CLINICAL DECISION SUPPORT SYSTEM FOR HEMATOLOGICAL DISORDERS

Assist Decision Making Concerning Hematological Disorders through Complete Blood Count and Evidence Based Medicine

By

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CERTIFICATION OF ORIGINALITY

This is to certify that I am responsible for the work submitted in this project, that the original work is my own as specified in the references and acknowledgement, and that the original work contained herein have not been undertaken or done by unspecified sources or persons.

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ABSTRACT

Evidence Based Medicine has become a popular approach to medical decision making. It is a method of assisting clinical decision making by using the most relevant research evidence to answer the clinical question. First formally described in 1992, the method offered the chance of improving the quality of clinical care by encouraging rigorous appraisal of new evidence (Thomas KB, 1974).

Complete Blood Count is one of the most commonly ordered blood test that could be done within minutes and is mostly used as a basis for future testing. (Siamak T. Nabili) Therefore CBC is a great way to quickly diagnose a patient and later on, use evidence via EBM to further diagnose the patient.

This project will answer the problem of general practitioners needing a system to accurately produce a minimized list of possible diseases as quickly and as accurately as possible through CBC test result data. The system would then help general practitioners overcome the problem with EBM by assisting them in browsing through the vast amount of evidence effectively and feasibly in order to make a quick decision.

The project scope mostly covers the clinical data needed for a clinical decision support system to run. Knowledge on CBC results and blood disorders are also required to form an algorithm that takes in all factors into producing a list of probable diseases. Ways of indexing and evaluating evidences are needed for producing a system that assists in EBM. The keyword filtering concept is used to allow general practitioner to browse through evidence quickly and capture tacit knowledge on evidence browsing. Methodology used for the project is the spiral development model where the project will be broken down into 3 parts and built step by step.

A fully developed prototype proposed by this project would promise a quick and easy way to diagnose patients with probable hematological disorders based on CBC test results and allow general practitioners to efficiently and feasibly browse through evidence to make a decision.

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INTRODUCTION

1.1 Background of Study

The main study of this project is about finding ways to get accurate symptoms or data from patients and tie it to a haematological disorder or blood disease. After determining the disease, the evidence based medicine (EBM) approach is used to determine a prescription for a patient.

In tackling the first challenge of extracting accurate symptoms from a patient, many problems will be faced. Firstly, relevant patient data needs to be extracted from patient. Age, sex, allergies, and many other factors would influence the disease's impact on the individual. These data also needs to be collected and carefully organized for it will assist general practitioners in making decisions later. Other than that, different patients might have different symptoms. Patients sometimes fail to convey how they are really feeling or their symptoms or they do not experience the symptoms as they should. An example would be for cancer patients. Not all cancer patients would show symptoms and sometimes when the symptoms shows, it is already too late. A way of getting accurate data from the patients is through their blood, which would not lie.

General practitioners could use the complete blood count (CBC) tests to learn more about the patient. CBC tests are one of the most commonly ordered blood test (Siamak T. Nabili, MD, MPH). The complete blood count is a calculation of the cellular (formed elements) of blood. For example, the major portions at cellular level of the blood would be the red blood cell, white blood cell and the platelets. The test is done by extracting a few millilitres (one to two teaspoons) of blood sample directly from the patient

According to a trusted website (Sonora Quest),

Results from the CBC test can help:

- Provide basic information about your health
- Detect a health condition before you have any symptoms
- Confirm that a health condition exists
- Identify the causes of your symptoms
- Find out if your medicine is working
- Rule out a disease
- Establish a baseline that can be used for comparison with future test results

The second challenge is to assist the general practitioners in making decisions once the disease has been diagnosed via CBC. To solve this problem, the evidence based medicine (EBM) approach will be used. It is a method of assisting clinical decision making by using the most relevant research evidence to answer the clinical question. First formally described in 1992, the method offered the chance of improving the quality of clinical care by encouraging rigorous appraisal of new evidence (Thomas KB 1974). These evidences would include top grade journals and would further assist general practitioners in diagnosing the patient and in making decisions on what to do with the diseases. The problem at hand is that there are too many journals to cope with. The system would have to allow general practitioners to easily breeze through the many journals and only showing important parts that those journals.

In conclusion, this study requires knowledge of extracting relevant patient data, Complete Blood Count, hematological diseases, Evidence Based Medicine, and programming skills to deliver a system that could integrate all these knowledge to assist in making decisions.

1.2 Problem Statement

1.2.1 Problem Identification

General practitioners face many challenges when diagnosing and prescribing medication to patients with haematological disorders especially under conditions of urgency and long working hours that could have increase the risk of making wrong decisions.

They need an efficient way of gathering important information from patients before diagnosing them. Later, they would need some assistance in diagnosing a disease, which could be thousands to choose from. After diagnosing the patient with a haematological disease, the general practitioner would have to use EBM methods to double check their diagnosis and to come up with a prescription. The online biomedical literature grows quickly with approximately 30,000 articles annually. Furthermore, many current repositories are characterized by poor indexing and querying methodologies. Doctors will have trouble referring to these journals for solutions.

Thus, general practitioners need a system to get accurate symptoms/data from patients and then tie it to a minimized list of possible diseases. General practitioners will then use EBM to pin point a disease and find a prescription using the system.

In the proposed system, CBC test results are used to determine the disease and EBM approach is used to finalize the diagnosis and assist in making prescriptions.

1.2.2 Significance and Relevancy of the Project

The significance of this project is that the system will provide general practitioners with accurate decisions with less risk of bad and possibly life threatening decisions. The general practitioners will also be able to make these decisions faster and with less hassle with the aid of the proposed system.

Besides that, there are many factors to be taken into account when diagnosing a patient with a hematological disorder. The factors are too many, and could sometimes be confusing and irritating. The system would include and organize all this factors in assisting the general practitioner in making decisions.

The system would also allow the general practitioner to use the concept of EBM easily to further diagnose a patient and finally write a prescription for the patient.

1.3 Objectives

The main objective of this study is:

- To develop a complete clinical decision support system that applies knowledge of CBC and the concept of EBM for general practitioners dealing with haematological disorders.

The other objectives of this study are:

- To study how to use Evidence-Based Medicine approach in making health decisions based on scientific evidence effectively.
- To develop methodologies for accurately ranking and presenting relevant aspects of clinical evidence for improved discrimination at the point of care.
- To learn how to relate Complete Blood Count test results with diseases.
- To find out what data needs to be collected from the patient for a clinical decision support system.

1.4 Scope of Study

The scope of studies revolves around the clinical decision support system specializing in hematological disorders. The studies will include knowledge on patient data collecting, CBC analysis, hematological diseases, the EBM concept and how to apply the EBM concept into a system.

The programming scope is the clinical decision support system in general using Visual Basic. The medical scope would be hematological disorders. The EBM concept is studied to be applied into the system.

1.5 Feasibility of Study within the Scope and Time Frame

Feasibility analysis was conducted to determine a programming language and database for this system. The results were Visual Basic programming language and the Microsoft Access database. The system could be completed feasibly with these tools because there is already basic knowledge on both subjects and the availability of both the software.

The vast online medical journals and some connections to the medical students allow the feasible collection of medical knowledge required in producing this system. Other than that, many books and online sources regarding to CBC and EBM are available. Obtaining knowledge on these topics would be feasible.

With all the help from tools and sources mentioned above, the proposed system should be able to complete its basic functions within the given time frame.

CHAPTER 2
LITERATURE REVIEW

2.1 Clinical Decision Support Systems

Reviews on today's current clinical decision support needs to be done. The purpose, usability, and importance of clinical decision support systems need to be reviewed. Furthermore, the data needed by a clinical decision support system needs to be confirmed. Information on what makes a clinical decision support system effective is also required.

A clinical decision support system is a computer systems designed to impact clinician decision making about individual patients at the point in time that these decisions are made. (S.Berner & Tonya J.La Lande)

A CDSS requires huge amounts of funds ad a dependable knowledge base but it is a worthy investment and would bring more effectiveness to a healthcare unit. In terms of healthcare as a business, CDSS could bring a competitive advantage to the business. Services and treatments provided by following the "best practice" methodologies are usually facilitated by CDSS and this gives the advantage. The benefits of a clinical information system are evident in terms of the reduction of medical error, the standardization of medical protocol, knowledge sharing, cost control, quality control, and decision support. (Fahhad Farukhi) The CDSS will also help general practitioners become more productive and efficient due to the assistance provided to them. CDSS is a very useful system that could help general practitioners if used correctly.

Developing a CDSS could face many problems and challenges. A CDSS usually needs to be integrated with an often complex health care organization's clinical workflow. Most clinical decision support systems are standalone products

that lack interoperability with reporting and electronic health record (EHR) software. The exceptionally high numbers of continuously increasing clinical researches and medial trials makes it difficult to incorporate the resulting data. Furthermore, incorporating large amounts of data into existing systems places significant strains on application and infrastructure maintenance. (Search Health IT, 2010) With these challenges known, the system created should be able to be integrated with current patient database and be able to grow/receive more new input which is the results of the never-ending researches being published. The system should be able to be updated regularly without affecting its performance. Data updates must be organized properly in the new system. Data entry is another form of challenge that will present itself in a CDSS development. Some systems require the user to query the systems and/or enter patient data manually. Not only is this "double data entry" disruptive to the patient care process, it is also time consuming, and, especially in the ambulatory setting, time is scarce. It is even more time consuming if the system is not mobile and/or requires a lengthy logon. Much of this disruption can be mitigated by integrating the CDSS with the hospital information system and EMR. (S.Berner & Tonya J.La Lande) Therefore, the development of the proposed system needs to make sure to allow the option of easily integrated databases. It cannot make data queries and information retrieval so stringent that its interoperability is compromised.

A review is also done on the application of the CDSS currently. There are many things that an expert system can accomplish. The list below shows some of the most common applications of a CDSS: (Health Informatics WikiSpace)

- **Alerts and Reminders:** An expert system connected to patient monitoring devices can provide real time alerts and warnings to medical staff in the case of a change in the patient's condition. Warnings in situations like where drugs that should not be used together are used or a dangerous fact that is overlooked could be very advantageous.
- **Diagnostic Assistance:** Patient data can be compared to the system knowledge base in order to present possible diagnoses. This is beneficial when the clinician is inexperienced (i.e. a GP trying to assess a hematological problem) or when the patient's symptoms are complex or seemingly unrelated. The project will focus on

this application where CBC test results are used based on a knowledge base to help general practitioners diagnose patients.

- **Prescription Decision Support:** A specialized CDSS known as a Prescribing Decision Support System (PDSS) can check for drug-to-drug interactions, dosage errors, and drug contraindications such as patient allergies. This is also another part of the system which will be applicable in this project. However, the EBM concept is used to assist in prescription instead of the PDSS.
- **Information Retrieval:** CDSSs can assist in the location and retrieval of appropriate and accurate clinical data which may be used for diagnosis or treatment planning. Depending on the complexity of the system, the CDSS may simply perform as a filter to search queries or be able to assess the importance, applicability, or utility of the information it retrieves. Information like patient data and other important information should be able to be easily and conveniently retrieved by general practitioners.
- **Therapy Critiquing and Planning:** Critiquing systems examine treatment plans looking for inconsistencies, errors, omissions, or potential contraindications. The system works by judging the proposed treatment (as in a CPOE) against the patient data and known standards of care. Essentially, a critiquing system looks at a treatment plan in comparison to a set of "rules". A planning system, on the other hand, uses a knowledge base of treatment protocols and guidelines to actually assist in the creation of a treatment plan. The project will be based on a planning system where the general practitioner will have knowledge base of treatment protocols called ;evidence' which will help the general practitioner create a treatment plan.

Based on the review above, the Hematological Clinical Decision Support System will be bounded by those applications above. By following, those general applications of current CDSS, the proposed system will be made viable in the real world.

