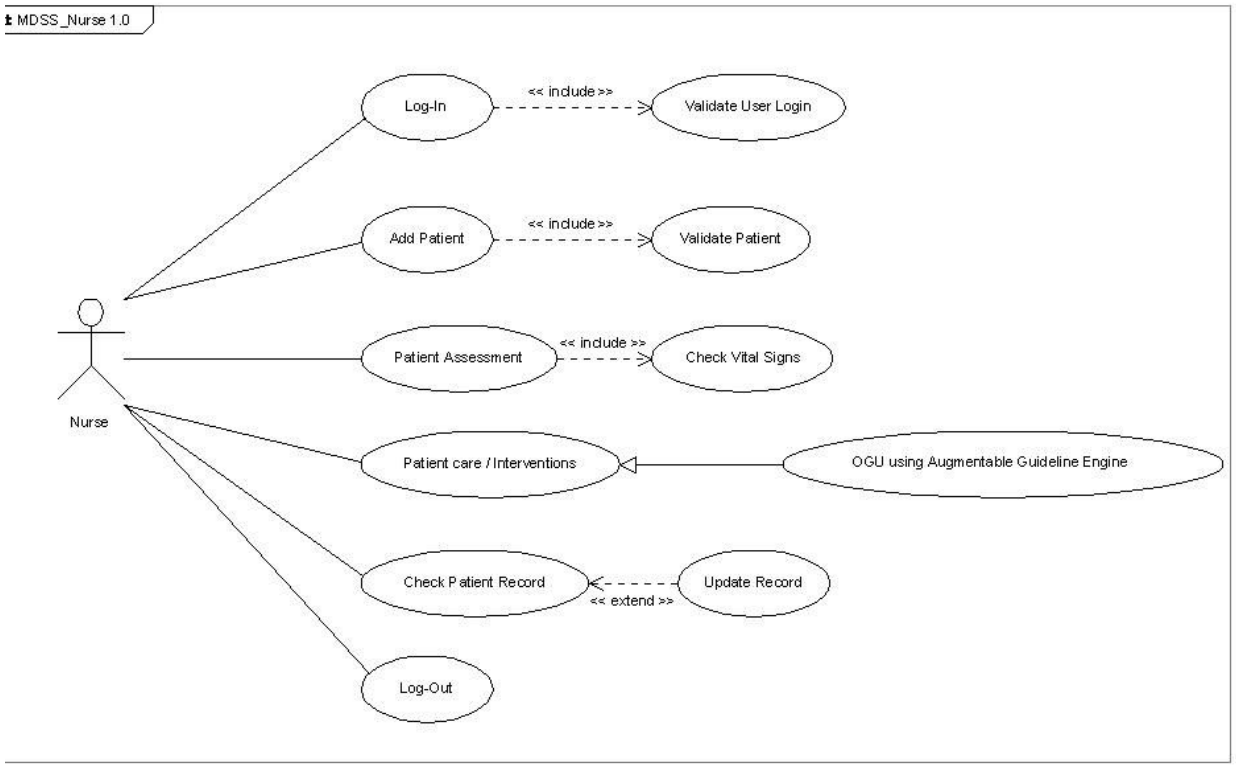


Figure 18 Use Cases for Nurse

CHAPTER 4

ANALYSIS

To evaluate the effectiveness of our technique, we implemented a web-based interface that allows users (for example, doctor and nurse) to login and gain access to their patient's medical record, in order to help manage their patient effectively. Having their patient's health record allows physicians and nurse, to be able to use this knowledge in properly applying the right guideline to use for that particular patient. It has been shown that using a medical decision support system that is developed to provide patient-specific assistances in decision making and integrated with clinical workflow will improve clinician and patient care outcome. We compare our technique to various medical decision support systems currently available. In addition to comparing our overall system with others, we compare the guideline representation models based on (a) whether their models were computer-interpretable and intended to be integrated with vMRs to provide patient-specific assistances in clinical decision making, and (b) whether their models were developed and implemented specifically for the representation of clinical guidelines.

