Developing Reliable Clinical Diagnosis Support System

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Glossary

AI	Artificial intelligence
CDDS	Clinical diagnosis support system
CT	Computed tomography
DD	Differential diagnosis
ECG or EKG	Electro cardiogram
EEG	Electro encephalogram
GP	General practitioner or General physician
GPS	Global positioning system
Health Informatics	Information technology that deals with medicine and healthcare related information
MDI	Multi document interface
MRI	Magnetic resonance imaging

Chapter 1 Abstract

Clinical diagnosis support software systems help clinicians in diagnosing clinical cases. Most of the clinicians are still relying on manual clinical diagnosis process. A manual clinical diagnosis is a very complex, cumbersome and error prone process; even very experienced doctors sometimes fail to diagnose a clinical condition correctly at an early stage.

Objectives of this paper is to investigate clinical diagnosis support software systems, problems with manual clinical diagnosis process, impact of current clinical diagnosis systems on healthcare and medics, approach and algorithm that can improve the clinical diagnosis support systems, and future of clinical diagnosis support systems. This paper also examines clinical diagnosis process, clinical diagnosis support software system's reliability and investigates and proposes a new way of developing a better and reliable clinical diagnosis support system.

I collected the data from various sources including interviewing many doctors and medics, and by studying the existing clinical diagnosis support systems which include knowledge based clinical decision support systems, non knowledge based or artificial intelligent based systems and search engine based systems. I studied more than 8 clinical cases, their signs, symptoms, examinations and laboratory tests and tested them with various available clinical diagnosis support systems.

There are wide varieties of clinical diagnosis support software systems available in the market and they use different algorithms and techniques to diagnose patient's clinical condition, which cover various domains of medicine, and also provide wide range of diagnostic functionality. However, they could not make big impact on healthcare or clinicians. There is lot of research currently going on clinical diagnosis support systems but because of huge commercial value for such systems, commercial vendors are not revealing the technical and implementation details of the systems.

Chapter 2 Introduction

Since ancient times, human beings have been trying to solve human problems with inventions and technology. Such inventions and technologies are not exception to solving human illness. Scientists and doctors are always tried to use latest technological inventions in healthcare for example Rontgen did not invent X-rays to diagnose human elements but it was successfully implemented in healthcare and the technology saved millions of human lives; similar story with other technologies like Microscope, CT Scan, MRI, pacemaker, artificial hearts, prosthetics, robotic surgical arms, digital ECG, EEG and so on, last but not least computers and information technology also includes in that technological adaptations.

In early days of medical related computer technology, the notion of that computer technology could help solving healthcare problems developed much interest and enthusiasm, and was prompted for pursuing the use of computers in medical field. For the past four decades a new branch of information technology is emerged and proliferated is called Health Informatics or Medical Informatics. [1][24]

Health Informatics is a branch of IT or computer science that deals with information and software technology related to healthcare, medicine and medical research. Health Informatics includes and relates to computers, computer science, IT, medical artificial intelligence, medical guidelines, medical information, medical research data, medical technologies, medical processes and practices, medical terminology and medical law and medical ethics. Health Informatics applied on healthcare, medicine & surgery, nursing, dentistry, public health, social and preventive medicine and medical research. [1][2]

Clinical diagnosis is an act or process of identifying or finding the nature and cause of a disease or a medical element through carefully studying patient's symptoms and signs, evaluation of patient history, clinical and laboratory examinations. A clinical diagnosis is the most important and critical part of medical and health care system and it is vital for treating the patients. A clinical diagnosis is still largely a manual process. Clinical diagnosis requires extensive knowledge, good interviewing skills, meticulous examination techniques, very high levels of analysis and synthesizing skills. Unfortunately, every doctor may not have same level of expertise and skills even most experienced doctors sometimes fail to diagnose the clinical condition correctly. Diagnostic mistakes are the major cause of medical errors. Any tool or technology that has potential to provide correct and timely medical diagnosis is worthy of serious consideration. Computer experts and scientists tried to develop a computer system that helps in complex clinical diagnosis that eliminates human errors and misdiagnosis such systems are now called clinical diagnosis support systems.[8][9]

Clinical diagnosis support systems are one of the recent and most important inventions in healthcare software systems or medical informatics. They guide and direct the doctors in diagnosing clinical conditions correctly and to make right decisions. The system analyses and processes the patient's data and come up with recommended diagnosis, this could be a multi stage process or one step process, it may request for more data or further clinical or laboratory examination based on the input.

Many research organisations and companies researched and developed clinical diagnosis support systems using various software and computer technologies. Current generation of clinical diagnosis support systems are cumbersome to use, and are unsuccessful. Even though some companies are claiming that their systems more than 90% accurate but in my research I found that their accuracy is far less than their claim and the system are seldom in use.

There are various reasons for the failure of these systems. Firstly, they are not mature enough to use as life critical systems, secondly analysts and developers haven't deeply understood the medicine and the clinical diagnosis process, and finally doctors do not have faith in the current systems which can actually mimic human reasoning. With my research I found astonishing revelation of the doctors and I examined the existing systems very closely and found new way of developing these systems.

Aim:

Main aim of this paper is to study the current clinical diagnosis support systems and to find out a better way of developing reliable clinical diagnosis support systems.

Objectives:

1. Analyze clinical diagnosis support systems.
2. Investigate current clinical diagnosis support systems and their impact on healthcare.
3. Look into a better way of developing clinical diagnosis support systems.
4. Predict future of the clinical diagnosis support systems.

Document Layout:

Chapter 1: abstracts the document. Chapter 2: introduces the clinical diagnosis support systems. Chapter 3: discusses clinical diagnosis support systems, clinical diagnosis process, and the human reasoning behind the clinical diagnosis process. Chapter 4: details of the clinical diagnosis development and the important steps required for the development. Chapter 5: Analyses the existing clinical diagnosis support systems and their advantages and disadvantages. Chapter 6: details of the proposed clinical diagnosis support system development. Chapter 7: exemplifies the prototype of the proposed solution Chapter 8: discusses the legal and ethical issues of the clinical diagnosis support systems. Chapter 9: speculates the future of the CDSS and concludes.

Chapter 3 Clinical Diagnosis Support Systems

Clinical diagnosis system is a computer based programme that helps a clinician in diagnosing a patient's clinical conditions.

Clinical diagnosis support systems (CDSS) can guide clinicians to the correct diagnosis and have the potential to reduce the rate of diagnostic errors in clinical diagnosis. Many research organization and companies developed clinical diagnosis support systems using different technologies and provide various levels of functionalities. Even though they use different technologies they all work similarly. Clinician enters the patent's clinical finding and the system process the input and comes up with probable diagnosis. These diagnostic support systems can also be used as teaching aid for medical students to train them in differential diagnosis. However, surprisingly most of these CDD systems haven't gained widespread acceptance for clinical use.

In order to analyze and explore clinical diagnosis support systems, it is important to understand clinical diagnosis and clinical diagnosis process, and human reasoning behind the clinical diagnosis.

Clinical Diagnosis

Clinical diagnosis is a process of finding and establishing the characteristics and type of an illness that a person is suffering based on signs, symptoms, and laboratory findings.

Formal definition of clinical diagnosis:

1. "The placing of an interpretive, higher level label on a set of raw, more primitive observations." [1]

2. "A mapping from a patient's data (normal and abnormal history, physical examination, and laboratory data) to a nosology of disease states." [1]

3. "The process of determining by examination the nature and circumstances of a diseased condition." [1]

Clinical Diagnosis Process

Clinical diagnosis process is a complex, loosely defined, and multistep process. It establishes what the illness is? When it is started? How the illness has manifested? And how it has affected the patient's normal life?

Clinical Diagnosis involves series of individual steps as follows:

1. Taking patient's history.
2. Physical examination and systemic examination.
3. Analyzing the patient's data.
4. Differential diagnosis & provisional diagnosis.
5. Further examinations including laboratory examination.
6. Confirming or refuting the diagnosis.
7. Starting the treatment.

Diagnosis process starts with as soon as clinician sees the patient. Clinician immediately makes some general assessment of the patient like appearance, status, and gait. Then clinician introduces himself to the patient usually with handshakes. By this time clinician assess general status of the patient like patient's conscious status, appearance, clothing, complexion, facial features, skin status, abnormal movements and odors and sometimes this general assessment itself provides a diagnostic clue. [Human reasoning of clinical diagnosis is explained in the following section][8][9]

After the introduction, doctor engages with the patient, gets the patient's details like age, sex and where he/she lives and starts taking the patients history. Next step of the doctor is to establish the presenting complaint. To make diagnosis, experienced clinicians recognize pattern of symptoms. After getting the presenting complaints, clinician gets patients past medical history, drug history, family history, and social history. After obtaining the patient's history, clinician also enquiries about the other systems of the patient and this uncover symptoms that might have been forgotten.