There are a few myths surrounding the development of a DSS according to Ted Shortliffe (2006). He challenged 3 basic assumptions which have strongly influenced the development on CDSS:

- "Diagnosis is the dominant decision-making issue in medicine"
- "Clinicians will use knowledge-based systems if the programs can be shown to function at the level of experts"
- "Clinicians will use stand-alone decision-support tools."

While developing the proposed system, these 3 myths will be kept in mind. The main objective of the system is not to diagnose the patient or to take over the job of the general practitioner but it is actually to assist the general practitioner and providing a more meaningful list of choices the general practitioner to make. The system should not aim to be so perfect as to be able to replace the general practitioner but to be able to help the general practitioner reduce chances of mistakes.

Knowledge based decision support system is what this project aims to accomplish. The system was expected to provide information for the user, rather than to come up with "the answer," as was the goal of earlier expert systems. The user themselves are expected to filter and discard unrelated information. The user should also be active and to interact with the system, rather than just be a passive recipient of the output. This focus on the user and his/her interaction with the system is important in setting appropriate expectations for the way the system will be used. (S.Berner & Tonya J.La Lande) Based on this information, the user needs to interact with the system to give him/her what she/he wants. The systems aim should not be to give the answer but to help the general practitioner make a decision. The 3 parts of the system should be the knowledge base, the inference or reasoning engine, and a mechanism to communicate with the user.

Knowledge maintenance is a very important issue that involves the responsibility for updating the knowledge base in a timely manner. New diseases are discovered, new medications come on the market, and issues like the threat of bioterrorist actions prompt a need for new information to be added to the CDSS. The proposed system should be able to allow easy maintenance of new data (diseases, journals, key words, CBC ranges). Allowing a qualified general practitioner to update the knowledge base is very important and authorization to update the knowledge base must be given stringently for data consistency.

Several online clinical forms were downloaded as a reference for what sort of data to be collected from the patients. The forms are shown in Appendix.

As for other similar clinical decision support systems that uses CBC results to diagnose and EBM to further diagnose and prescribe, none of the current systems are similar to the proposed system in this project which is to incorporate CBC results and EBM to diagnose a patient. Using CBC as parameters of diagnosis in a system is new because of CBC being a very basic form of test and cannot give a final diagnosis. However, the objective of this project is to use CBC to create a list of 'probable' diseases, not a final diagnosis.

EPR or the electronic patient record is the software that maintains the patient database in most clinics. Today's outcomes-focused healthcare environment makes best practice — the delivery of evidence-based, high-quality, cost-effective care— more critical than ever. Several information management tools are now being implemented by healthcare organizations to help clinicians achieve the desired outcomes. Below are some examples of the most current information system tools used:

- The electronic patient record (EPR)
- Clinical decision support (CDS) system
- The clinical data warehouse (CDW)

(Craig S. Ledbetter & Matthew W. Morgan)

The proposed system will have to be able to similar with the above 3 important parts; EPR, CDS, CDW.

CDS capabilities are useful in all phases of the clinical process: (1) assessment, (2) planning, (3) intervention, and (4) evaluation. A good clinical decision should be able to help the clinician at every point of care by allowing quick access to relevant knowledge and interactive criteria based alerts. (Craig S. Ledbetter & Matthew W. Morgan) The proposed CDSS should be able to do those functions mentioned. Rapid relevant information must flow from the knowledge base to the general practitioner with ease and in a feasible manner.

In an article about developing a clinical decision support system for the practice of evidence based medicine (Ida Sim, et al., 2001), five prominent areas which were essential for achieving the goal of increased adaptation of a CDSS for evidence based medicine were found:

- Capture of both literature-based and practice-based research evidence into software readable formats suitable for CDSS use (Microsoft word, text files)
- Establishment of a technical and methodological foundation for applying research evidence to individual patients at the point of care
- Evaluation of the clinical effects and costs of CDSSs, as well as how CDSSs affect and are affected by professional and organizational practices
- Promotion of the effective implementation and use of CDSSs that have been shown to improve clinical performance or outcomes
- Establishment of public policies that provide incentives for implementing CDSSs to improve health care quality

Example of existing hematological CDSS includes the 'iron-deficiency anemia detection from hematology parameters by using decision trees' (Sengul DOGAN & Ibrahim TURKOGLU) and 'the online decision support system for diagnosing hematologic malignancies by flow cytometry immunophenotyping' (You-Wen Qian, Dinesh P. Mital, Stephen Lee, 2008).

Both are hematological decision support systems for very detailed diagnosis of hematological diseases. These systems use a more complex, detailed and process intensive way to diagnose a specific disease. However, the proposed system plans to provide a quick diagnosis from CBC results to give a probable list of diseases where the general practitioners could continue with more testing from there on with the help of some evidence.

2.2 Complete Blood Count and Haematological Disorders

A literature review on complete blood count testing has been done to determine how such results from such tests could be used to diagnose a disease. This knowledge will then be applied in the clinical decision support system, making it an expert system due to its ability to make expert decisions based on CBC testing.

The first step is to look into the complete blood count testing. Basic understanding of the CBC test needed to be there. For example, how is it done, how long will it take, and what would a normal healthy person's CBC report will be. Studies also needed to be done in finding out the normal ranges of blood composition in a CBC report to determine a healthy person.

After acquiring information on basic CBC knowledge and what a healthy person's report should be like, the second step is to know what an unhealthy person's report should be like. A list of haematological diseases will be reviewed to find out its symptoms, its effect on the human body and how these diseases will be reflected in the CBC report. Furthermore, certain diseases will be looked into more detailed for the purpose of acquiring journals regarding the disease to be used as evidence for the evidence based medicine concept.

2.2.1 Complete Blood Count

The CBC test will bring about a report such as bellow:

Abbreviation	Test Name	Definition	Associated Disorders
WBC WBC Diff	White blood cells WBC differential Neutrophils Lymphocytes Monocytes Eosinophils Basophils	WBCs fight infection. The 5 different types of WBCs are listed to the left.	Infection, leukemia
RBC	Red blood cells	RBCs (with the help of hemoglobin) carry oxygen throughout the body	↓ Anemia, bleeding, malnutrition, kidney disease ↑ Polycythemia, heart and lung disease, dehydration
Hb or Hgb	Hemoglobin	Protein that carries oxygen	↓ Anemia, bleeding, malnutrition, cirrhosis, cancer ↑ Dehydration, polycythemia
Hct	Hematocrit	Amount of space in the blood that is occupied by RBCs	↓ Anemia, bleeding, malnutrition, cirrhosis, cancer
			↑ Dehydration, polycythemia, hemochromatosis
MCV	Mean corpuscle volume	Average size of the RBCs	Anemia, thalassemia, malnutrition
MCH	Mean corpuscle hemoglobin	Average amount of Hb in each RBC	Anemia, thalassemia, malnutrition
MCHC	Mean corpuscle hemoglobin concentration	Average amount of Hb in the RBCs compared to the average size of the RBCs	Anemia, thalassemia, malnutrition
RDW	Red cell distribution width	Amount of variation in size of the RBCs	Anemia, thalassemia, malnutrition
Plt	Platelet count	Platelets are sticky cells that help to form blood clots	Bleeding and clotting disorders
MPV	Mean platelet volume	Average size of the platelets	Bleeding and clotting disorders

Figure 1: Items included in CBC test report

By using the data obtained from CBC tests, many diseases including viral and non symptom inducing diseases could be determined. A CBC report could determine a vast amount of diseases (Adrian C Newland, Tyrrell G J R Evans). Some of the extreme cases of blood disorders would be the different types of anemia and HIV. Even simple problems like vitamin K deficiency could be determined through this test.

A complete blood count, often referred to as a CBC, is a common blood test. A CBC provides detailed information about three types of cells in your blood: red blood cells, white blood cells, and platelets. These blood cells are made in the bone marrow, the spongy tissue filling the center of your bones. Bone marrow in the skull, sternum (breast bone), ribs, vertebral column (backbone), and pelvis produces these blood cells. Each type of blood cell plays an important role in your body's normal function. (Elaine N. Marieb, Katya Hoehn 2009) This proofs that CBC results can effectively tell whether a body is functioning normally or not. This is because each cell plays an important role in regulating normal body functions. A drop or an increase in numbers of certain cells could mean something is wrong.

Now that CBC testing is known to be able to detect abnormalities in the human body, what is and what is not considered to be a normal CBC test result and what affects the normal ranges of this test?

Alberta Health services have prepared an online chart depicting how the different ages and sex affect the normal ranges of the CBC results. (Alberta Health Services, 2011) The chart is shown below:

Age	HGB g/L	HCT L/L	RBC 10E12/L	MCV fL	MCHC g/L	RDW %	PLTS 10E9/L	WBC 10E9/L	NEUT 10E9/L	BAND 10E9/L	LYMPH 10E9/L	MONO 10E9/L	EOS 10E9/L	BASO 10E9/L
0-6 DAYS	145-225	0.45-.67	4.0-6.6	95-121	310-350	11-16	150-400	9.4-34.0	5.0-21.0	0 - 5.4	2.0-11.5	0.5-1.7	0.2-0.7	0-0.3
7-13 DAYS	135-215	0.42-.66	3.9-6.3	88-126	305-355	11-16	150-400	5.0-21.0	1.5-10.0	0 - 6.5	2.0-17.0	0.3-1.3	0.2-0.8	0-0.2
14-29 DAYS	125-205	0.39-.63	3.6-6.2	86-124	305-355	11-16	150-400	5.0-20.0	1.0-9.5	0 - 3.5	2.0-17.0	0.5-1.8	0.2-0.6	0-0.2
1 MON	100-180	0.31-.55	3.0-5.4	85-123	310-350	11-16	150-400	5.0-19.5	1.0-9.0	0 -2.5	2.5-16.5	0.5-1.8	0.2-0.6	0-0.2
2 MONS	90-140	0.28-.42	2.7-4.9	77-115	310-350	11-16	150-400	5.0-19.5	1.0-9.0	0 -2.5	2.5-16.5	0.5-1.8	0.2-0.6	0-0.2
3-5 MONS	110-147	0.31-.45	3.5-5.2	74-98	305-350	11-16	150-400	6.0-18.0	0.6-6.7	0 -2.0	2.8-14.4	0.2-1.6	0.0-1.1	0-0.2
6 MONS - 2 YRS	106-145	0.31-.44	3.5-5.6	71-90	310-350	11-16	150-400	6.0-16.0	0.6-5.1	0 - 1.8	2.7-12.0	0.2-1.4	0.0-1.0	0-0.2
3-11 YRS	110-157	0.34-.46	3.8-5.6	75-91	315-360	11-16	150-400	4.0-14.0	0.8-7.2	0 - 1.3	1.3-8.0	0.1-1.1	0.0-0.7	0-0.2
MALE 12-14 YRS	125-170	0.36-.50	4.4-5.7	82-100	320-360	11-16	150-400	4.0-11.0	2.0-7.0	0 - 1.3	1.5-6.5	0.0-1.0	0.0-0.7	0-0.2
FEMALE 12 YRS AND OVER	120-160	0.36-.48	4.0-5.6	82-100	320-360	11-16	150-400	4.0-11.0	2.0-9.0	0 - 1.3	0.5-3.3	0.0-1.0	0.0-0.7	0-0.2
MALE 15 YRS AND OVER	137-180	0.40-.54	4.5-6.0	82-100	320-360	11-16	150-400	4.0-11.0	2.0-8.0	0 - 1.3	0.7-3.5	0.0-1.0	0.0-0.7	0-0.2

Figure 2: CBC normal ranges

Other than age and sex, there are other factors affecting the normal ranges of CBC test results. Normal values for the complete blood count (CBC) tests depend on age, sex, how high above sea level you live, and the type of blood sample. (E. Gregory Thompson, Joseph O'Donnell, 2010) Pregnancy is also a factor to be looked into when determining the normal ranges of a CBC test result.

A wrong normal range of CBC test result could cause a misdiagnosis of a patient and it is very important to extract patient data like age, sex, type of blood, and pregnancy. The lab should also account for its location being how high above the sea level and make sure the system is ready to take that into account.