To assist finding the systems to compare our technique, we searched MEDLINE using various key words (a) "decision systems" (b) "practice guidelines", (c) knowledge representation, and (d) "model" as a subject heading. We aggregate the results of (a) to (d) and performed the evaluation of the relevant subjects. We completed the result of

our evaluation with the reviews of papers published in the proceedings of AMIA symposium, journal of the American Medical Informatics Association, Artificial Intelligence in Medicine, Methods of Information in Medicine, Medinfo.

There are two important standards: Health Level Seven - HL7 and International Classification of Diseases, 9th Revision - ICD9 in medical knowledge systems that we did not compare our system to because they are more about hospital information systems as opposed to decision making systems. But, they are important enough that we will review them.

Health Level Seven, Inc. (HL7) [41, 44] is an all-volunteer, not-for-profit organization involved in development of international healthcare standards. Headquartered in Ann Arbor, Michigan, U.S., Health Level Seven is a Standards Developing Organization (SDO) that is accredited by the American National Standards Institute (ANSI). Standards Developing Organizations operate the healthcare arena. Standards Developing Organizations produce standards (sometimes called specifications or protocols) for a particular healthcare domain such as pharmacy, medical devices, imaging or insurance (claims processing) transactions. Health Level Seven's domain is clinical and administrative data. "Level Seven" refers to the highest level of the International Organization for Standardization (ISO) communications model for Open Systems Interconnection (OSI) - the application level. The application level addresses definition of the data to be exchanged, the timing of the interchange, and the communication of certain errors to the application. The seventh level supports such functions as security checks, participant identification, availability checks, exchange

mechanism negotiations and, most importantly, data exchange structuring. Its members: providers, vendors, payers, consultants, government groups and others who have an interest in the development and advancement of clinical and administrative standards for healthcare develop the standards. A frequent misconception about Health Level Seven is that it develops software. In reality, Health Level Seven develops specifications; the most widely used, being a messaging standard that enables disparate healthcare applications to exchange keys sets of clinical and administrative data. Founded in 1987 to produce a standard for hospital information systems. HL7 and its members are dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing and retrieval of electronic health information. The standards, which support clinical practice and the management, delivery, and evaluation of health services, are the most commonly used in the world. HL7's main mission is to create standards for the exchange, management and integration of electronic healthcare information. HL7 promotes the use of such standards within and among healthcare organizations to increase the effectiveness and efficiency of healthcare delivery for the benefit of all. HL7 has saved time, effort, and money as institutions attempt to interface. According to David John Marotta [41], co-chair of the Health Level Seven Education and Implementation Subcommittee, custom-built interfaces - prior to the introduction of the HL7 standard - cost between $50,000 and $250,000. In 2000 the expense of an HL7 interface with similar functionality ranges between $2,000 and $10,000. An interface analyst can complete HL7 interface connections in a matter of hours. Guidelines or data standards are an agreed-upon set of rules that allow

information to be shared and processed in a uniform and consistent manner. Without data standards, healthcare organizations could not readily share clinical information. Theoretically, this ability to exchange information should help to minimize the tendency for medical care to be so geographically isolated and highly variable. The Reference Information Model (RIM) is the cornerstone of the HL7 Version 3 development process and an essential part of the HL7 V3 development methodology. RIM expresses the data content needed in a specific clinical or administrative context and provides an explicit representation of the semantic and lexical connections that exist between the information carried in the fields of HL7 messages. The RIM is essential to increasing precision and reducing implementation costs.

HL7, Inc. develops Conceptual Standards (i.e. HL7 RIM), Document Standards (i.e. HL7 CDA), Application Standards (i.e. HL7 CCOW) and Messaging Standards (i.e. HL7 v2.x and v3.0). Messaging standards are particularly important because they define how information is packaged and communicated from one party to another. Such standards set the language, structure and data types required for seamless integration from one system to another. Currently, HL7's messaging standard is supported by every major medical information systems vendor in the United States.

In 1994, HL7 became accredited by ANSI. In the years since its founding, HL7 has expanded its influence well beyond traditional messaging protocols. The Arden syntax is a language for encoding medical knowledge. HL7 adopted and oversees the standard beginning with Arden syntax 2.0.