After taking the history, doctor will have a differential diagnosis in his mind. Doctor examines the patient, trying to elicit the signs that will confirm or refute the diagnosis that is in the doctor's mind. First doctor carries out general routine examinations. [8] The sequence of routine examinations is:

1. Inspection
2. Palpation
3. Percussion
4. Auscultation

The following picture shows you the typical clinical diagnosis steps:

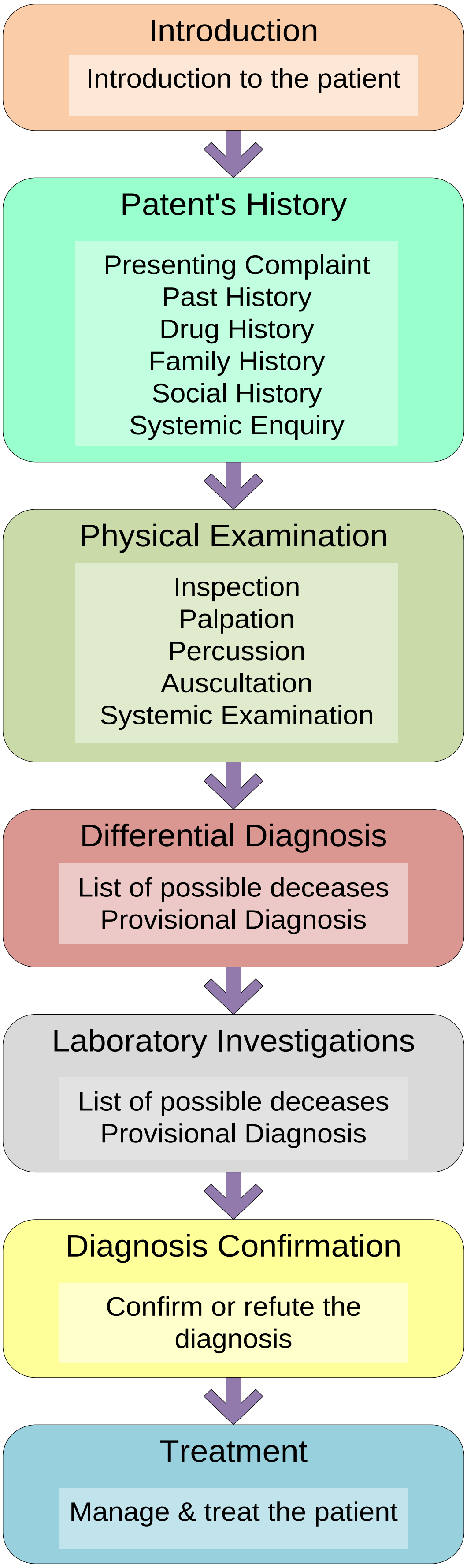

Figure 1Clinical diagnosis process --Picture by Kaukuntla (Author)

Inspection: The clinician carefully observes the patient from top to bottom for clinical signs and notes down all the findings

Palpation: The clinician tries to find the signs or their characteristics that are not visible to eye by palpating the patient's body.

Percussion: The clinician tries to find some abnormal signs by hearing resonance from the patient's body by striking the tip of clinician's curved (middle) finger against the middle phalanx (that is, the middle part of the finger) of the (middle) finger of the opposite hand.

Auscultation: The clinician tries to find abnormal sounds by examining with a stethoscope. The most obvious use of auscultation is for listening to heart sound, breath sounds, bowel sounds and foetal sounds.

On completing the general examination, clinician does the systemic examination. Systemic examination involves examining each system of the patient's body (e.g. hair, skin, hearing, sight, head & neck, CNS, CVS, GI, renal, and other systems).

After obtaining the details of nature and circumstances of the patient's clinical findings and assembling all the relevant information, clinician should be able to produce a provisional or a confirmatory diagnosis.

After completing the general and systemic examination, based on his/her diagnosis, if necessary, clinician sends the patient for laboratory examinations to confirm or refute his diagnosis and also to decide what type of therapy can be applied to the patient. Because of advancements in laboratory investigation technology, lab investigations have become more common and important in diagnosis process. [8][9][10]

After diagnosing the case, clinician starts the treatment based on patient's clinical condition.

A typical case sheet format is as follows:

Table 1Patient's case sheet - by Kaukuntla (Author)

Patient's Case Sheet
Personal Details: Name, age, sex, DOB, ethnicity, demographic details, date and time, and GP details.
Presenting Complaint (PC): Major or chief complaint in patients own words followed by duration.
History of Presenting Complaint (HPC): Onset, nature, and course of each symptom. All the relevant information to the symptoms
Past History(PH): Previous medical history of the patient in chronological order
Drug History (DH): Previous drug use and allergies to any drugs.
Family History (FH): Pedigree of chart of family medical history.
Social History (SH): Occupation, marital status, living circumstances, smoking, alcohol, illicit drug use and any other hobbies.
Systemic Enquiry(SE): Positive responses of the following systems that are not included in HPC CVS(Cardiovascular system), CNS(Central nervous system), RS(Respiratory system), GI(Gastro intestinal system), GUS(Genito-urinary system), PMB(Postmenopausal bleeding), MSS(Musculoskeletal system) and ES(Endocrine system)

On Examination(OE): Inspection Palpation Percussion Auscultation
Systemic Examination: CVS examination RS examination Abdominal examination CNS examination MSS examination
Impression: Suggestive diagnosis
Plan: Laboratory investigations Treatment and management
Progress Notes: Progress notes, impression, plan, and follow-ups

Clinical diagnosis process steps may not be identical for every clinical case. The steps one clinician follow may be very different from another clinician. Sometimes the same clinician may take different steps for two nearly similar cases. Because expertise and skill varies among clinicians, different clinicians encounter different diagnostic problems in diagnosing the similar clinical case. Also circumstances like availability of the laboratory investigation facility in the medical centre and emergency of the clinical case changes the steps of clinical diagnosis process. [1][9]

Understanding clinician's diagnosis process and pattern is very important to develop clinical diagnosis support systems. Studies of "clinician's information requirements" help us to understand variability in clinical diagnosis process among clinicians. Forsythe and colleague's participant observation studies indentified three types of information requirements during clinical diagnosis process.

- Currently satisfied information requirements (information recognized as relevant to a question and already known to the physician).
- Consciously recognized information requirements (information recognized by the clinician as important to know to solve the problem, but which is not known by the physician).
- Unrecognized information requirements (information that is important for the clinician to know to solve a problem at hand, but is not recognized as being important by the physician). [1][8][9][10]

Failure to detect a diagnostic problem at all comes under latter category. For the same patient, depending on clinician's expertise and knowledge of the patient, different clinicians will experience different diagnostic problems.

Because of this varying knowledge and expertise of clinicians, diagnosis varies depending on the circumstances and the clinician. Also human being has many limitations like number of things he can remember at one time. Clinical diagnosis support systems do not have human limitations like short term memory and they can help clinicians to overcome the problems in manual clinical diagnosis process. However, the clinical diagnosis support systems also pose different problems. These systems are developed by various research organizations and companies using various algorithms and techniques. Their usage and output is not always the same [problems with CDSS are discussed in chapter 5].

Like any other information storage, medical and clinical data like patient's clinical findings (case sheets) are stored in various ways depending on the medical centre. Some clinicians write on a paper and then input them into patient record software systems, some busy clinicians record them with voice recorder and then medical transcriptors convert them in to text and later save them in to computer systems. Also there are medical centers that still maintain the paper based medical record.

There are many medical information management systems in the market and they provide wide variety of functionality, some provide just information management and others provide much more integrated functionality. These other medical system can be integrated to clinical diagnosis software systems. For example if you integrate the clinical diagnosis software system to these systems, if the patient's findings are already saved in to a medical information management system then the clinician does not need to re-type the finding in to the CDSS to get diagnosis suggestion.

It is not only the clinical diagnosis process, understanding the human reasoning behind the clinical diagnosis is also important to develop CDSS. The following section explains the human reasoning behind the clinical diagnosis process.

Clinical Diagnosis Human Reasoning

Human diagnostic reasoning is not based on precise logic. For example in other words in diagnosis terms 2+2 is not always equal to 4; this is the major reason for most doctors to believe that computers may not be helpful in clinical diagnosis. Diagnostic reasoning involves various complex, diverse and relative activities including gathering of patient's data, typical pattern recognition, provisional judgment under given circumstances, solving the problem, trial and error, decision making, judgment under uncertainty, further investigation based on the previous judgments and combining and comparing the data. Very sophisticated, organized, in-depth knowledge, and skills are required to work in this relatively complex loosely structured area. Doctor's knowledge of human diagnostic reasoning is based on generic human psychological experiences and experiments about logic and reasoning on direct studies of the diagnostic process itself. This reasoning has some similarities but not the same to chess-game playing, meteorological judgments, and crypto-arithmetic patterns; hence such patterns have been studied in comparison with diagnostic reasoning. The psychological experiments about judgments made under uncertainty have provided reasoning behind individuals imperfect partially logical reasoning skills. [1][2]

Judgment under uncertain clinical data is one of the most important and complex aspect of the human reasoning for clinical diagnosis. In my research I found one very interesting case that comes under judgment under uncertain clinical data. A patient in Chennai India was suffering with very severe headache, doctors could not establish any diagnosis, they tried all the sophisticated laboratory invitations including EEG, CT-Scan and MRI and tried various treatments without any success, most of the doctors concluded it as a psychological headache and some said idiopathic headache but finally one doctor decided to investigate this case further and found that she does not get headache while oil bathing but the doctor could not establish link between the oil used in bath and the headache relief and found that she removes all her ornaments including her diamond nose-pin while the oil bath. And the doctor finally established the diagnosis the light reflection from the diamond nose-pin in to her eye is causing the headache. [20][21]

To examine the complex clinical diagnosis process, researchers' study human behavioral patterns combined with the diagnostic procedure with introspection. Researchers followed the clinicians thinking process including clinical and non-clinical activities from the beginning of the diagnostic process till the end and interpret the whole process in depth including knowledge, skill, motive, reasoning, hypothesis, logic and strategies involved in the making diagnostic decisions. However, they might have carried out the studies, I strongly believe that it is almost impossible to say that every doctor's thinking process and reasoning is the same and it is the actual thinking process and reasoning behind every diagnostic process.[1][20][21]

The main elements of the diagnostic reasoning is developing a working hypothesis, testing of the hypothesis, getting and analyzing the additional information, and either accepting the hypothesis or rejecting it or adding new hypothesis based on further analysis.