Blood is typically drawn from a vein, usually from the inside of the elbow or the back of the hand. The site is cleaned with germ-killing medicine (antiseptic). The health care provider wraps an elastic band around the upper arm to create a pressure that causes the vein to swell with blood. Next, a needle is gently inserted into the vein. The blood collects into an airtight vial or tube attached to the needle. The elastic band is then removed before the needle is taken out. Once the blood has been collected, the needle is removed, and the puncture site is covered to stop any bleeding. In infants or young children, a sharp tool called a lancet may be used to puncture the skin and make it bleed. A pipette or test strip is then used to hold the blood. The area will be bandaged if there is any bleeding. (David Zieve, et al., 2010) The process above depicts how the blood is drawn from a patient and then later it would be sent to a lab to count the cells in the blood. The whole process would take only a few minutes and could be used as a quick way to diagnose patients.

There are 3 values in the CBC report that are derived from the blood counting. They are mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH) and the mean corpuscular hemoglobin concentration (MCHC). MCV is average volume of red blood cells, MCH is the average mass of hemoglobin per red blood cell and MCHC is the average concentration of hemoglobin in the red blood cell. The formula to calculate these values are as follows:

mcv = pcv(L) * 10 / rbc(x10^12\L)

mch = hb(gm/L) / rbc(x10^12\L)

mchc = hb(gm/L) * 100 / pcv(L)

The values calculated above is very useful in determining the type of diseases other than the basic blood compositions: red blood cell, white blood cell, platelets, haemoglobin, and red blood cell distribution width.

For example, diagnosis of the type of anemia may be assisted by relating the measurements of red blood cell count, hematocrit and hemoglobin to derive the mean corpuscular volume (MCV) and the mean corpuscular hemoglobin concentration (MCHC).

Erythrocytes that have a normal size or volume (normal MCV) are called normocytic. When the MCV is high, they are called macrocytic. When the MCV is low, they are termed microcytic.

Erythrocytes containing the normal amount of hemoglobin (normal MCHC) are called normochromic.When the MCHC is abnormally low they are called hypochromic, and when the MCHC is abnormally high, hyperchromic.

The terms above are used together to describe different forms of anemia. For example, iron deficiency anemia is described as microcytic and hypochromic, whereas vitamin B12 deficiency is macrocytic and normochromic. (McGill Physiology Virtual Lab)

So far, reviews on what is in a CBC report, how its normal ranges are computed, how blood is drawn from patients and some important calculations in CBC has been done. The figure below shows what is tested in a CBC test, what it means and what are its nor mal values for an average male and female in general (excluding other factors that affect the normal ranges

CBC NORMAL VALUES (Hoffbrand and Pettit 2006)

1) Red blood cells

Test	What is measured	Units of measurement	Normal Values
Red Cell Count	Number of red blood cells	-	Male : 4.5 to 6.5 x 10^12/L Female : 3.9 to 5.6 x 10^12/L

Haemoglobin (Hb)	Concentration of the protein haemoglobin in blood	Grams in every 100ml of blood (g/dl)	Male : 13-17 g/dl Female : 11-13 g/dl
Packed Cell Volume (PCV, haematocrit)	Percentage of total blood volume occupied by red cells	%	Male:40-52% Female : 36-48%
Mean corpuscular volume (MCV)	Average volume of red cells = PCV / RBC count	Ferntoliter (fl)	80-95 fl
Mean corpuscular haemoglobin (MCH)	Average mass of haemoglobin per red blood cells in sample of blood = Hb level / RBC count	Picograms (pg)	27-34 pg
Mean corpuscular haemoglobin concentration (MCHC)	Average concentration of haemoglobin in red cells	Grams in every 100ml of red cells (g/dl)	20-35g/dl
Red cell distribution width (RDW)	Variation in red cell volume. Higher RDW volume indicated greater variation in size	%	10-15%

Table 1: Red Blood Cell Count

2) White blood cells

Test	Normal Values
Total white blood cells count	4.0 to 11.0 x 10^9/L
Neutrophils	2.5 to 7.5 x 10^9/L
Lymphocytes	1.5 to 3.5 x 10^9/L
Monocytes	0.2 to 0.8 x 10^9/L
Eosinophils	0.04 to 0.44 x 10^9/L
Basophils	0.01 to 0.1 x 10^9/L

Table 2: White Blood Cell Count

3) Platelets

Test	Normal Values
Total platelets count	150 – 400 x 10^9 cells/L
Clotting time	2-7min
Prothrombin time	11-16s
Thrombin time	15-19s
Partial thromboplastin time (PTT) / Activated partial thromboplastin time (APTT)	30-40s

Table 3: Platelets Count

2.2.2 Haematological Disorders

The second part of the CBC literature review is to study some haematological diseases and how these diseases could be linked to the CBC test results. Symptoms, causes and journals of haematological diseases will also be looked into for the purpose of giving the system sufficient knowledge on the disease to help general practitioners diagnose patients.

The book depicts a table showing the normal ranges of the many cells found in the Human Blood. It also shows the complete composition of blood and how the different figures tie to a haematological disorder (Hoffbrand and Pettit 2006). The relationship between blood composition and diseases could be seen from this book. It is possible to use CBC results to determine or filter the possibilities of diseases accurately. Below are the information extracted from the book:

HAEMATOLOGICAL DISORDERS ACCORDING TO CBC RESULTS
(Hoffbrand and Pettit 2006)

Disorders	Symptoms	Definition	Normal range	Treatment
Anaemia	-low blood pressure -dizzy -weakness -shortness of breath -chest pain -fatigue -irritability -headache -decrease body temperature -elevated heart rate	Haemoglobin below lower limit of normal range	Haemoglobin normal range 1)Newborn a) <1 week : 14-22g/dl b) 6 mths : 11-14 g/dl 2)Children (1-16yrs) : 11-15 g/dl 3)Adults a) Men : 13-16 g/dl b) Women : 12-14 g/dl	-Oxygen support -Blood transfusion
Thalassaemia		Defects in the synthesis of the globin chains of haemoglobin	Decrease in Haemoglobin (Hb), MCV, MCH Increase in RBC count, HBA2	

Aplastic anaemia		Condition due to damaged bone marrow	Low RBC, neutrophil, WBC, platelet count	
Erythrocytosis / Polycythemia	-Purpura (purplish area of skin where haemorrhage occurred) -painful erythema (redness of skin) -blood in stool -blood clots -blackening of fingers or toes -fever -weight loss -itching -heat tolerance -warmth in parts of limbs	Excess RBC	Normal range of haematocrit Male : 52% Female : 47% Normal range of haemoglobin concentration Male : 17.7 g/dl Female : 15.7 g/dl	Depending on the underlying cause
Thrombocytopenia	-tiny, pinpoint-sized/ purple spots on skin (Petechiae) -nose bleed -bleeding gums -prolonged bleeding from a cut -black or bloody stool -brown or red urine -increased vaginal bleeding	Low platelet count	Results show < 50,000/µl	
Neutropenia	-fever -shaking chills	Low neutrophils	Normal 2500-6000 Abnormal	

	-flushed skin -sweating -frequent urination or burning when urinating -redness, tenderness, body pain -tiredness -flu-like symptoms		when neutrophils < 1000	
Leukopenia		Low white blood cells	Normal range : 4.0 to 11.0 x 10^9/L	

Table 4: Hematological Disorders

Some other diseases have also been looked into through online articles and journals. In an article about CBC results by a mayo clinic staff, a low red blood cell, hematocrit, or hemoglobin could mean anaemia which would be looked into further later. A high level of these counts could mean a heart disease or polycethemia vera. A low white blood cell count could mean leukopenia. A platelet count that's lower than normal (thrombocytopenia) or higher than normal (thrombocytosis) is often a sign of an underlying medical condition. (Mayo Clinic Staff, 2011, CBC)

Anemia is the condition where the red blood cells within a person's body decreases. Red blood cells mainly help the body to produce oxygen for the tissues. (Types of Anemia, 2011) From this article, many types of anemia could be found and many different types of causes that could lead to these types of anemia. A CBC test result could only pin point some of these anemia types but it would usually need extra diagnosis to really find out the type of anemia the patient is suffering from. Below are some of the types of anemia:

1) Iron Deficiency Anemia or Microcytic Anemia

It is the most common type of anemic disease. It is where the red blood cells appear smaller than normal. This is actually caused by iron deficiency and thalassemia, inherited disorders of hemoglobin. A smaller red blood cell could mean higher red blood cell distribution width in the CBC test results due to its small nature.

2) Sickle Cell Anemia

This kind of disease is characterized by sickle-shaped red blood cells. These cells have faster rate of breaking down than the normal cells. This often results to red blood cell shortage or low RBC count in the CBC results.

3) Pernicious Anemia

This is a kind of anemia also called Vitamin B12 deficiency anemia. Vitamin B12 is particularly helpful in formation of red blood cells. This anemia occurs when the intestines weren't able to acquire the necessary amounts of Vitamin B12. This kind of anemia could be a result of hereditary factors. Certain symptoms of this anemia include the typical anemia symptoms, numbness of feet and hands, eye vision problems, and difficulty in walking.

4) Thalassemia

This is one of the genetically inherited types of anemia. It is where body genes are destructed and damaged. Body genes are helpful in proper hemoglobin production in the body. Some of its symptoms include dark urine, yellow eyes and skin, fatigue, swollen abdomen, and weakness.

5) Aplastic Anemia

It is one of the rare anemia types. This is commonly caused by chemotherapy, radiation therapy, and some other medications.

Leukemia is another famous hematological disease. This disease will induce a high level of white blood cells (an effort of the body in fighting it) and low hemoglobin/platelets levels. Leukemia cells are what travel around the human body causing problem to normal bodily functions. (Medicine Net)

Lupus is an autoimmune disease. It is a disease where it causes the body to produce antibodies that attack its own immune system instead of viruses and bacteria. This disease confuses the body on what to attack and what not to. Lupus does not have fixed symptoms. No two lupus cases would be alike and this makes it very hard to

detect without using a blood test like CBC. Through the CBC results that show a high red blood cell count (similar to anaemia) followed by a low white blood cell count and platelet count could mean Lupus. (Mayo Clinic Staff, 2011, Lupus)

Polycythemia Vera is a disease that thickens the blood causing slower blood flow and even clotting within the body. A clot in the head could cause a stroke and is highly dangerous. The obvious signs of this disease in a CBC result would be high levels of red blood cell, hematocrit and haemoglobin. In some cases, a high amount of platelet count could occur. (Mayo Clinic Staff, 2011, Polycythemia)

Two diseases have been researched more in depth to allow EBM to take place. They are Myelodysplastic syndrome and Polycythemia Vera. 3 journals from each disease were acquired for the purpose of using it as evidence to help general practitioners make decisions.