Today HL7 standards development initiatives include the following:

- Standardization of knowledge representation (Arden syntax)
- Specification of components for context management (known as CCOW)
- Support for healthcare data interchange using object request brokers
- Extend interoperability for the development of Health Information Exchange
- Standardization of XML document structures
- Specification of robust vocabulary definitions for use in clinical messages and documents (cf. SNOMED CT, LOINC)
- Functional specifications for an electronic health record
- Work in the area of security, privacy, confidentiality, and accountability.

Such innovation has allowed for everything from the availability of a patient's online medical record to a pharmacy's formulary to be represented and exchanged in an HL7 XML document. In fact, the HL7's Patient Record Architecture in (message standard) version 3.0 allows for a common format for exchanging a patient's medical record between different hospital systems or even different hospitals. This HL7 standard has come to serve as a foundation for the universal electronic medical record.

The scope of HL7's progressive activities is not limited to the electronic medical record, however. Indeed, recent activities and standards of HL7 have included modeling and methodology, vocabulary, financial management, administration, regulated clinical research and information management, scheduling and logistics, clinical guidelines, community-based health, government projects, medication, security and accountability, templates, XML, and public health and emergency response.

HL7 has allowed for the interoperability between electronic Patient Administration Systems (PAS), Electronic Practice Management (EPM) systems, Laboratory Information Systems (LIS), Dietary, Pharmacy and Billing systems as well as Electronic Medical Record (EMR). HL7 encompasses the complete life cycle of a standards specification including the development, adoption, market recognition, utilization, and adherence.

Health Level Seven's version 3 strives to improve the V2 process and its outcomes. New capabilities offered in Version 3 include:

- Top-down message development emphasizing reuse across multiple contexts and semantic interoperability;
- Representation of complex relationships;
- Formalisms for vocabulary support;
- Support for large scale integration;
- Solving re-use and interoperability across multiple domain contexts;
- A uniform set of models;
- Expanded scope to include community medicine, epidemiology, veterinary medicine, clinical genomics, security, etc.

HL7's Strategies [41]:

1. Develop coherent, extendible standards that permit structured, encoded health care information of the type required to support patient care, to be exchanged between computer applications while preserving meaning.

2. Develop a formal methodology to support the creation of HL7 standards from the HL7 Reference Information Model (RIM).

3. Educate the healthcare industry, policy makers, and the general public concerning the benefits of healthcare information standardization generally and HL7 standards specifically.

4. Promote the use of HL7 standards world-wide through the creation of HL7 International Affiliate organizations, which participate in developing HL7 standards and which localize HL7 standards as required.

5. Stimulate, encourage and facilitate domain experts from healthcare industry stakeholder organizations to participate in HL7 to develop healthcare information standards in their area of expertise.

6. Collaborate with other standards development organizations and national and international sanctioning bodies (e.g. ANSI and ISO), in both the healthcare and information infrastructure domains to promote the use of supportive and compatible standards.

7. Collaborate with healthcare information technology users to ensure that HL7 standards meet real-world requirements, and that appropriate standards development efforts are initiated by HL7 to meet emergent requirements.

The currently available version of HL7 is Version 3.0, Version 2.5 was approved as an ANSI standard in June 26, 2003, Version 2.4 was approved as an ANSI standard October 6, 2000, Version 2.3.1 was approved as an ANSI standard April 14, 1999, Version 2.3 Was approved as an ANSI standard May 13, 1997; The Clinical Document Architecture was approved as an ANSI standard November 2000, The Clinical Context Management Specification (CCOW) was implemented in Version 1.3, Version 1.2 was approved as an ANSI standard September 21, 2000, Version 1.1 was approved as an ANSI standard March 15, 2000, Version 1.0 was approved as an ANSI standard July 26, 1999. HL7 is important because it is a selected standard for interfacing of clinical data in health institutions to provide a comprehensive framework for the exchange, integration, sharing and retrieval of electronic health record.