The working hypothesis first developed in the process of information gathering when only few facts are known about the patient's case. Because of limited human memory and analysis capacity only less than five such hypothesis are developed simultaneously; these hypothesis are basically developed from pattern recognition with use of existing knowledge and experience. Experts are usually more capable of applying the collected knowledge and experience than the novice physicians and experts rarely use the casual reasoning. [1][20][21]

Popel and others [19] noted that Clinical diagnosis reasoning is similar to Simon's criteria (reasoning for ill structured problem); according to Simon ill-structured problem can be divided into small well-defined small tasks. These small sub-tasks can be easily solved when compared with one big ill-defined task. Studies conducted by researchers shown that physicians employ hypothetic-deductive method after early hypothesis generation; usually early hypothesis reasoning produces results when there is very high possibility of correct diagnosis. Some researchers like Kassirer and Gorry [21] described the process called "process of case building" where the hypotheses are evaluated against diseases data by emulating using computer systems with Bayes' law, Boolean algebra, or pattern matching(There are some Clinical Diagnosis Support Systems developed using this principle). Popel also observed that separating complex differential diagnosis into problem areas allows clinicians to apply very powerful additional reasoning heuristics. Physicians can assume the DD (Differential Diagnosis) list is within the problem domain, consists mutual exclusion hypothesis and that the list is extensive or complete that means correct diagnosis is always within that list and anything out of that list is incorrect. Another researcher Kassirer has recognized three abstract categories of human diagnostic reasoning strategies probabilistic, causal, and deterministic. The Bayesian algorithm logics is based on the probabilistic reasoning strategy that computes clinical findings statistics using mathematical models results in to optimal decisions. Some other experimental studies showed that humans are naturally not very good statisticians, human problem solving mostly based on judgmental heuristics. [2][19][21]

Human reasoning for medical diagnosis is very complex, many researchers observed and presented many other human diagnosis reasoning models. Causal patho-physiological reasoning establishes relations between biochemical, anatomical, physiological, pathological and genetical representations of a clinical problem. Causal, patho-physiological reasoning uses shared, global, patient independent information and provides an effective way of verifying and describing diagnostic hypotheses. M. Scott Blois (late) explained clinical judgment with funnel illustration. At the wide end of the funnel are improperly defined vague symptoms and at the narrow end of the funnel are fine grained, isolated and treatment specific decisions. Blois illustrated that clinical decision support systems should be applied at narrow end of the funnel. [1][2][22][23]

History of Clinical Diagnosis Support Systems

Most of the basic concepts related to clinical diagnosis support systems were formulated before or in early 1970. In 1979 review of reasoning strategies by Shortliffe, Buchanan, and Feigenbaum identified the following methods: [24]

1. Clinical algorithms.
2. Clinical databanks that include analytical functions.
3. Mathematical patho-physiological models.
4. Pattern recognition systems.
5. Bayesian statistical systems.
6. Decision-analytical systems.
7. Symbolic reasoning.

[24]

In 1959, Ledley and Lusted [22] published a paper that clinicians have imperfect knowledge of how they solve clinical diagnostic problems, and they published the principles underlying work on Bayesian and clinical diagnostic support systems that has been followed over new few decades. Their detailed logic and probabilistic reasoning was most important parts of the human diagnostic reasoning. Bayes' rule can be applied to larger areas and in 1960-1961 Warner and colleagues developed one first medical application systems based on Bayes' rule. [22]

Gorry and Barnett in 1968 developed a model for sequential Bayesian diagnosis, Dombal and colleagues developed first practical Bayesian system to diagnose acute pain abdomen and that is one of the first clinical diagnostic support system that used at many medical centers. Bayesian methods gained popularity and many other developers developed diagnostic related systems using Bayesian logic. [21]

In late 1950s, Lipkin, Hardy, Engle, and their colleagues [25] developed a first heuristics based diagnostic application called HEME to diagnose haematological disorders. HEME program heuristically matches stored disease data to lexical description of patient's clinical findings. Later CONSIDER system was developed by Lindberg and RECONSIDER program was developed by Blois and his colleagues using heuristic lexical matching techniques. Weiss and Kulikowski developed EXPERT system shell and it has been used in systems that utilize criteria tables for example AI/Rheun mainly developed for diagnosis of rheumatological disorders.[2][25]

In 1968 Gorry [21] published general principles for expert system approach to clinical diagnosis systems, based on the Gorry's principles clinical diagnostic systems were developed in 1970 and 1980. Gorry principles demonstrate many clinical diagnostic systems developed by various development groups, systems including PIP (the Present Illness Program), developed by Pauker et al, MEDITEL for adult illnesses developed by Waxman and Worley from its predecessor pediatric version, Internist-I developed by Pople and Myers Miller in University of Pittsburgh, QMR developed by Miller, Masarie, and Myers, and DXplain developed by Barnett and colleagues, Iliad developed by Warner and colleagues, and many other systems developed by diverse group. [19][21]

Shortliffe [24] introduced the rule based expert system to develop medical applications; many rule based clinical diagnosis support systems were developed over the years but rule based expert systems are applied only in small area of the domain because of its complexity in maintaining thousands of predefined rules. The philosophy of clinical diagnosis software systems development has been changed with advent and proliferation of the personal computers. Developers developed systems that take advantage of strengths of user knowledge and the system capabilities. The goal of the developers was to improve performance of the user and machine capabilities. [17][24]

In 1980s and 1990s several advanced techniques were developed to existing clinical diagnosis software systems and models and improvements were made with adding more mathematical rigor to the models. However mathematical approaches have one downside that is they are dependent on the quality of the data. Many systems were developed based on fuzzy set theory and Bayesian belief networks logic to overcome limitations of heuristic approaches and the old models. [1]

With advent of artificial neural networks and artificial intelligence, developers and researchers are taking completely new approach to develop clinical diagnosis decision support systems. Even though simple neural network may be similar to Bayesian probabilities logic but in general neural networks technology is very complex requires lot of patient’s data to train the neural network. Use of artificial patient data to train the neural network may not be realistic and may affect its performance on real patient’s data.

Some important methodologies & technologies for clinical decision support are Information retrieval, evaluation of logical conditions, probabilistic and data-driven classification or prediction, heuristic modeling and expert systems, calculations, algorithms, and multistep processes and associative groupings of elements. [2]

The following picture shows you the methodologies and technologies for CDSS:

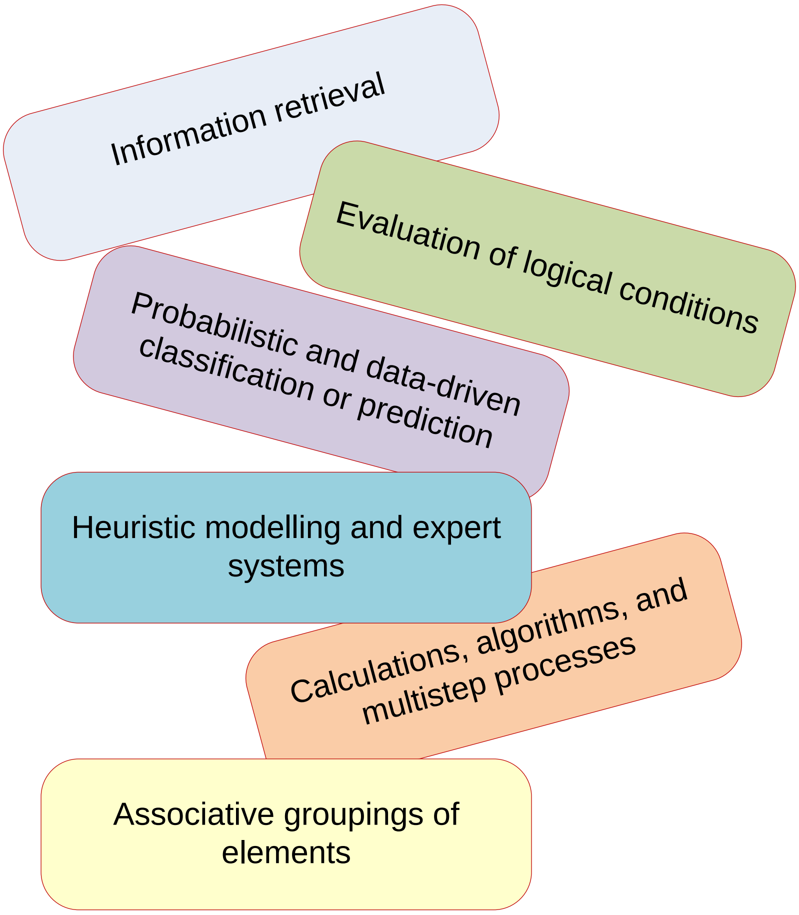

Figure 2 Methodologies & technologies for CDSS picture by Kaukuntla (Author)

Details of the picture explain in the following paragraphs:

Information Retrieval: The ability to search medical related basic information form clinical decision support systems. Basic data related laboratory test and their normal ranges and information related to drugs and side effects. Basic search using search tools to retrieve medical data using keywords. Text search algorithms are also used for searching information regarding patient's data. [2]

Evaluation of Logical Conditions: Widely used logics for clinical diagnosis support systems and various logical conditions were explored. Decision Tables were used for refining and reducing the numbers of diagnostic possibilities. Venn Diagrams were used to represent clinical logic. Logical expressions with Boolean combinations of terms were used along with comparison operators. Alerts reminders and other logical algorithms were developed. [2]

Probabilistic and Data-driven Classification or Prediction: As most clinical decisions are precise, Clinical Diagnosis Support Systems needs to recognize the various types of medical data. Key developments are Bayes theorem based on a formula, decision theory e.g. whether the patient should be treated now or not. Data mining is a database technology to find hidden valuable data and evidence based system processes the data based on evidence. Artificial neural networks and artificial intelligence relative modern technology are still evolving in rapid phase, belief networks, and meta-analysis. [1][2][3]

Heuristic modeling and expert systems: Used for diagnostic and therapeutic reasoning, finding uncertainty in human expertise. Key developments are rule-based systems model that is based on pre-defined rules, frame-based logic.