2.3 Evidence Based Medicine

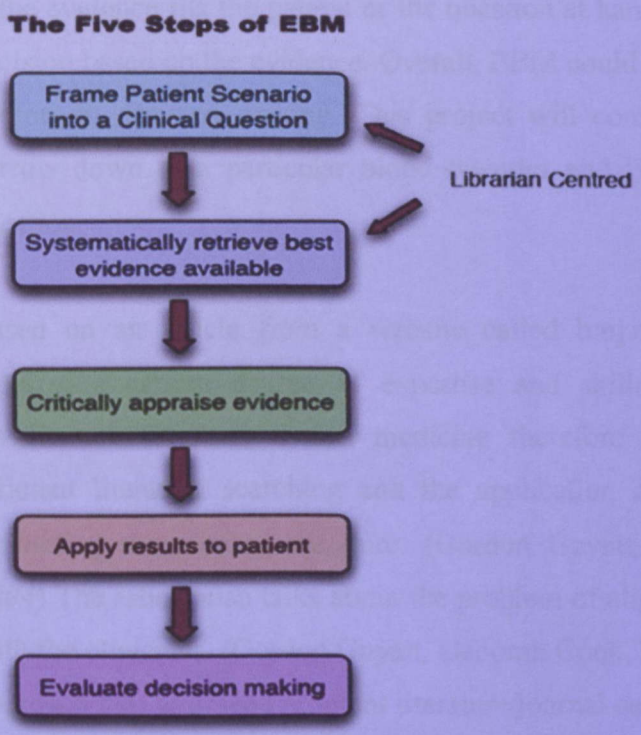


Figure 3: 5 steps of EBM

In formulating a clinical question, EBM deals with only very specific patient based question. The 4 characteristics of this answerable question would be described by PICO (patient, intervention, comparison, and outcome). (Robert C Hawkins, Clin Biochem, 2005) Next, a concise method of searching, organizing and ranking the evidence will be needed. After choosing the evidence, it would need to be critically appraised by the 4 questions as mentioned by Robert C Hawkins:

1. Was there an independent, blind comparison with a reference standard of diagnosis?
2. Was the diagnostic test evaluated in an appropriate population of patients comparable to the patient of interest?
3. Was the reference standard applied regardless of the diagnostic test result?
4. Was the test validated in a second, independent group of patients? Have the initial performance parameters (sensitivity, specificity etc.) been confirmed by application to a second independent group of patients?

If the evidence fits the patient or the question at hand, the doctor can now make the decision based on the evidence. Overall, EBM could be an effective method to assist doctors in decision making. This project will combine both CBC test results to narrow down to a particular blood disorder and EBM to find the answer to the question.

Based on an article from a website called bmj.com, evidence based medicine requires a certain degree of expertise and skills in searching and evaluating 'evidences'. Evidence based medicine therefore required new skills including efficient literature searching and the application of formal rules of evidence in evaluating the clinical literature. (Gordon Guyatt, Deborah Cook, Brian Haynes, *2004*) The article also talks about the problem of aligning patient values/preferences with the clinicians. (Gordon Guyatt, Deborah Cook, Brian Haynes, *2004*) EBM is an approach that will need efficient literature/journal searching and an effective way of evaluating it before recommending it. Problems also arise when the clinician's preferences and values differ from the patient. Data needs to be collected from the patients in a proper easy, and feasible for better accuracy.

The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. By best available external clinical evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient centred clinical research. The difficulties that clinicians face in keeping abreast of all the medical advances reported in primary journals are obvious from a comparison of the time required for reading with the time available. (David L Sackett, et al., 1996) For EBM to be successful, we need both an expert clinician and the best clinical evidence that can be achieved through a systemic research. The system built must have a way of filtering these journals. Possible ways would be found from the book *Information retrieval: A health and biomedical perspective* by R.Hersh, William (2009). Another problem faced by clinicians in using evidence is the shortage of time in reading the many journals/evidence that are growing quickly day by day. The proposed system should have a knowledge base of journals that could easily be expanded and should allow general practitioners to breeze through it in an efficient manner.

R. Hersh, W. (2009). *Information retrieval: A health and biomedical perspective* () Springer.

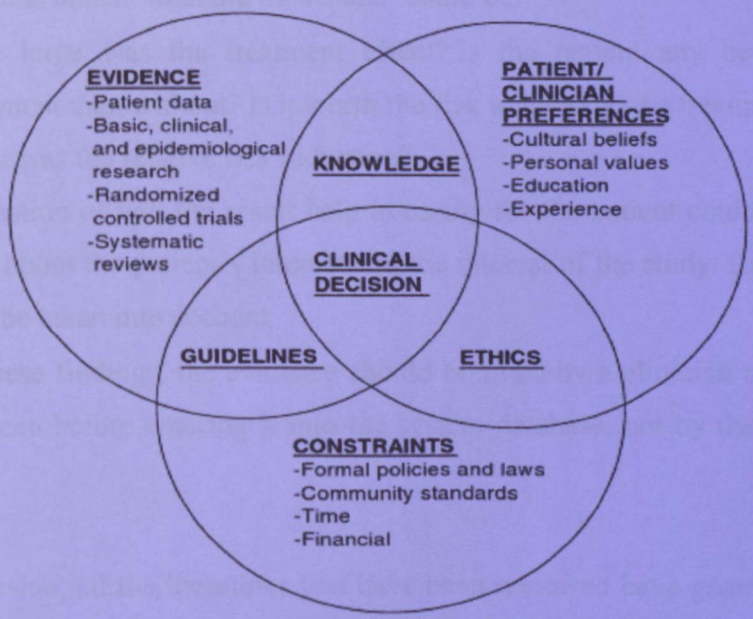


Figure 4: Variables affecting clinical decision

From the book and figure depicted above, ways of indexing the journals could be learnt. Some examples would be manual indexing and word indexing. The book also touches on match searching. It is concluded that it is possible to index and search the evidence effectively through a programmed system. The figure retrieved from the book depicts what are the variables that effect decision making. These variables will have to be accounted for filtering of evidence.

There are three basic questions that need to be answered for every type of study:

- Are the results of the study valid?
- What are the results?
- Will the results help in caring for my patient?

(Guyatt, G. Rennie, D. Meade, MO, Cook, DJ. 2008)

From this book, a method or standard of evaluation useful evidence was found.
To find out whether the results are valid, certain questions need to be asked. For example, is the study blinded or placebos were used? Placebos are medicine that carries more of a psychological value than a physical value. For instance, a medicine which does not really do anything to the patient but the patient somewhat feels better due to psychological reasons.
Some questions under 'what are the results' could be:

- How large was the treatment effect? Is the patient any better with the treatment than without? Is it worth the risk to undergo the treatment?
- What was the relative risk reduction?

The last question of will the result help in caring for the patient could be answered by thinking about the patient's interest and the interest of the study. Risks and costs should also be taken into account.
Based on these findings, the evidence should be rated by a clinician through a user friendly screen before entering it into the system database, not by the developer of the system.

As a conclusion, all the literatures that have been reviewed have given a foundation to what the proposed system will be like. It will need to function as a proper CDSS with a CBC data knowledge base incorporated into it. The reason for having a

CDSS, its effectiveness and challenges faced when developing a CDSS are also reviewed. A GUI to help general practitioners navigate through the many journals is also needed based on the EBM literature reviews. The review has bought about the basic understanding of CBC tests and what its results mean. Basic understanding of some haematological diseases is also achieved. Through the review, the EBM concept is all about using evidence to back up medical diagnosis and prescription but it is time consuming and hard to do. The proposed system will have to fix these problems. All in all, the literature reviews on CDSS, CBC tests, and the EBM concept has been completed.

CHAPTER 3
METHODOLOGY

3.1 Research Methodology

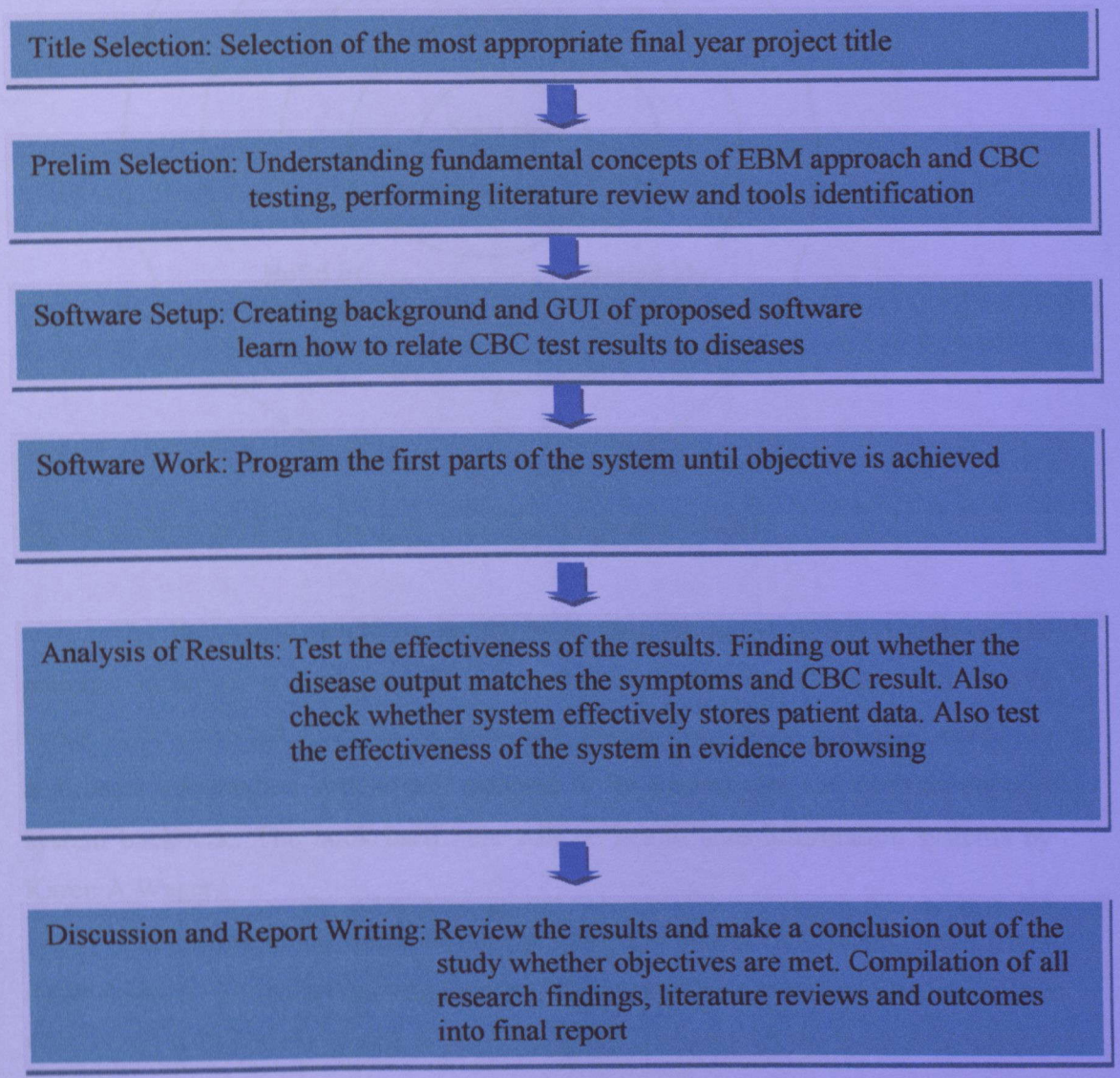


Figure 5: Flowchart Representation of General Project Methodology

3.2 System Development Methodology

The software methodology used is the spiral development model.

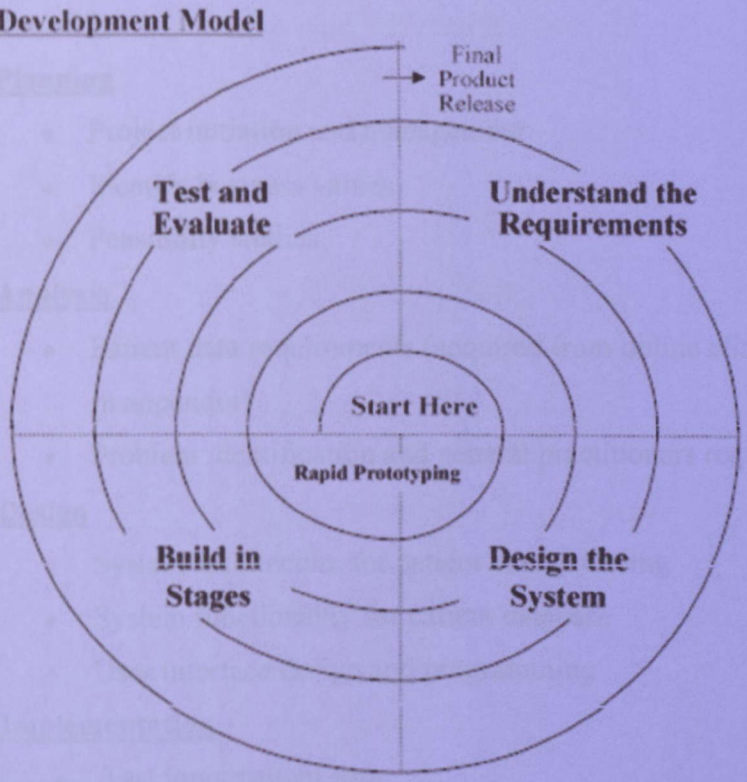


Figure 6: Software Methodology, Spiral Development Model

The first spiral would be for the basic data gathering of the system for the patients. Interview a clinician will be conducted to understand what kind of data needs to be collected from the patients for clinical use. Other than that, books on healthcare information system will referred to for planning of the decision support system backbone. The book used here will be health care information systems by Karen A. Wager.