The International Classification of Diseases (ICD) [41, 45] is the classification used to code and classify mortality data from death certificates. The International Classification of Diseases, Clinical Modification (ICD-9-CM) is used to code and classify morbidity data from the inpatient and outpatient records, physician offices, and most National Center for Health Statistics (NCHS) surveys. NCHS serves as the World Health Organization (WHO) Collaborating Center for the Family of International Classifications for North America and in this capacity is responsible for coordination of all official disease classification activities in the United States relating to the ICD and its use, interpretation, and periodic revision. International Classification of Diseases (ICD) provides codes to classify diseases and a wide variety of signs, symptoms,

abnormal findings, complaints, social circumstances and external causes of injury or disease. Every health condition can be assigned to a unique category and given a code, up to six characters long. Such categories can include a set of similar diseases. The International Classification of Diseases is published by the World Health Organization (a.k.a. WHO). The International Classification of Diseases (ICD) is used world-wide for morbidity (the proportion of sickness or of a specific disease in a geographical locality) and mortality (the state or condition of being subject to death) statistics, reimbursement systems and automated decision support in medicine. This system is designed to promote international comparability in the collection, processing, classification, and presentation of these statistics. The International Classification of Diseases is a core classification of the WHO Family of International Classifications (WHO-FIC). An important alternative to International Classification of Diseases coding is the American Psychiatric Association's (APA) Diagnostic and Statistical Manual of Mental Disorders (DSM), which is the primary diagnostic system for psychiatric and psychological disorders within the United States and is used as an adjunct diagnostic system in many other countries. The International Classification of Diseases is revised periodically and is currently in its tenth edition. The ICD-10, as it is therefore known, was developed in 1992 to track mortality statistics. Annual minor updates and three yearly major updates are published by WHO. Prior to the sixth revision, responsibility for International Classification of Diseases revisions fell to the Mixed Commission, a group composed of representatives from the International Statistical Institute and the Health Organization of the League of Nations. In 1948, the World Health Organization (WHO) assumed

responsibility for preparing and publishing the revisions to the International Classification of Diseases every ten years. WHO sponsored the seventh and eighth revisions in 1957 and 1968, respectively. The ICD-9 was published by the WHO in 1977. At this time, the National Center for Health Statistics created an extension of it so the system could be used to capture more morbidity data and a section of procedure codes was added. This extension was called "ICD-9-CM", with the CM standing for "Clinical Modification". ICD-9 consists of two or three volumes:

- Volumes 1 and 2 contain diagnosis codes. (Volume 1 is a tabular listing, and volume 2 is an index.) Extended for ICD-9-CM
- Volume 3 contains procedure codes. ICD-9-CM only

According to the World Health Organization Department of Knowledge Management and Sharing, the WHO no longer publishes or distributes the ICD-9 which is now public domain. The International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) is based on the World Health Organization's Ninth Revision, International Classification of Diseases (ICD-9). ICD-9-CM is the official system of assigning codes to diagnoses and procedures associated with hospital utilization in the United States. The National Center for Health Statistics (NCHS) and the Centers for Medicare and Medicaid Services are the U.S. governmental agencies responsible for overseeing all changes and modifications to the ICD-9-CM.

Work on ICD-10 began in 1983 and was completed in 1992. Adoption was relatively swift in most of the world, but not in the United States. Since 1988, the USA had required ICD-9-CM codes for Medicare and Medicaid claims, and most of the rest of

the American medical industry followed suit. On 1 January 1999 the ICD-10 (without clinical extensions) was adopted for reporting mortality, but ICD-9-CM was still used for morbidity. Meanwhile, NCHS received permission from the WHO to create a clinical modification of the ICD-10, and has produced drafts of the following two systems:

- ICD-10-CM, for diagnosis codes, is intended to replace volumes 1 and 2. A draft was completed in 2003.
- ICD-10-PCS, for procedure codes, is intended to replace volume 3. A final draft was completed in 2000.