Calculations, algorithms, and multistep processes: used in computational processes executions, flowchart based decision logic, interactive user interface control, biomedical imaging, image processing, and signaling. Key developments are Process flow and workflow modeling, programming guidelines and modeling languages, procedural and object oriented concepts. [1][2][4]

Associative groupings of elements: Used for structured and relational data, structured reports, order sets, other specialized data views, presentations, business views, and summaries. Key developments are report generators, business intelligence tools and document construction tools, document architectures, document and report templates, mark-up languages, ontology tools, and ontology languages. [2]

Chapter 4 Developing Clinical Diagnosis Software Systems

Any software development requires many disciplined steps to accomplish the product and clinical diagnosis support systems are no exception to that. Every software development requires the following basic steps whether you do it in traditional software development model or iterative agile software development model. (This document does not analyze the general software development methodologies like waterfall or iterative or agile methodologies and their suitability)

Basic steps required for the software development:

- Requirement gathering
- Analysis and design
- Implementation
- Testing
- Releasing

To develop successful clinical diagnosis support systems, developers must start it with clear vision, it should not be started merely to test one algorithm or to test a new technology. Developers should carefully define scope and nature of the application and also need to understand the manual process to be automated. Developers must understand limitations which include technical limitations, scope, boundaries, and data limitation and also make sure that stake holders are aware of it. (This paper does not detail the general development methodologies like traditional, Iterative, or agile. This paper focuses on development of CDSS)

Developers must analyze clinical requirements to determine the usage of the proposed systems and the scale of the system. Algorithms must be studied in depth and find possible condition they might fail. Developers and stake holders must evaluate the automated system carefully outside of the patients area should never be tried on real patients immaturely. Once its functionality is fully established and thoroughly evaluated then it can be evaluated in actual patient's area. Developers and analysts must demonstrate the practicality and usage of the system that can be adopted by physicians for productive daily use. If the system is not used by anyone then it is worthless no matter how great the algorithm and technology is.

There are many critical phases of development that impacts the development and the final product. These include understanding clinical diagnosis process, selecting the clinical area, system analysis, knowledgebase development and maintenance, development, algorithms, and user interface development, testing & quality control, user acceptance testing, and training.

Understanding Clinical Diagnosis Process:

Like any other software development understanding the business is important but in clinical diagnosis software development, understanding the clinical diagnosis process is vital; if the developers don't understand the diagnosis process correctly then it is least likely that they can develop any usable medical diagnosis software. Clinical diagnosis is a specialized knowledge that can only be understood correctly with some substantial medical knowledge. Doctors learn diagnosis process using the knowledge of many medical branches such as human anatomy, medical biochemistry, medical physiology, pathology, microbiology, parasitology, forensic medicine, medicine, epidemiology, surgery, ENT, ophthalmology, pediatrics, radiology, pharmacology, and forensic medicine. Ideally, developer must have some knowledge in these medical branches. Even though there are many defined principles and guidelines for the medical diagnosis, diagnosis process is still considered as kind of art that can only be learnt through medical knowledge and experience. Physicians help in the development process is very important. [1]

Selecting the Clinical Area

If you want to develop a clinical diagnosis system that addresses all the medical diagnostic processes (e.g. querying patient, examining the patient, taking radiological images, and processing them and so on), probably you never will release the product until unless you have infinite number of resources. Selecting the clinical area and domain is very important. Selection of little area results in developing a small tool; whereas selection of very large clinical area and domain will be complex to develop and requires enormous amount of resources and dozens of person-years. Commercial vendors need to analyze the commercial value of the product. Currently clinical diagnosis support systems are not hugely successful in the commercial software market. Even though most large clinical support systems were originally developed in academic and research environment, many such projects may not have findings to sustain development over a period of time.

Selection of narrow domain may probably address small amount of audience, for example if you develop a system to diagnose single rare disease (public screening is not required) then usage of such system is very limited. [1]

System Analysis

Building a clinical diagnosis support system is a complex process and it requires good analytical skills, knowledge, and also capabilities to understand and follow a systemic procedure towards developing such systems. There are various methods, models, and approaches defined for software system analysis. Functional, technical requirements, and nature of the problem need to be analyzed carefully and a feasibility study needs to be conducted. Required time effort should be estimated and cost-effectiveness should be analyzed. All the alternative methods of building the system must be studied. Data structure and knowledgebase construction strategies should be fully analyzed. [14][16]

Knowledgebase development and maintenance

Every software systems require some kind of data to process or rely on. Knowledgebase development and maintenance is vital for clinical diagnosis support systems. Data gathering is the crucial element of the knowledgebase development and it depends on the type of application that you are going to develop. Most of the time knowledgebase development is not a onetime work it evolves continuously. Source of the data varies due to change in medical literatures, medical journals medical statistics, patients' clinical data like hospitals case records, or research data. Conversion and encoding the data relevant to the application is also very important. Initial reports of new clinical discoveries and inventions in medical journals must await confirmation by medical authorities before their content can be added to a medical knowledge database. The nosological terminology and mark-up used in diagnosis must reflect the latest scientific understanding of the disease and pathology. Maintenance of such terminology and data is crucial because they may change over with time.

Knowledgebase development must be scientifically re-constructible so that experts can reconstruct it when required. Additional data like rankings must be based on medical literature, medical statistics and authoritative experts' opinion. Ideally it should be verifiable by medical experts with a user interface. The long term value and reliability of the systems depends on accuracy, quality and latest information of its knowledgebase. Long term success of the successful diagnosis software depends on updating and maintaining the medical knowledgebase. For example MYCIN system was considered very good system for diagnosing infectious diseases but its knowledgebase was never been updated hence the system became outdated and unreliable. [1]

Development (designs, algorithms and user interface)

Even though computer memory has become cheaper and CPU speed has been increased, a developer needs to analyze and plan for complex algorithm's resources usage, and the amount data it processes. Analysts and developers need to converts theory based models into practical implementation of specific models. Development of clinical diagnostic systems involves balancing theory and practicality and also maintaining medical knowledge database. Developers need to design data store or database to store medical knowledgebase and the data access methods. Broad based clinical diagnosis systems require more robust and detailed designs. The resources required to construct and maintain medical knowledgebase is measured in dozens of person years of effort complex and big knowledgebase may require more resources.

At least in current time, human to human interaction is more advanced than computer to human interaction hence the physician interaction with a patient is more advanced than direct computer patient interaction. A physician may not be able to express his complete understanding of an involved patient case to a computer system hence many authors and researchers believe that computers will never replace physicians but I strongly dispute this notion and I strongly believe that computers can replace physicians if the researchers and developers correctly understand the evolution of medical knowledge, immaturity uncertainty of medical data and human centric medical knowledge. However the designs and algorithms should be realistic for given circumstances.

Like any other software development, developers need to follow the development standards and best practices. Algorithms should be developed to solve the diagnostic decision problems using constructed medical knowledgebase. Automating human (clinician) process does not always produce the best results. Sometimes understanding the problem in different perspective and resolving it using existing computational methods may produce better result. If the clinical diagnosis software system interfaces with the patient's medical record systems then developer need to give outmost importance for the security of the patient specific data may need to encryption technologies. [1]

User Interface Development: User interface is one core part of the application, user interface must be appealing to the audience and easy to use. Self explanatory user-interfaces require little end-user training. Developer must understand the audience and the limitation of certain user-interface technologies for example web interfaces are stateless and they have some limitations. Good user-interfaces usually have certain qualities they are intuitive and self-explanatory, have better navigational options, take minimum steps to accomplish the task, provide some shortcuts, and provide help. The design of user interface impacts the user's time to input the data, and the training required for the user; there are no well defined principles to design user interface but there are many best practices advised. Usability is the most important factor to consider while designing the user interface.

Understanding system's audience is crucial to good user interface development.

Testing and Quality Control

Testing and evaluation of clinical diagnosis software should be ongoing process unlike other system it ends with release of the product testing and evolution should be continued for long period of time. Medicine and clinical practices evolve in rapid phase; systems should be upgraded and tested continuously. Testing and evaluation of the clinical diagnosis systems should also test whether the system improved the quality of clinicians work or not

In iterative environment testing starts at the beginning of the development and continues cyclically along with the development. Developers and testers interact closely. Every result must be carefully analyzed; failed and successful diagnosis should be carefully analyzed and new clinical data should be tested and compared with experts decisions. Review of the medical knowledgebase must be carried out with every test results and in addition regression test must be carried out with every change or upgrade.

Evaluations of clinical diagnosis support systems should take into account the following four perspectives:

1. Appropriate evaluation design.
2. Specification of criteria for determining diagnostic support systems functionality and efficacy.
3. Evaluation of the application boundaries or limitations of the clinical diagnostic support systems.
4. Identification of possible reasons for lack of system effect.

[1][26]

Appropriate evaluation/testing design: Test and evaluation case should be appropriate for project requirements or functionality. Testing must be within the scope of the application; initial evaluation must be based simulations or sample data. It should not be evaluated or tested in real environment initially. Each system function may require different types of evaluation. Testing should clearly state which clinician’s or user’s objective is being evaluated and what system’s functionality does that job.

Test/Evaluation of the system must answer the following questions:

- Are the problems real-time clinical practice problems, or simulated problems used for the evolution?
- Is the test case generated from real patient's medical data?
- Are the evaluation subjects to clinicians whose participation occurs in real time patient care environment as a test case?
- Is a clinician evaluating abstract of the case that they have never seen, or is other user evaluating abstracted clinical case using the computer system?
- Is the user has full access to the system and can use all the components or the study/test/evolution is limited to the certain parts of the system?

[1][2][26]

Specification of criteria for determining diagnostic support system's functionality and efficacy

Test criteria for passing the test should be same as what physician would need in actual clinical practice. Diagnostic advantage and practical benefit must be defined. Final or confirmatory diagnosis criteria must be agreed, for example, provisional diagnosis data should never be used for comparison study.

Evaluation of the application boundaries or limitations of the clinical diagnostic support systems

A diagnosis system may not give you desired results if tested outside the scope of the application for example MICIN is developed for infectious diseases if you test that application for a non-infectious clinical case then results may be different. You test application for out of scope functionality once the application thoroughly tested for in-scope functionality. Application should be initially tested with in the scoped clinical domain.

Identification of possible reasons for lack of system effect

Some time there many other external and internal dependencies are required for the clinical diagnosis system to function correctly. Testing strategy should examine the factors that influence the systems output. For example, a clinical diagnosis system that uses lexical analysis systems to process the user input may impact the functionality of clinical diagnosis system. It is also important to find out the system related factors for example medical knowledgebase errors, faulty algorithms, or any other factor that impact the systems performance. [1]

User Training

Clinician's training is essential, once the system is ready to use. Clinicians need to be aware of the limitations of the system and has to know most effective way of usage User should also have the awareness of authenticity and reliability of the system. False assumption of the system's functionality t could potentially harm the patient; over or under estimation of the system's capability is not useful. .