The second round would be for the system to accept CBC results and narrow down diseases. The programming logic will be created here to compare values of the CBC result with normal values. If the CBC result is abnormal, the logic will output a list of possible diseases.

The third round would be to develop the EBM approach into the system to advice for prescriptions. The programming logic would be as simple as giving an output of evidence related to the disease. The challenging part of the third round would be to properly index and evaluate the evidences.

Each round will have the planning, analysis, development, and implementation phase for the particular part of the system until it is successfully implemented before proceeding to the next round.

Round 1:

Planning

- Project initiation and management
- Identify business values
- Feasibility studies

Analysis

- Patient data requirements (acquired from online clinical forms, shown in appendix)
- Problem identification and general practitioners requirements

Design

- System architecture for patient data gathering
- System functionality for patient database
- User interface design and programming

Implementation

- Test input patient data.

Round 2:

Planning

- Studies on CBC blood test
- Studies on haematological blood diseases

Analysis

- Linking haematological diseases to CBC blood test results

Design

- System architecture for linking patient data from round 1 with CBC results to determine probable diseases
- User interface design and programming

Implementation

- Testing with real patient and patient CBC report.
- Testing with dummy data of patients with haematological disease. (to see if the disease was being determined by system or not)

Round 3:

Planning

- Studies on the EBM concept
- Plan how to implement EBM in system

Analysis

- Analyze how the system can help general practitioners implement EBM easily

Design

- System architecture for viewing EBM evidence effectively and efficiently
- User interface design and programming

Implementation

- Testing with journals related to determined disease from round 2

3.3 Project Activities

1. Interview with a clinician.
2. Relearning Visual Basic programming and Database Management.
3. Building up a database in Microsoft access
4. Reading books on EBM.
5. Collecting evidence in journal form
6. Studying the variables of a CBC test result
7. Retrieving details on how to match CBC results to certain blood disorders.
8. Learning what influences the normal range of CBC results.
9. Going through current clinical decision support systems to see what data is being used and how they usually function.
10. Programming the system via spiral development model.

3.4 Equipment and Tools

Minimum Requirements:

- CPU that is equipped with :-
    - Windows
    - Pentium 4 2GHz or better
    - 10gb Hard Disk (additional disk space might be needed depending on size of database)
    - 512 MB RAM or better

Development Tools Used

- Hardware
    - CPU
    - Monitor
    - Mouse
- Software
    - Microsoft Visual Basic
    - Bytescout PDF Extractor SDK
- Database
    - Microsoft Access

Additional Items Used

- Books from UTP IRC
- Online articles and journals (Internet)

3.5 Key Milestones and Planning

(Refer to appendix C for Gantt chart)

***System flow covered in results 4.3.1**

CHAPTER 4
RESULTS AND DISCUSSION

4.1 Data Gathering and Analysis

Patient Data- Patient data needed for the system to work is gathered by various sources: Informal interview with a general practitioner, online patient data forms, etc.

The patient data needed by the system is then analyzed based on what information Complete Blood Count needs from the patient to tie a disease to the patient.

Complete Blood Count Data – Data gathering on normal ranges of the cell counts and calculations in the Complete Blood Count testing was done. Equations on how to calculate mean cell volume, mean corpuscular hemoglobin and mean corpuscular hemoglobin concentration has been found. Variables influencing the normal ranges of a person's CBC results were sex, age, altitude, and pregnancy period. Analysis on how these variables affect the normal ranges was done.

Diseases and Journal Data- Data of diseases was gathered from online websites and journals. Data was also gathered with the assistance of a medical student from International Medical University, Kuala Lumpur. The diseases were analyzed to extract the abnormalities it causes in blood and tie it to the CBC results. Two diseases were looked into more deeply and more journals about it were gathered for the purpose of the EBM approach later.

EBM information- Analysis on how to allow general practitioner to view evidence quickly and efficiently is done. Found ways to convert journals into text file format to be read by the program. Going online to find what sort of keywords general practitioner usually finds in a journal.

Programming Data- Programming data was attained by knowledge of the programming language itself and online Visual Basic forums.

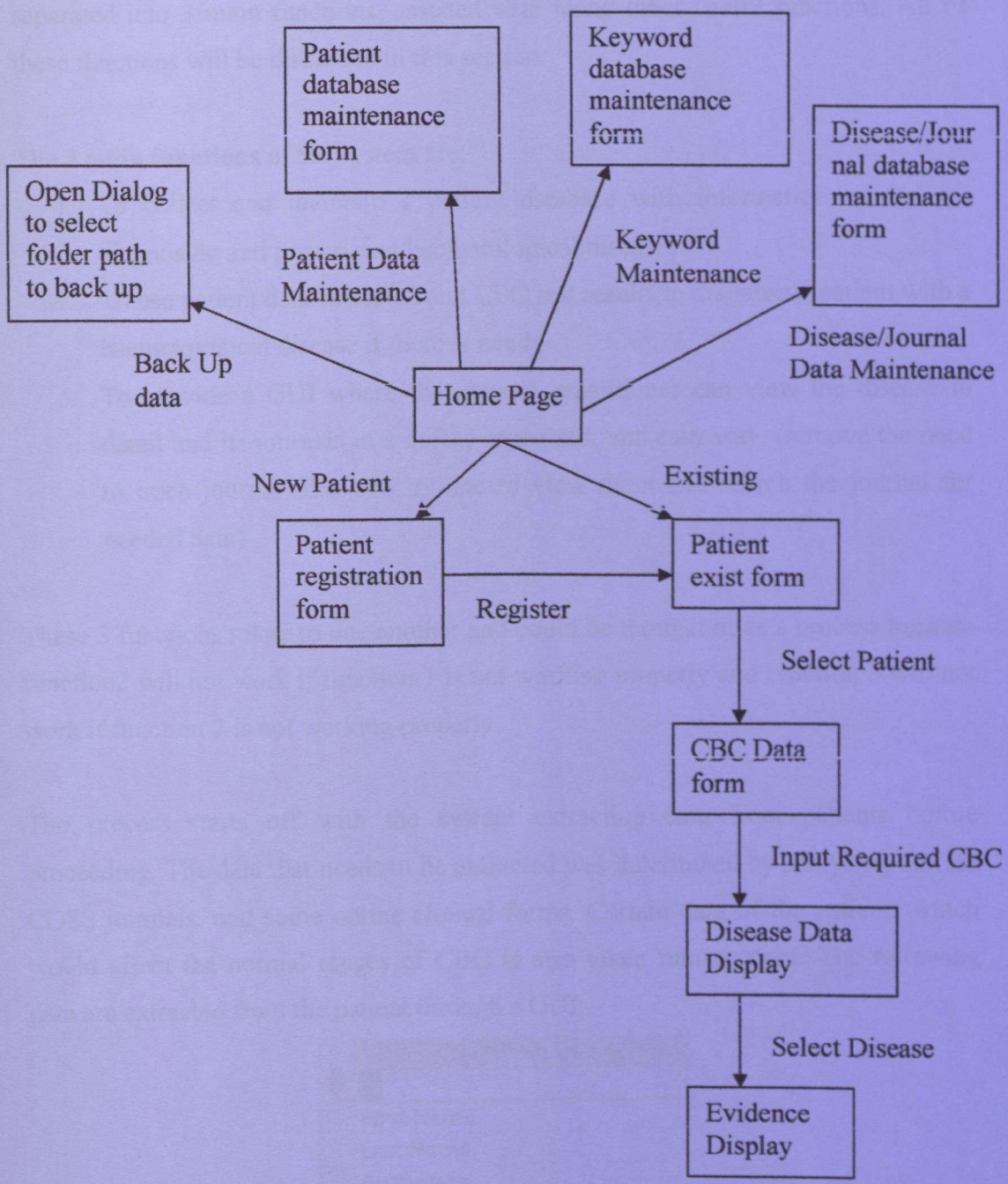
4.2 Experimentation Modeling

Data used for experimentation of the system:

1. Healthy Patient – Real CBC report of a healthy patient was attained by the consent of both the patient and the doctor in poliklinik & surgery serdang. The female patient's report shows a CBC result of a healthy person.
2. Disease ridden patient – The CBC results for disease ridden person is made up based on the manipulation of certain data of the healthy patient above. This is to see if the system could detect the abnormalities in the blood and provide a list of probable diseases that could have caused it.
3. Further different patients with different sexes, pregnancy period, altitude, and age are used to test the efficiency of the system.

4.3 Hematological Clinical Decision Support System

4.3.1 Process of the Haematological Clinical Decision Support System



The Hematological Clinical Decision Support System is the product of the literature reviews done. It is meant for the general practitioners who want to diagnose and prescribe medication to a patient with a hematological disease. This system is separated into 3 main functions, assisted with many other useful functions. All of these functions will be discussed in this section.

The **3 main functions** of the system are:

1. To collect and maintain a patient database with information needed for diagnosing and prescribing haematological diseases.
2. To use patient data collected and CBC test results to diagnose a patient with a haematological disease if there is need.
3. To provide a GUI where the general practitioner can view the disease in detail and its journals in a quick, organized, and easy way. (remove the need to open journal files one by one to view them and search the journal for needed data)

These 3 functions relate to one another and could be thought of as a process because function2 will not work if function 1 is not working properly and function 3 will not work if function 2 is not working properly.

The process starts off with the system extracting data from patients before proceeding. The data that needs to be extracted was determined by analyzing current CDSS journals, and some online clinical forms. Certain data of the patients which would affect the normal ranges of CBC is also taken into account. The following data are extracted from the patient through a GUI:

	Field Name
🔑	ID
	First Name
	Last Name
	Birth Date
	Sex
	Contact
	Contact 2
	IC
	Allergies
	Address

After the patient is registered, the patient can proceed with the system diagnosis. If the patient has already been registered before, the general practitioner could go to the 'patient_exist' form and key in the patient's IC or ID to search for his/her data. With that data, the general practitioner could proceed to the second step.

The second process of the system is extracting the CBC test results of the patients. The variables that needs to be extracted in their respective units are total red blood cell count(x10^12/L), hemoglobin(gm/L), packed cell volume(L), mean corpuscular volume(fl), mean corpuscular hemoglobin(pg), mean corpuscular hemoglobin concentration(g/L), red blood cell distribution width (%), total white blood cell(x10^9/L), and platelet count(x10^9/L). The differential count and the absolute count of polymorphs, lymphocytes, monocytes, eosinophils, and basophils are also needed. All these are types of white blood cell the blood contains. This information will help in further diagnosing the patient. Absolute count is the percentage of a subset of cell while differential count is the same thing as absolute count but expressed in x10^9/L for better indication of abnormalities. It means that absolute count and differential count could be derived from each other. Another calculation that will take place is to calculate the mean corpuscular volume (fl), mean corpuscular hemoglobin(pg), and mean corpuscular hemoglobin concentration(g/L). The formula to calculate these values are as follows:

mcv = pcv(L) * 10 / rbc(x10^12\L)
mch = hb(gm/L) / rbc(x10^12\L)
mchc = hb(gm/L) * 100 / pcv(L)

After the CBC values have been finalize, the results are compared to a normal range of results based on age, gender, altitude, and pregnancy. The variables mentioned affects the normal ranges of the CBC results. After determining whether the values are high or low compared to the normal ranges (for example, low total red blood cell), a database of diseases are analyzed by the system to determine a list of possible diseases. Each disease in the database has a set of CBC result projection tied to it. For example, 'high' RBC, 'low' Hb, or 'normal' PCV. By comparing the CBC results of the patient and the disease's CBC result projection, a list of probable

diseases could be determined. The CBC result must have an 83% match of the disease's projected CBCV results to be considered a probable disease.