However, neither of these systems is currently in place. There is not yet an anticipated implementation date to phase out the use of ICD-9-CM. There will be a two year implementation window once the final notice to implement has been published in the Federal Register. ICD has become the most widely used statistical classification system in the world. Although some countries found ICD sufficient for hospital indexing purposes, many others felt that it did not provide adequate detail for diagnostic indexing. The original revisions of ICD also did not provide procedure codes for classification of operative or diagnostic procedures. As a result, interested persons in the United States began to develop their own adaptation of ICD for use in the United States. Hospitals and other healthcare facilities index healthcare data by referring and adhering to a classification system published by the U.S. Department of Health and Human Services [45]: International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM). The Clinical Modification or CM system was developed and

implemented in order to better describe the clinical picture of the patient. The CM codes are more precise than those needed only for statistical groupings and trend analysis. The diagnosis component of ICD-9-CM is completely consistent with ICD-9 codes. ICD-10 was adopted in 1999 for reporting mortality, but the ICD-9-CM remains the data standard for reporting morbidity. Revisions of the ICD-10 have progressed to incorporate both clinical code (ICD-10-CM) and procedure code (ICD-10-PCS) with the revisions completed in 2003. However, ICD-9 has not been phased out by the new revision.

ICD-9 and -10 represent a standard way to code and classify mortality data from death certificates and morbidity data from the inpatient and outpatient records, physician offices, and most National center for health statistics surveys [45].

Comparing our approach to some of the medical decision support systems mentioned in chapter 2, our method have several advantages over these systems, these advantages include the following (1) An adequate method to handle security and privacy issues, (2) Modification of knowledge base without hard coding them in the system, (3) Integration of virtual medical records, and (4) Model implemented specifically for the representation of clinical guidelines.

CHAPTER 5

CONCLUSION & FUTURE WORK

In this thesis, we presented a new medical decision support system called OGU using augmentable guideline engine. Our approach consists of Patient Management system and a Guideline Engine. The patient management system facilitates user account management and maintenance of patient's medical record. The user account management provides secure access to the entire system and creation of new account for new users. There are many ethical issues that we addressed in the creation of our medical decision support systems, for example, privacy, security, and validity of the implemented systems, a malfunctioning or misuse pose great danger to patient safety, physicians could relinquish their own independent medical judgment to rely solely on medical decision support systems advice, dehumanization of patient care due to the use of computer which could lead to the adverse effects on the physician-patient relationship, increase reliance on medical decision support systems could lead to a degradation of physicians' reasoning skills, and confidentiality and security of the processed patient data. One of the most important issues out of the entire issues list above is the protection of patient privacy and confidentiality. Privacy is central to the doctor-patient relationship. Privacy and security are very important in our system. A Guideline engine uses the virtual medical record of a patient and the patient's symptoms, and duration of the occurrences of the symptom to decide the step in the

patient's care. The guideline engine is based on the InterMed Project's GLIF; interMed project is a collaboration among medical informatics groups at Stanford, Harvard, McGill, and Columbia universities, supported by the National Library of Medicine, developed a representation for sharable clinical guideline. The author tool that will be used in the creation of all the guideline is called PROTÉGÉ. Whenever a new clinical trial is available, an update is made to the current clinical guideline using PROTÉGÉ, therefore the medical decision support system will use the current clinical guideline in it's next step decision. Our technique was developed to assist physicians and not relinquish their own independent medical judgment to rely solely on medical decision support systems advice, and also not to dehumanize the patient care due to the use of computers which could lead to the adverse effects on the physician-patient relationship.

In the future, we hope to evaluate our approach in a more specify domain e.g. in detection and diagnostic of bioterrorism agent in case of terrorist attack for Emergency Medical Service. For example, during terrorist attack emergency response personnel, clinicians, and public health officials can use our approach in responding to the overwhelming requests for detecting and diagnosing bioterrorism agents and bioterrorism-related illnesses, these agents include bacteria and viruses that cause diseases such as: anthrax, botulism, tularemia, viral hemorrhagic fever. Finally, we intend to test our technique in a real clinical setting.

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BIOGRAPHICAL INFORMATION

Adetayo A. Aiyedun plans to work for awhile and later attend graduate school for this PhD because he believes an advanced degree will fully develop his reasoning and advance his studies in computer engineering. Adetayo A. Aiyedun is a member of the McNair Scholars Program, which prepares undergraduates for graduate study at the master's and doctoral level by engaging in undergraduate research under the guidance of a faculty mentor, among other activities. His long-term professional and career objectives are to obtain a doctoral level degree (PhD) and ultimately become a scientific researcher.