Chapter 5 Existing Clinical Diagnosis Software Systems

There are many Clinical diagnosis support systems in the market that aid and guide clinician to diagnose the clinical cases correctly like Present Illness Program (PIP) developed by Pauker, MEDITEL for adult illnesses developed by Waxman and Worley, MYCIN developed by Stanford University, Internist-I developed by Pople[19], Myers, and Miller[17] in University of Pittsburgh, QMR developed by Miller, Masarie, and Myers[28], DXplain, developed by Barnett and colleagues, and Iliad developed by Warner and colleagues. Almost all the clinical diagnosis systems take the user input and process the input and come up with possible diagnosis list. Even though there are many clinical diagnosis system are developed or under development. The most popular are the following. [17][18][19]

1. QMR(Quick Medical Reference) --First Databank, Inc, CA
2. MYCIN -- Stanford University.
3. Iliad --University of Utah.

4. Internist-I --University of Pittsburgh.
5. DXplain --Massachusetts General Hospital, Boston, MA
6. Isabel --Isabel Healthcare Inc, USA

These systems haven't made big impact on healthcare.

The following graph shows the percentage of the usage of the systems (Usage of these systems for 100 doctors who is aware of the information technology).

[Appendix A: Questionnaires]

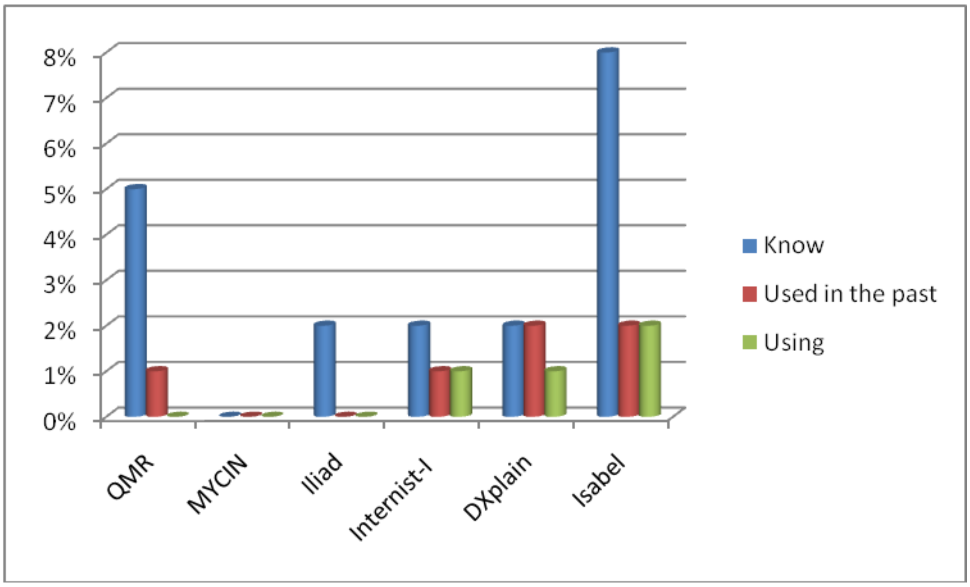

Figure 3 Clinical diagnosis support systems usage by Kaukuntla (Author)

QMR (Quick Medical Reference)

Developed by First Databank / Camdat Corp, CA

It is one of the first tried applications to help in the clinical diagnosis; it provides detailed information and resources that help doctors and clinicians to diagnose the diseases. It provides electronic data bank access to more than 750 common diseases and their complete symptomatology that acts as a decision support tool. QMR knowledgebase includes more than 6,000 clinical signs, symptoms and laboratory findings that describes and explain the disease. QMR developers claim that all the clinical findings in the QMR database are extensively reviewed by medical experts.

QMS provides functionality to generate extensive DD (differential diagnosis), suggests possible test to diagnose the case, store and manage the case history, QMR developers claim that it is an “expert system” improves medical care by allowing doctors to manage the medical cases more efficiently. The performance of the program is reasonably good, installation and usage is simple; Physicians enter their clinical findings and search for the suggestions and further help, the program processes the physician input comes with the results similar to search engine. Physician can search by disease for example “Hodgkin lymphoma” is entered then it lists the disease symptomatology, physical signs, lab investigations associated with the disease and differential diagnosis. Developers claim that it is very rare that it returns error however I could not verify and confirm the claim. QMR also provides list of associated conditions and provides you the details of severity, possible complications and the clinical measures of the disease. However it was noticed that the systems was missing many possible complications of many diseases. [28]

QMR is developed mainly to provide a medical diagnostic tool; it provides functionality to generate diagnostic hypotheses based on entered clinical signs and symptoms. The first method is user enters maximum six clinical finding then searches for differential diagnosis to get possible diagnosis. The second method is user enters complete clinical findings of the patient in response it processes the input and provides notes for each finding. Once a list of differential diagnosis is generated, the physician can apply other program features to the proposed diagnostic hypothesis to refine the diagnosis further.[28]

For example “Finger clubbing” generates list of diagnosis that includes Crohn's disease by double clicking on the disease gives you further details like physical signs, lab tests and its complications. The programme also suggests further input so that physician can get more information from the patient by questioning more and further clinical examinations.

I could not get the copy of the software to test it myself and I could not find any doctor used or using this software; my analysis is purely based on the available literature. This software has many significant flaws and errors that potentially misguide the physicians, algorithms used in this software is not sophisticated enough to provide good diagnostic help. I could not find a single hospital or a medical centre using this product, apparently First Databank withdrawn its support for this product and I consider this is a failed product.

MYCIN

Developed by Stanford University

MYCIN was one of earliest diagnosis support systems developed with a short range of functionality operated using simple inference engine with a database of over 600 rules. It is relatively simple diagnostic system and uses simple yes or no questions to get input from the clinician and finally comes up with the possible name of the bacteria. It uses certainty factors as opposed to uncertainty factors and this makes the application fairly simple.

MYCIN usage is simple and limited. Researchers tried the system for therapeutics and they have observed that it suggested relatively correct treatment in about 69% of the cases which was surprisingly better than diagnosing infectious diseases for which the system was originally developed. However there is no agreed standard for treatment hence the observation was not agreed by many researchers. MYCIN's strength was in its reasoning approach, it introduced the rule based system development which was used and implemented by many other non-medical domains after MYCIN. [17][18][19]

Even though it exceeded the expectations and outperformed the Stanford medical school faculty, it was never actually used in practice for various complex reasons. It covers only small area of internal medicine. Doctors are not convinced that computers can actually diagnose the diseases, and for ethical and legal issues relegated the usage of computers in medical diagnosis. MICIN takes very long time to complete its diagnosis process and this time consumption may be realistic to the physicians. Even though this was technically successful but it has failed to impact on the health care system. The system is not in use anywhere outside the Stanford medical school.

Iliad

Developed by University of Utah

Iliad is a diagnostic expert system for Internal Medicine; developing and improving by the University Of Utah School Of Medicine's department of Medical Informatics for last two decades. The system supports more than 5000 clinical findings and provides reasonably accurate diagnosis for more than 1,500 medical conditions. One of the important features that Iliad offers is the ability to analyze a particular patient's case and to determine the most cost-effective method for diagnosing and treating the patient. Iliad was developed originally for the Apple Mac; and a version for the PC running windows has also been released. Iliad is primarily used as a teaching tool for medical students. This helps the students to improve their skill in differential diagnosis. A clinical case can be simulated through this system and students have to diagnose the case.

Students can query Iliad for useful patient history, physical examinations, or required laboratory investigations for the patient. Iliad process the query and evaluates alternative decision strategies with the use of "best Information Algorithm" this is combination of content, weightage and the cost. Process result then provides alternative work-ups in the order of cost-effectiveness

Iliad is developed based on Bavesean logic and Boolean knowledge frames to illustrate disease in internal medicine. The frames allow the use of sensitivities, specifics, and rules to describe the relationship between disease and its symptomatology and provides a basis for Iliad logic.

Internist-I

Developed by University of Pittsburgh

Internist-I is a broad based clinical diagnosis support systems and the major contributors for the development of the project include Randolph A. Miller, Harry E. Pople, and Victor Yu. It was originally developed for cases in internal medicine. Internist-I was core part of “The Logic of Problem-Solving in Clinical Diagnosis” course in university of Pittsburgh for nearly 10 years. With the help of medical experts the fourth year medicos in university of Pittsburgh has been entering and updating the medical data in to the system. They encoded the clinical and pathological finding and standard medical reports in to the system. By 1982 INTERNIST-I project had fifteen person-years medical data entry, and covered 70 to 80% all the possible diagnosis in the medicine. [17][19]

Information stored in the system includes symptoms and signs, laboratory investigation results, and the patient’s case history. Internist-I did not follow the traditions of other systems instead it used the powerful ranking system. It ranks clinical findings in relation to the disease and it ranks disease itself depending on its occurrence. It also uses heuristic rule based partition algorithm to create problem area and exclusion functions to eliminate diagnostic possibilities. These rules create list of diagnosis in probable ranking order. When input data is not enough to suggest the diagnosis then system asks for further information or further examinations to resolve the case. Some documentation claims that Internist-I works better if the clinical finding of the patient is related to the one disease but other documentation disputes the claim and claims that it handles very complex cases very well. However I believe that it can diagnose cases with a single decease when compared to complex disease because of its dependence on hierarchical decision tree logic which links to the one root disease.