The third process is where the system assists the general practitioner in making the final diagnosis and prescription using the EBM concept. The goal of this process is to allow the general practitioners go through journals related to the diseases in a convenient and quick manor. The system will extract the selected disease's symptoms and related journals from the database. Each disease will have a keyword database tied to it for different diseases could call for different keywords to be scanned through the journals.

The users could open the journal using an external program through the system or use the system GUI to browse through the journals using selected keywords. A single keyword or composite keyword (combination of two keywords) is chosen and searched throughout the selected journal. If there is a keyword match, the page of the journal is sent to the system GUI. The user can navigate through these selected pages with the 'next' and 'previous' buttons. After browsing the journals, the general practitioner should have gathered enough information to proceed with a finalized diagnosis and prescription.

Other than the above 3 main processes, the proposed CDSS also has **database maintenance and database back up features.** The database maintenance function allows authorized users to update, delete, and insert new data into the database tables while maintaining data consistency. A change log is also included in the database maintenance GUI for tracking purposes. The tables involved are the 'patient_data' table, 'CBC_data' table, 'Disease_data' table, and the 'Keywords' table. The database back up features allows the user to back up the database on a designated path for data protection or for movement of data. (Increases feasibility of using the system)

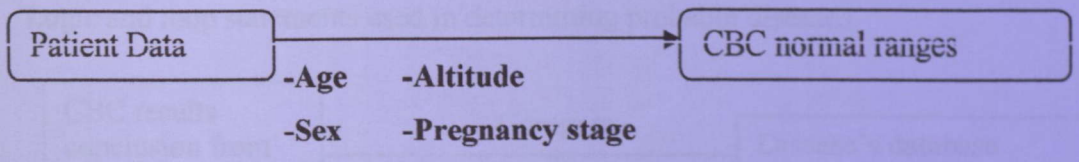
The 'patient_data' table contains information on the patients and important information that could assist in diagnosis and prescription. The 'CBC_data' table contains information of normal ranges of CBC results based on different age group, sex, altitude, and pregnancy stages. The 'Disease_data' table contains information on

diseases and the journal names tied to these disease. The 'Keywords' table contains keyword which are tied to a disease name.

The database maintenance for the 'Disease_data' table is slightly different from the others because the system breaks down the journals into pages and stores it into a folder at this stage. These pages are later retrieved by the GUI in the third main process mentioned before. Every time a new journal is inserted into the database, the system checks if the journal already existed in the repository. If it exists, then the insertion/change is allowed. The system would later check for the broken down pages of the new journal. If these broken down pages is yet to be produced, the system will break down the journal into pages and store it in the repository.

In conclusion, the Hematological CDSS has 3 main processes that the general practitioner must go through in order to get assistance in diagnosing and prescribing. The CDSS also includes other supporting processes, mostly dealing with database maintenance.

4.3.2 CBC Normal Range and CBC Results Conclusion Algorithm



An algorithm is used to collect the CBC normal ranges from the database. The age is calculated to a 0.1 decimal precision based on date of birth. Age, sex, altitude, and pregnancy stage (in months) if pregnant are the factors that affect the CBC normal ranges.

The variations of the factors are as follows:

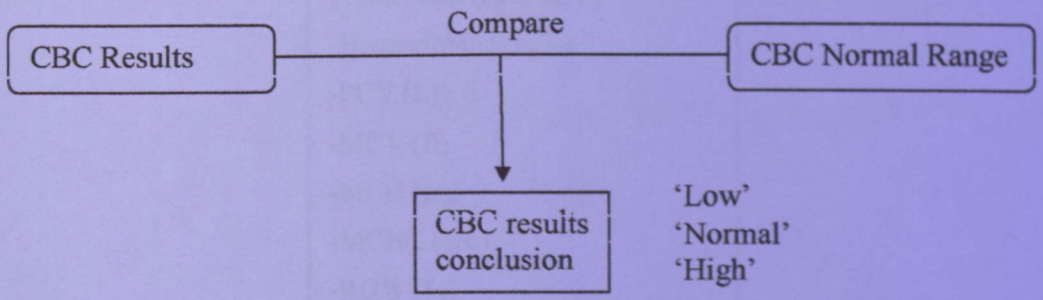
Age: Range of 0.0 to any age (etc. 105.3)

Sex: Unisex, Male, Female

Altitude: Meters above sea level.

Pregnancy stage: Range of 1 to 9 months. Sometimes more than 9 months.

After the normal range is determined:



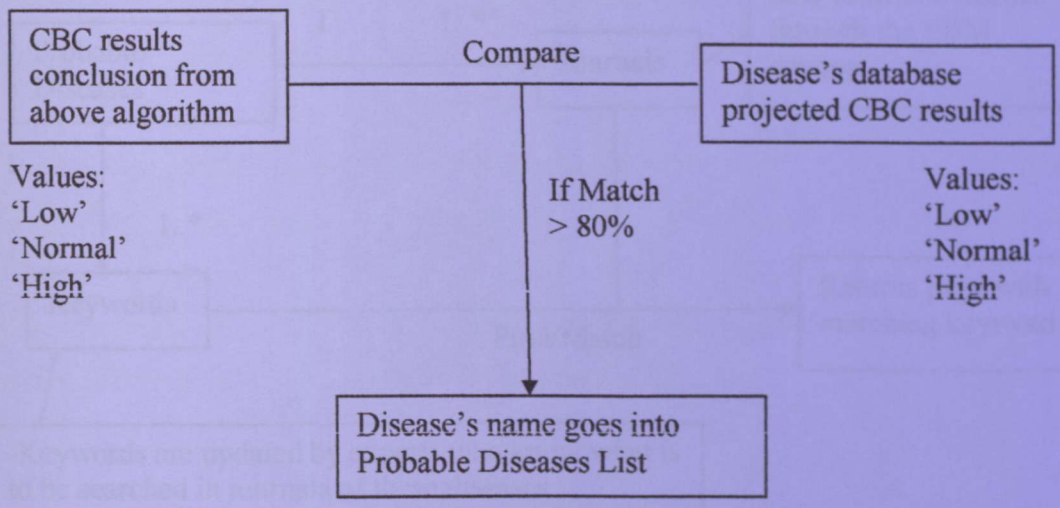
If 'variable from CBC result' >= 'variable minimum value' and 'variable from CBC result' <= 'variable maximum value' Then variable is 'Normal'.

If 'variable from CBC result' < 'variable minimum value' Then variable is 'Low'.

If 'variable from CBC result' > 'variable maximum value' Then variable is 'High'.

4.3.3 CBC Results and Disease Matching Algorithm

Logic and loop statements used in determining probable diseases.



For each disease in database (loop), compare CBC results conclusion with the disease's projected CBC results.

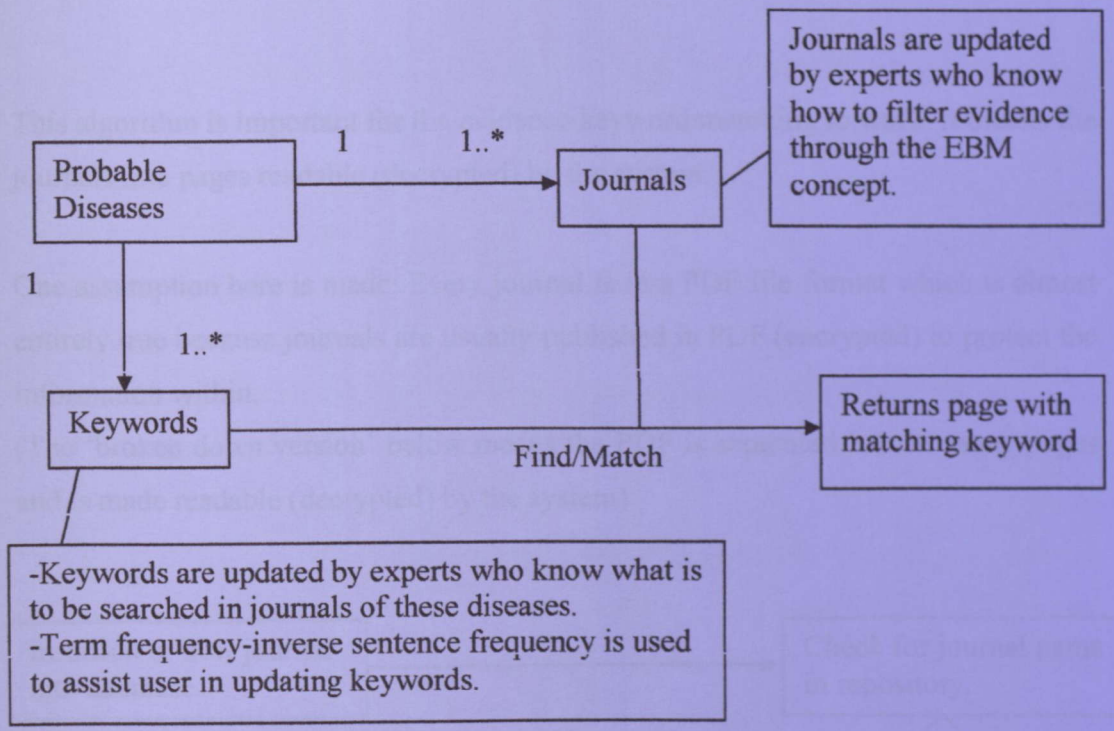
Variables from CBC result being matched:

- -Total RBC (x10^12/L)
- -Hemoglobin (gm/L)
- -PCV (L)
- -MCV (fl)
- -MCH (pg)
- -MCHC (g/L)
- -RDW (%)
- -Total WBC (x10^9/L)
- -ESR (mm/hr)
- -Platelet Count (x10^9/L)

Each variable holds values 'low', 'normal' and 'high'.

An above 80% match of CBC results conclusion with the disease's projected CBC results will include the disease into probable diseases list. An above 80% match is used to provide the 'probable' list because not 100% of variables will be affected by the disease. For example, in theory, a disease would affect 6 of the variables above. However, only 5 variables are seen with the abnormalities matching the disease. The disease would still qualify to be in the probable disease list.

4.3.4 Evidence Matching Using Keywords Algorithm



The keywords evidence matching is a function that allows the general practitioner to select a keyword or multiple keywords to search in a journal. If the keywords are found in a page, the page is returned to the GUI for the general practitioner to read. The keywords system captures tacit knowledge of what to look for in a journal of that certain disease. This system allows more efficient evidence searching and reading.

Loop into every word of journal page:
If word = keyword array () Then return page to GUI and mark current page. (Marked for navigation purposes)
If 'no match found' Then proceed to next page.
If 'no match found at the end of page' Then tell user, no match found.