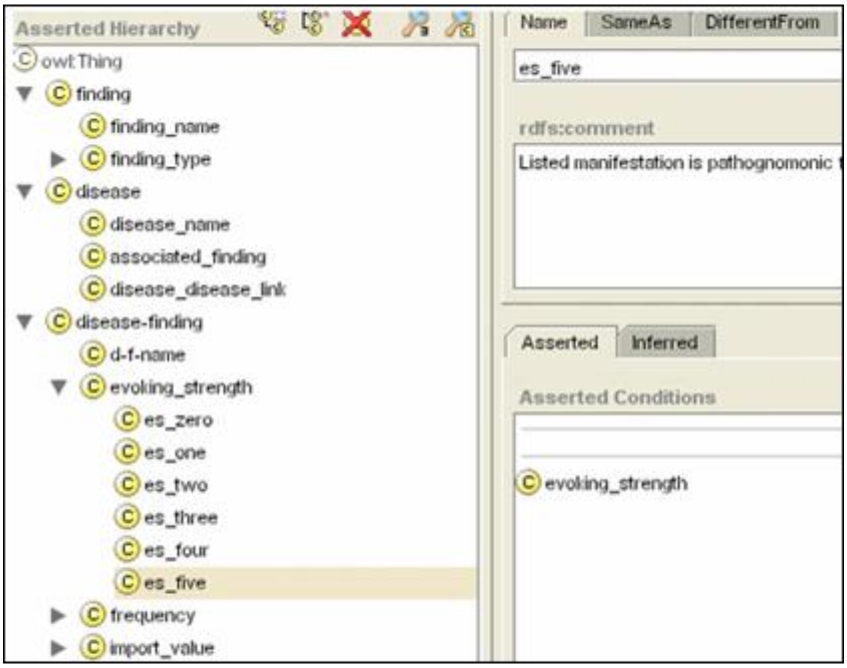

Figure 4 Internist-I user interface --From Internist-I web site

In 1979s Internist-I was used as an experimental clinical diagnostic tool for educational and internal use purpose in the university hospital of Pittsburgh. Even though it was used internally, the developers always intended to make it a global product. Still it is not widely used and lengthy training is required to use the application effectively. It takes longer time to input all the required data and an average consultation may take up to ninety minutes. I could not find any doctor using this product outside the University Hospital in Pittsburgh. I believe it is still used internally as a research and learning tool.

DXplain

Developed by Massachusetts General Hospital, Boston, MA

DXplain has been in use for the last two decades. It has evolved and gained some popularity over the time. First version was developed in 1984 with illustrations of about 500 common diseases and it was released in 1986. Further versions were released in 1987, 1090, 1991, 1095 and 1996 with deceases and functionality. Since 1996 DXplain has been completely web based.

DXplain is a clinical decision support system and it functions in two modes, electronic medicine book and a medical reference system or case analysis mode. In reference or case analysis mode, it accepts patient's clinical data like signs, symptoms, and laboratory findings and processes the data and produces the list of probable diagnosis in an order. It also provides logical reasoning for each of the diagnosis and why it was considered so that the physician/student can explore more regarding its manifestations. In medical textbook mode, DXPlain provides illustrations of over 2300 diseases and it explains the signs and symptoms of the each disease. It also provides epidemiology, etiology (cause of the decease), pathology, complications, and the prognosis of the disease. In addition it also provides up to ten references for each disease and these references provide more information, reviews and research information regarding the disease.

The current version of DXplain includes over 2300 diseases and over 4900 clinical manifestations (symptomatology, physical signs, epidemiology, laboratory investigations and other modern investigation findings like endoscopy, CT-Scan and MRI findings). Every disease consist minimum 10 clinical findings to maximum 100 clinical findings. Each clinical finding is related to one or more diseases and with the frequency of its appearance in the disease. There are over 230,000 data relationships between a clinical finding and a disease. Each clinical finding has 1 to 5 disease independent rating to indicate its significance. Each disease also has two related values crude approximation and prevalence and disease also ranked between 1 and 5 based other reasons.

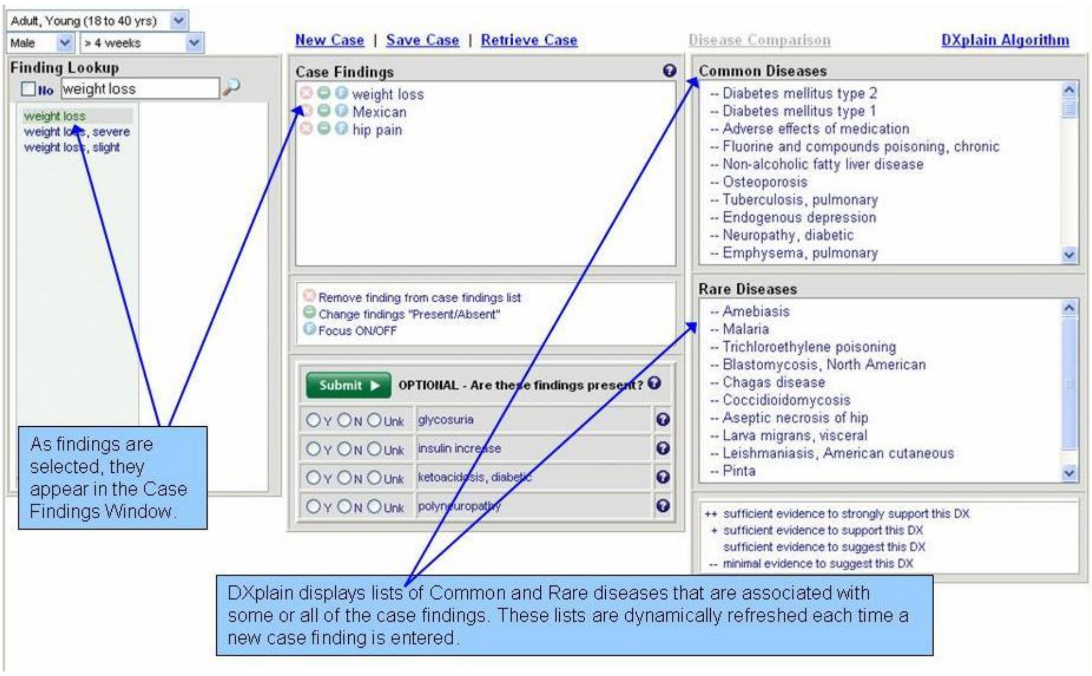

Figure 5 DXplain user interface --from DXplain website

DXplain accepts variety of clinical findings, including epidemiological findings, signs symptoms, laboratory investigations list such as pathological findings, X-Ray, Ultrasound, Doppler, ECG, EEG, endoscopic findings, Angiocardiogram, CT-Scan, MRI and breathing tests etc can be entered as comma separated values. [17][18][19]

In my opinion DXplain is based on very good pragmatic logic; it is very close to my proposed solution and similar to Internist-I. However, it is not hugely popular so only a few doctors are actually using it. It is not clearly mentioned where the stats that the system is using are coming from and what is the credibility and authority behind its ranking. I thing its success is average but it has a good future.

Isabel

Developed by Isabel Healthcare Inc., USA

Isabel is a widely used web based clinical diagnosis support system, Isabel accepts either key clinical findings or whole text entry of the clinical case and processes the request by using novel search strategy and identifies probable diagnosis from the given clinical findings. The physician can enter unlimited clinical conditions or complete case to find the probable diagnosis. The program also includes the data dictionary of the medical terms and clinical conditions and the library includes six medical textbooks and 49 major medical journals. The search results are filtered on epidemiological findings geographic location, age, sex and hobbies and system then displays more than 30 probable diagnosis. Up to ten diagnoses are presented on first webpage with web links. Physician can then explore each disease by clicking the link, to see other possible diagnosis; physician can click more diagnosis link. [27]

Isabel has web based user friendly interface and usually no training is required to use the interface, and all the links are self explanatory.

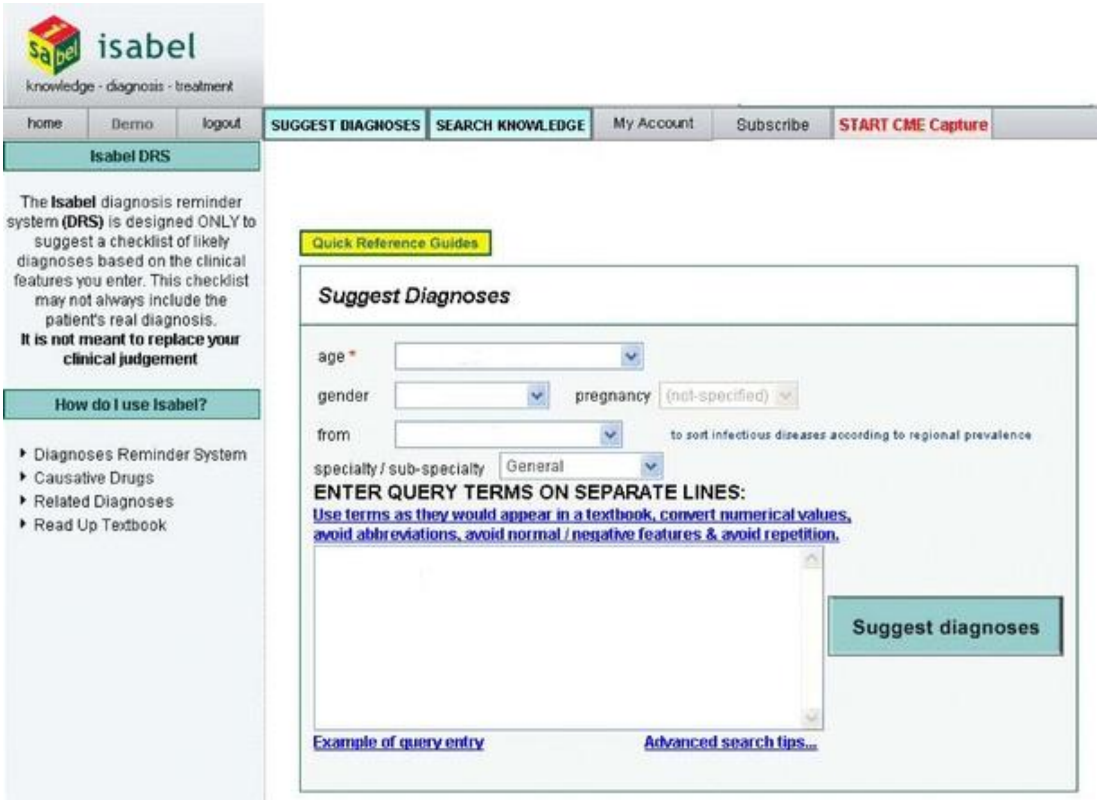

Figure 6 Isabel user interface -- From Isabel website with permission

The Isabel Clinical Diagnosis Support System originally developed to aid pediatricians, and about 13 clinical staff at St Mary's Hospital, London submitted 99 clinical case presentations for DD (differential diagnosis). Isabel claimed that it has diagnosed the cases with 91% accuracy, Also Isabel claimed that out of 100 real clinical cases from four major UK teaching hospitals it has diagnosed with 95% accuracy. After these trials Isabel was improved and upgraded to support adult diseases.

Isabel uses natural language processing and search algorithm that searches clinical data in the database system and comes up with new 30 diagnosis. However exact algorithm that Isabel uses is undisclosed and company does not want to reveal it.

Recent release of Isabel is called Isabel PRO and it has two major components Isabel PRO Diagnosis Reminder System (IDRS) and Isabel PRO Knowledge Mobilizing System (IKMS). [27]

Isabel PRO Diagnosis Reminder System: Gives a probable diagnosis list for given signs, symptoms, and epidemiological finding and laboratory investigation results. Many physicians were involved in the development of Isabel and many doctors evaluated it. Isabel can be used in every stage of diagnosis process cycle from case taking to the treatment. Physicians can explore improve and refine their differential diagnosis knowledge. [27]

Isabel PRO Knowledge Mobilizing System (IKMS): Has tutored taxonomy of over 10,000 diagnostic categories each of this process kernel of knowledge this intern uses concept search as opposed to keyword search. It also provides tagging functionality that can be used for physician’s workflow. [16]

Isabel Pro is currently available for hospitals and poly clinics interfaced with high profile electronic medical records (EMR) systems in the USA, Isabel provides input filed for age, sex, and clinical conditions and a “Suggest Diagnosis” link button to the process the data. It returns results in separate window when the “Suggest Diagnosis” link is clicked. User can explore and refine the diagnosis by entering more finding and clicking relevant links. It also provides additional intelligent layer suggest more options to the clinician. [27]

Even though Isabel claims that it is more than 95% accurate but in my opinion it is far less than that. No authority approved the Isabel and the search algorithms are dependent on database text that is not 100% accurate. Diagnosis is a life critical process and I do not think searching text database for input clinical condition is appropriate for life critical systems. Even though it gives somewhat better results comparing with other systems, it may not make very big impact on clinical diagnosis and health care.

Most of the existing system can diagnose the cases up to certain extent but they are not mature enough to use in life critical environment, they need to be evolved further with above 99% accuracy with better algorithms and with better data store.

Clinicians are not much impressed with existing clinical diagnosis support systems. [Appendix A: Questionnaires]

The following graph shows usefulness of the systems:

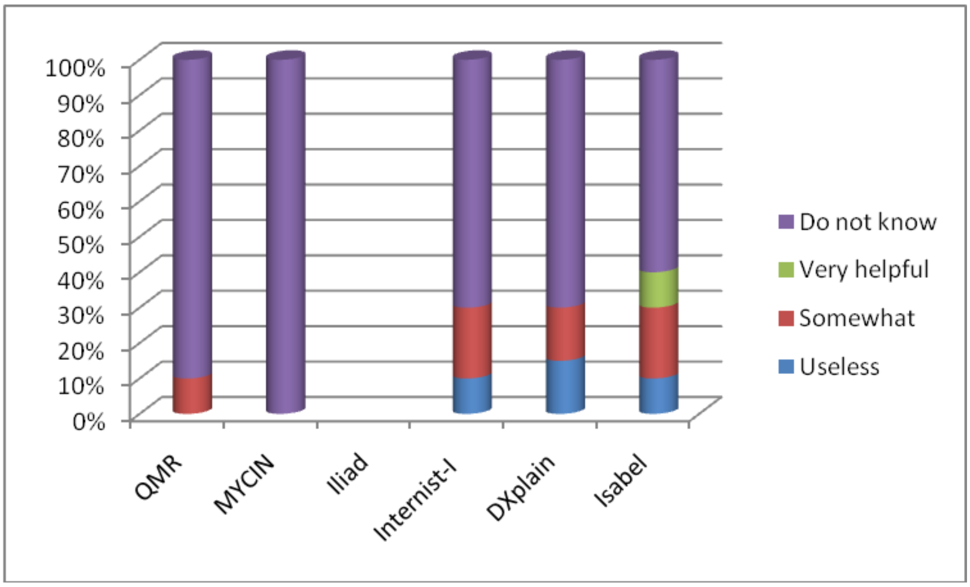

Figure 7 Usefulness of clinical diagnosis support systems by Kaukuntla (Author)

Reasons for CDDS unpopularity:

- CDD systems are not mature enough to use in a life critical environment.
- Developers haven't deeply understood the medicine, clinical diagnosis process.
- Doctors do not have faith that current systems can actually diagnose a clinical case like an experienced physician.

Chapter 6 Proposed Clinical Diagnosis Support System

All the current medical knowledge and information is evolved as a human centric data; for example symptoms of a disease are defined as common, rare and very rare in their occurrence. This information is easier for humans to use but for computers it is not a very good data to process.

Many researchers studied and analysed human diagnostic reasoning [explained in chapter 3] and developers tried to mimic human diagnostic reasoning through complex software algorithms.

It is very hard to mimic human reasoning. For example, to develop a auto driver system for a car, if you try to read roads and objects with a computer programme like human beings do then it would be tremendously complex to write such algorithm. At least for now it is difficult. If you try to solve the problem with a precise data (e.g. digital marking of road borders and GPS) and objects then there will be a better chance of success.

Current CDD systems either use text search algorithms or mimic human diagnostic reasoning with complex algorithms. Text search algorithms never really provide accurate diagnostic suggestion and on the other hand mimicking human diagnostic reasoning by using human centric medical knowledge is very complex.

Because of advancement of information technology, networks, and the availability of medical statistics, now it is possible to convert human centric medical data in to computational centric medical data. For example "clubbing of fingers rarely seen in cirrhosis of the liver" can be converted to "clubbing fingers seen 0.1% of cirrhosis of liver" and this computational centric medical data is easy to process. Then the question is "Is it possible to convert all the current medical knowledge into computational centric medical knowledge?" and my answer is "Yes".

Proposed clinical diagnosis support system will use computational centric medical data. First, medical knowledgebase will be converted into statistics based computational centric medical knowledgebase. Each sign, symptom, and laboratory result will be saved with exact percentage of occurrence in relation to decease. And deceases will be saved in exact percentage of their occurrence globally, geographically, and epidemiologically. Then the system takes clinician's input and processes the data and calculates percentages of occurrences and brings best matched result. However, the algorithm does not simply compute the total percentages but also does other logical calculations. For example one symptom occurrence is 100% in a particular disease but if it is not present in the input even with the other symptoms which suggest the disease, the system downgrades the rank of the disease.

The proposed system is very close to DXplain but there are fundamental differences between these systems. DXplain uses 1-5 raking that is nowhere near to accurate and it is still based on human centric medical knowledgebase whereas the proposed system uses precise computational centric data. Percentages of clinical findings, epidemiological percentages of disease occurrence, and deductive method for non-present clinical findings will give better results. Proposed system's algorithms will be very close to chess game algorithms which give the highest points move.

Advantages of the proposed system:

- It will diagnose more accurately than the existing systems.
- It will be based on precise percentage based data hence results will have some kind of authentication.
- Epidemiological occurrences of diseases will give better results.
- System will evolve along with medical statistics.
- It will use simple algorithms.(do not need to mimic human reasoning)
- Will be easy to implement and maintain.

Disadvantages of the proposed system:

- Converting existing medical knowledge into statistics based medical knowledge is difficult and expensive.
- Requires extensive medical statistics

- May not give you accurate results with partial data input.(it suggests for missing data)

Chapter 7 CDSS Prototype

I have developed a prototype to support my proposed clinical diagnosis support system. However, to develop real prototype takes huge number of person-years; this is a basic prototype to support my proposal. CDSS prototype demonstrates diagnosis by taking clinical findings as user input and displays possible diagnosis. This prototype makes differential diagnosis of pain abdomen between Gastritis and Appendicitis.

Technologies and programming languages used: C#.NET, ADO.NET, MS Access, and Windows Vista.

Business Logic: Diagnosis, Diseases, Disease, DeseaseFindings, DeseaseFinding, Findings, Finding and DbAccessor classes provide business logic of the prototype. They are developed using C# programming language. DbAccessor class access' data from MS access database. [Ms Access is widely used database for prototypes].

User interface: Windows and MDI (Multi document interface) based user interface is provided. Diagnosis, Disease, and Finding windows take the user input.

To find a diagnosis, user clicks on new menu or toolbar button and enters the clinical findings and clicks "Diagnose" button. It displays all the possible diagnoses in probability rank.