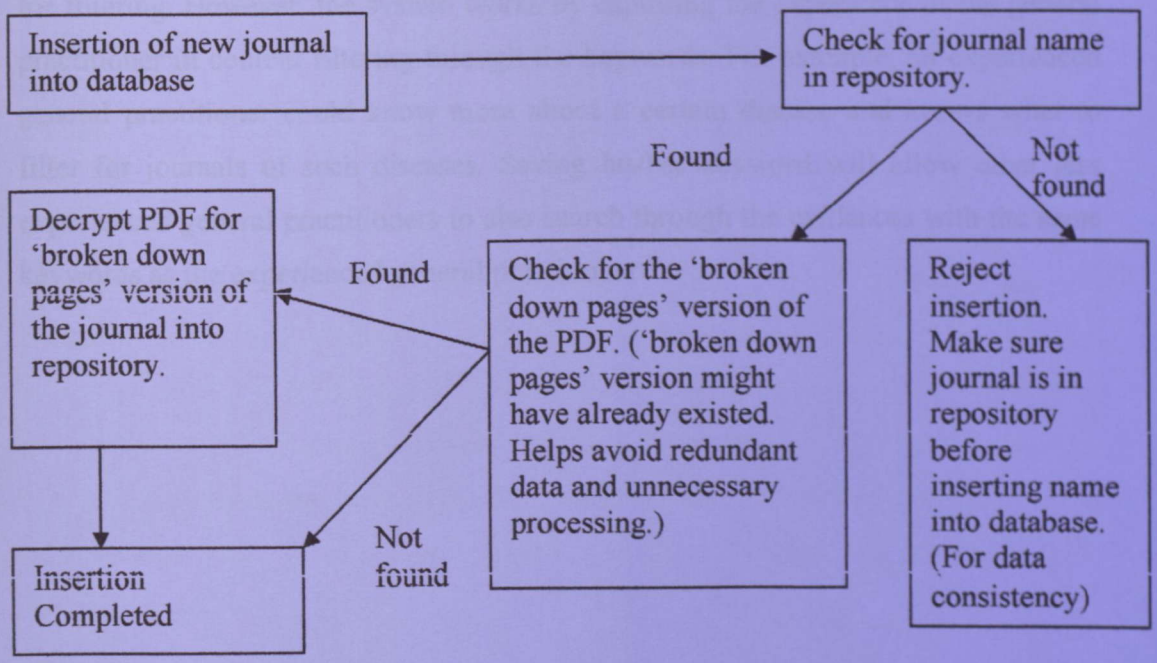
The 'next' and 'previous' button in the GUI allows the user to navigate between pages containing keyword.

The combo box in the GUI allows user to select between related journals efficiently. Every time a new journal is selected, the logic above refreshes to allow the new pages of data to come in.

4.3.5 Updating Journals Algorithm

This algorithm is important for the evidence keyword matching to work. It breaks the journals into pages readable (decrypted) by the system.

One assumption here is made: Every journal is in a PDF file format which is almost entirely true because journals are usually published in PDF (encrypted) to protect the information within.
(The 'broken down version' below means the PDF is separated into its many pages and is made readable (decrypted) by the system)



The end product of the above algorithm is the name of the journal will be tied to the disease in the system and another 'system readable' and decrypted version of the journal is in the repository for processing purposes.

4.3.6 Term Frequency-Inverse Sentence Frequency Algorithm

Term frequency-inverse sentence frequency is the method used by the system to help generate a key word for filtering the evidences. The steps for this method are as follows:

1. Gather all evidences related to a disease.
2. Decrypt evidences into a format readable by the system
3. Remove all stop words in the evidence.
4. Count the occurrence of each word in the document. (including –ing –ed)
5. Words with a high number of occurrences could be a potential keyword.

This method is just a way in assisting the general practitioner in creating a keyword for filtering. However, the system works by capturing the experience of the general practitioner in content filtering through the keywords. For example, an experienced general practitioner could know more about a certain disease and knows what to filter for journals of such diseases. Saving his/her keyword will allow other less experienced general practitioners to also search through the evidences with the same keywords as the experienced general practitioner

4.3.7 System Prototype

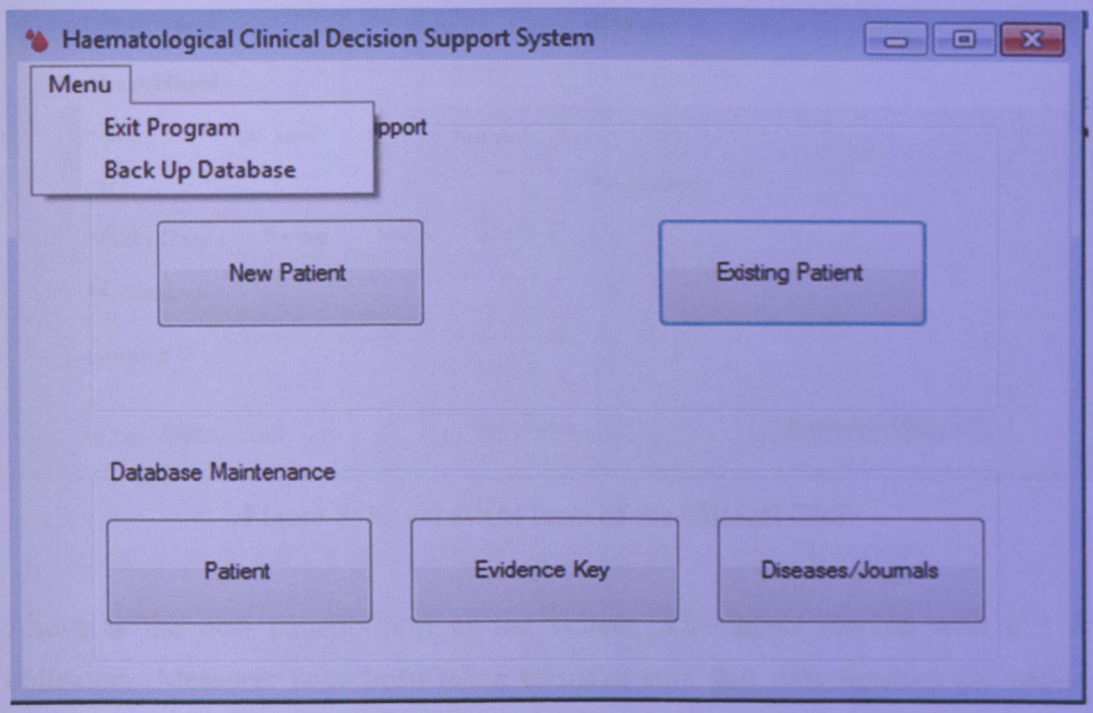


Figure 7: Home Page of the Clinical DSS

The above image shows the homepage of the system. The user clicks on the new patient if there is no existing patient data for the current patient and will click existing patient if there already is. The 3 buttons under database maintenance allows user to update patient data, evidence key, diseases and journals. The backup database on the menu screen will back up the database of the system in the computer based on a chosen file path. This is to maintain feasibility, and protect the data if anything were to happen to it.

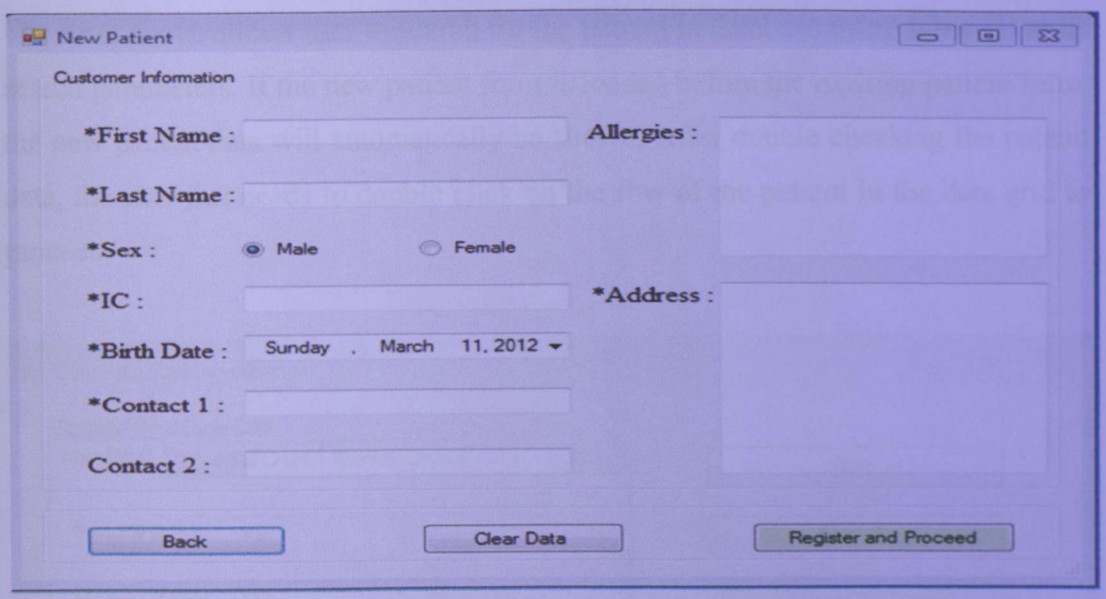


Figure 8: New patient form of the Clinical DSS

Above is the new patient form of the system. The labels marked with a * is obligatory. Measures have been taken to make sure that data inputted are within database format and is acceptable. The register and proceed button will bring user to the 'existing patient' form.

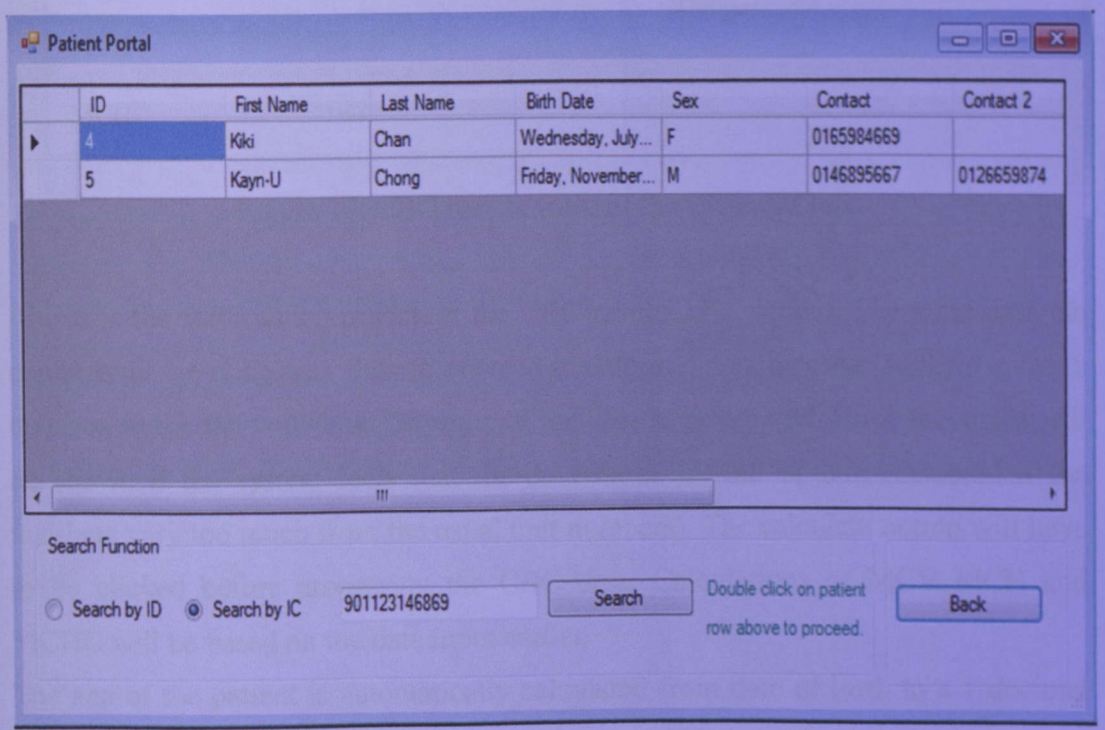


Figure 9: Existing patient form of the Clinical DSS

The form above allows user to search for the patient in database using ID or IC as its search parameters. If the new patient form is loaded before the existing patient form, the new patient data will automatically be shown. After double checking the patient data, the user just needs to double click on the row of the patient in the data grid to proceed.