The following screenshot shows you the diagnosis window of the prototype

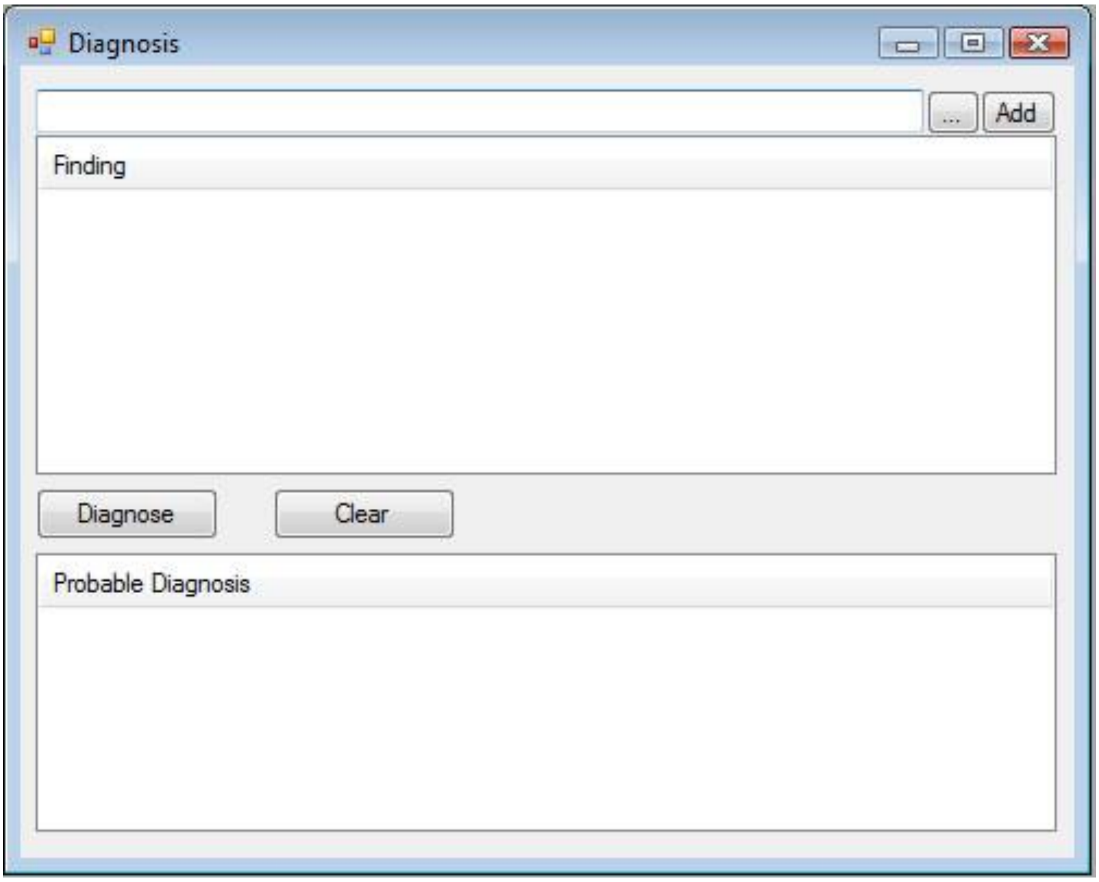

Figure 8 Diagnosis window of the CDSS prototype by Kaukuntla (Author)

Conceptual class diagram of the prototype is shown below:

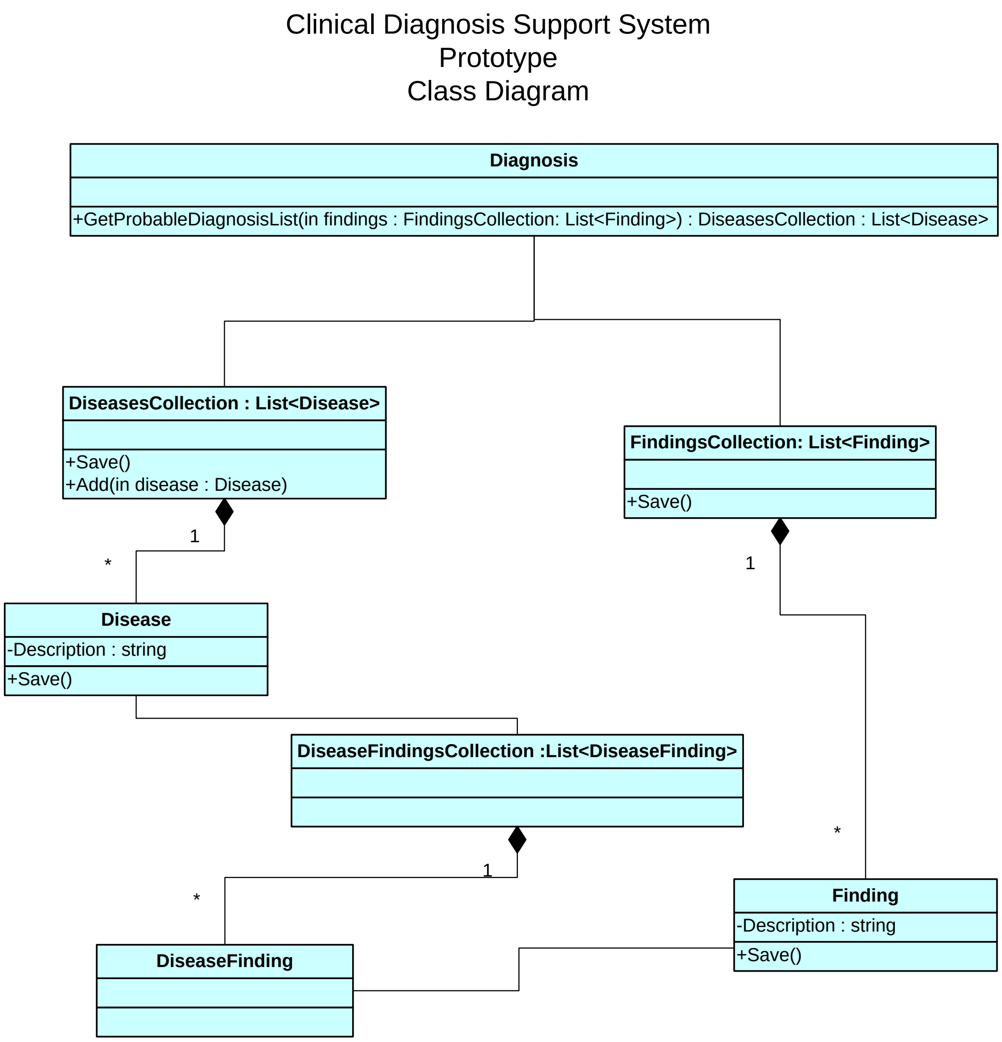

Figure 9 Prototype class diagram by Kaukuntla (Author)

Prototype also provides user interface for medical knowledgebase entry, user can build diseases and clinical findings database that will used for diagnosis logic. It also provides basic print functionality.

Chapter 8 Legal and Ethical Issues

In USA, proposals have been submitted for US Food and Drug Administration (FDA); these proposals include a variety of recommendations that vendors of clinical support systems require to perform to guarantee that the systems would function as per recommended standards. It would be very expensive for the governments to standardize and regulate the clinical diagnosis systems. Before regulating the clinical diagnosis support systems they should undergo huge number of real-time trials and that would cost a huge amount of money. [1]

Another major dilemma of government authorities on regulating the clinical diagnosis support system is “medico legal cases”. If there is a disputed diagnosis case brought to authorities and doctor can claim that the diagnosis system was wrong. How the investigators can confirm what the actual correct diagnosis was and if they want to create same environment once again they need complete system’s information and status and the entire patient’s information at the disputed diagnosis was offered. This could potentially breach patient’s confidentiality and also there may many other issues that come-up like how well clinician was trained on that particular system. To investigate such cases the investigation agency or author must have complete knowledge of such systems.

For last one decade, clinical diagnosis software systems and other medical software systems raised many important ethical issues including who should use these systems and under what circumstances, what about the physician autonomy, and who is responsible for the mistakes made by the system. Three main areas of ethical concern have emerged in discussions of medical software systems:

- Care standards
- Appropriate use and users
- Professional relationships

[1][2]

Many ethical concerns arise if these systems do not maintain medical standards, if the users do not understand well how to use these systems, and this might affect the professional relationships. In the future, scepticisms about the usefulness of the clinical diagnosis support systems in medical practice may decline. Because of the improvements in quality, reliability and accuracy of these systems, usage of the stems will increase in clinical practices. When these systems become routine in clinical practices then the authorities may try to formulate regulations and may increase the vigilance to make sure that the legal and ethical issues cannot be ignored. [1][2][15][16]

If these systems evolve in to more advanced and intelligent expert systems that could diagnose a medical case without a clinical expert then the systems will pose greater ethical and moral issues.

Chapter 9 Conclusion

With the advancement of computer technology and networks, clinical practices are using information technology more and more in their clinical practices and it is changing the way they work. Not long time ago, Doctors used to read ECG (or EKG American) manually by analyzing P, Q, R and S nodes and generate the ECG report but now doctors are using the automated ECG machines that analyses the lead graphs and generates the accurate ECG report and it is more than 99% accurate, and some of the doctors are even forgetting the ECG reading skills and are relying completely on the automated ECG machine's report. I can easily speculate that clinical diagnosis support systems will have the same future as we have seen for ECG machines.

In future, clinical diagnosis systems will proliferate, and clinicians will use them extensively; new and advanced expert systems will be developed. Human reasoning centric medical knowledge databases will be converted into computational centric medical databases and they will be used more affectively. Large scale generic clinical diagnosis systems will be developed and used extensively. As internet and network speed is increasing, centralized mega systems like Google search engine will be developed and will be used by medical centers all over the world. In very near future, many other medical devices like ECG, blood, pathological, histo-cellular analysis machines, radiological image processing devices and patient record systems will be integrated in to the clinical diagnosis support systems and they will function as a single unit. However, a number of important challenges of clinical diagnosis support systems will remain to be solved for at least few more years. CDSS will pose potential danger of “clinicians over relying on the systems” that could lead into decreased clinician’s diagnostic skills and standards.

Many experts believe that the clinical diagnosis support systems never will replace physicians in diagnosing a clinical case, even though there are many reasons to believe that but I strongly disagree with it. I believe within next two decades clinical diagnosis systems will be as good as or even better than expert and experienced physicians. And within next five decades these systems will directly interact with a patient without any help from a clinician.

Clinical diagnosis support software systems can greatly improve clinical diagnosis and reduce the clinician’s errors. Most of the doctors are still relying on manual clinical diagnosis process; this is because most of the current systems are not very accurate in suggesting clinical diagnosis and doctors do not trust these systems.

There is very bright future for these systems and the capabilities will improve and clinicians will adapt to the technology. Manual clinical diagnosis process is based on human centric medical knowledge, developing applications based on human cantering knowledgebase is more complex, I think, there will be better chances of developing a most reliable clinical diagnosis application if the human centric medical knowledgebase are converted into computational centric data.

In the future there will be no surprise if the patients are treated by robotic doctors.

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