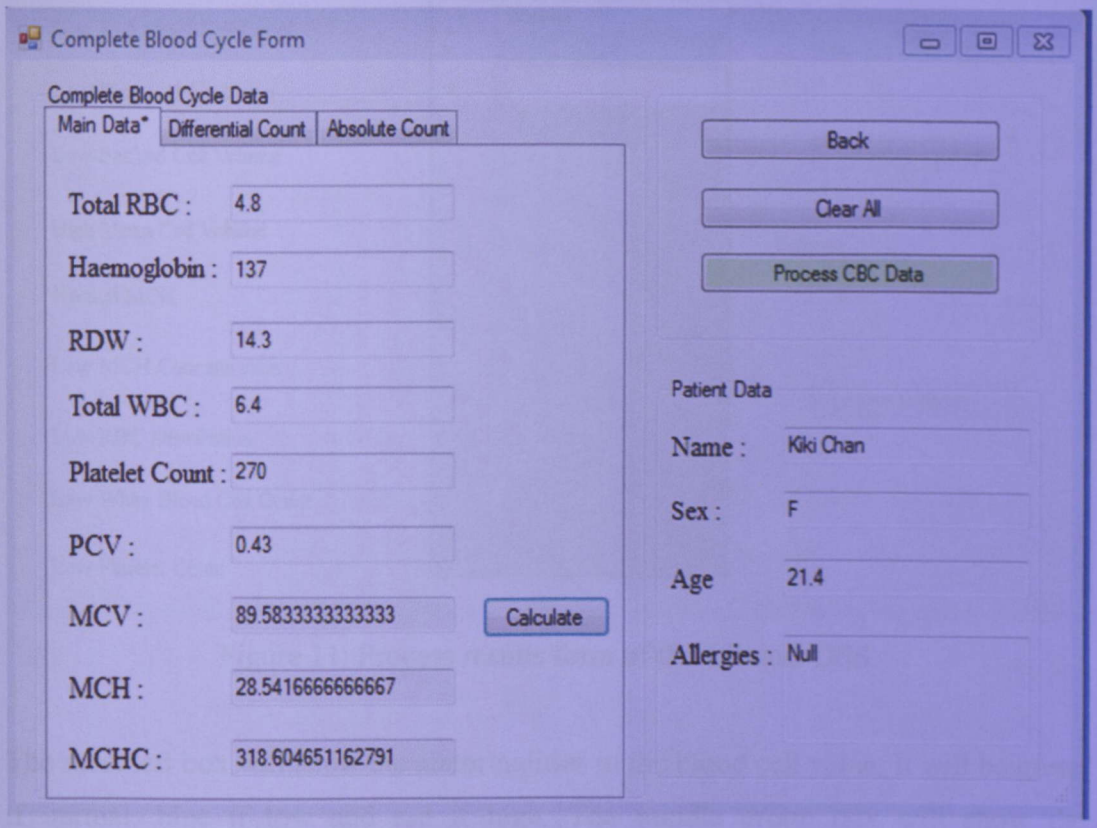


Figure 10: CBC results form of the Clinical DSS

Above is the form which processes the CBC results of a patient. The main data tab contains all the obligatory data to proceed in determining a disease. Tool tip on each text box in the tab will show the units of the data to be entered. Error messages will be shown if the system feels that the data input are out of unit (detected if the numbers vary too much from the usual unit numbers). The calculate button will have to be clicked before processing the CBC data. Calculations of MCV MCH and MCHC will be based on the data input earlier.

The age of the patient is automatically calculated from date of birth to a 1 decimal precision for reasons involving the normal ranges of CBC results.

The CBC data is the processed based on the patient data and CBC values input in the tab.

Results will be shown in the next form ('Process_results' form) along with possible diseases.

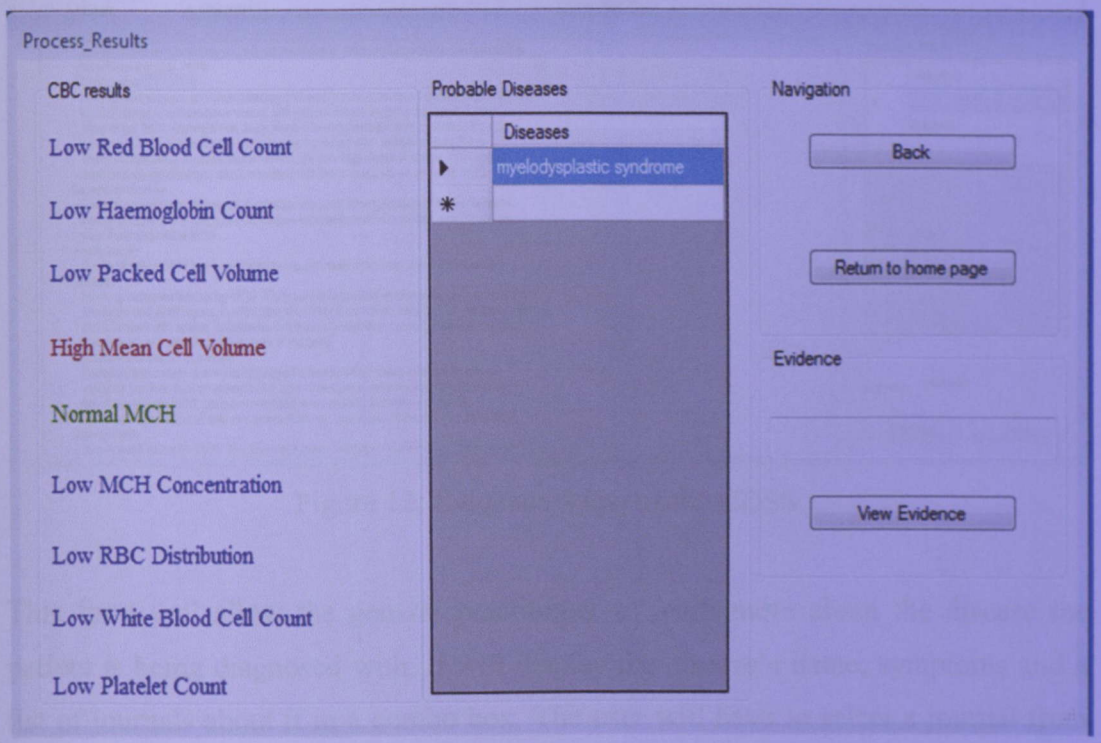


Figure 11: Process results form of the Clinical DSS

The most left box will show the abnormalities in the blood cell value. It will be green if normal, blue if low and red if high. The middle group box will show the possibilities of diseases. User can select it and click view evidence which will bring the user to a next form to view the journals, symptoms and pin point its contents.

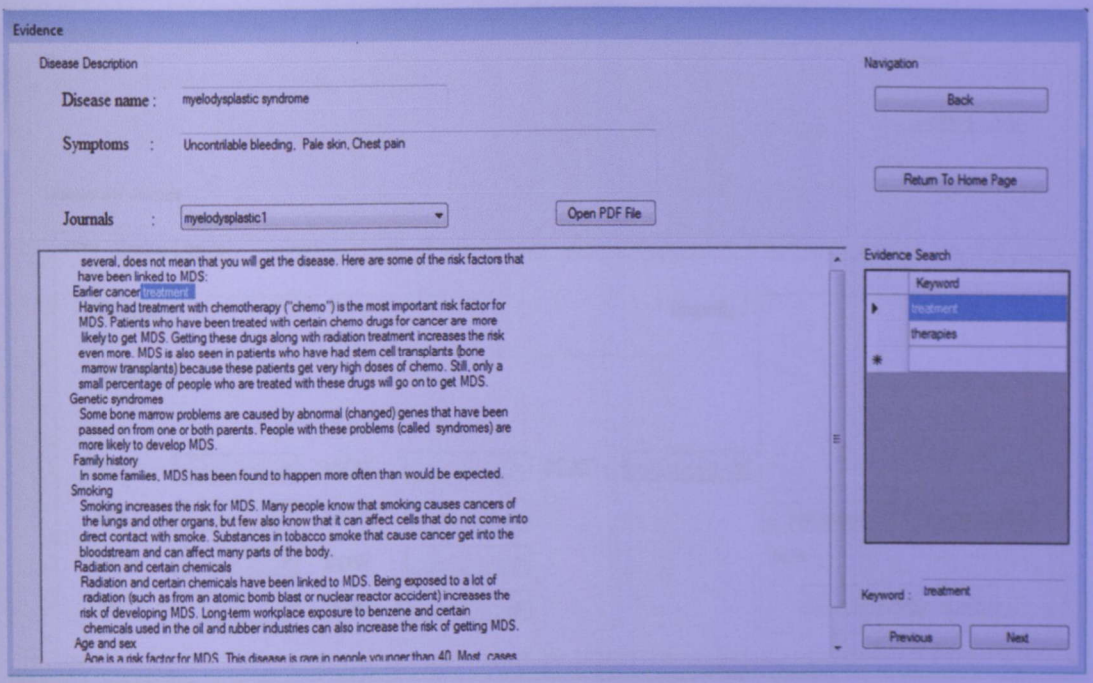


Figure 12: Evidence View of the CDSS

This form will allow the general practitioner to learn more about the disease the patient is being diagnosed with. It will display the disease's name, symptoms and a list of journals about it in a combo box. The user will have to select a journal from the combo box and has the option to use the system to breeze through it using the system GUI or press the 'Open PDF File' button to view the PDF version of the journal. The system GUI allows for general practitioners to easily search for key words between pages of the journals. If the keyword is found, the user will get the page of that journal with the keyword in the rich text box. This function could also be altered to return a single paragraph or half the page too so that too. These keywords are tied to a disease name. It is understood that different diseases calls for different keywords to find its important information in these journals.

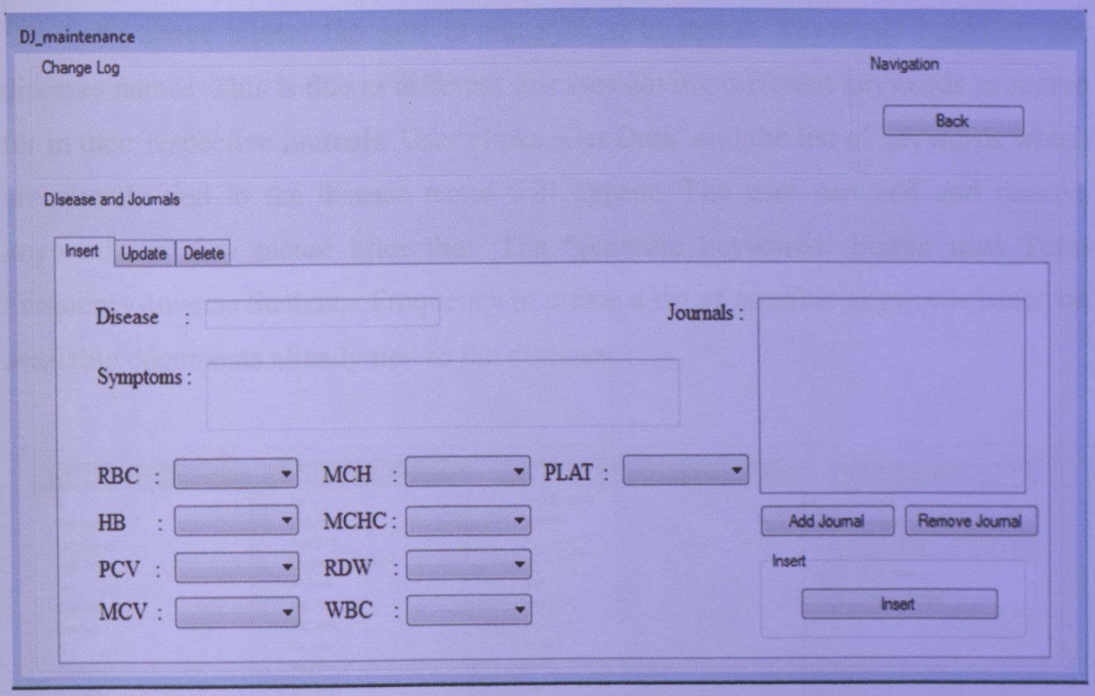


Figure 13: Disease/Journal database maintenance

This is the database maintenance GUI for the disease/journals database. Journals are tied to a disease. This GUI allows for the general practitioner to enter, delete, and update data with the security of data consistency. A change log is also provided to allow users to know what has been changed recently.

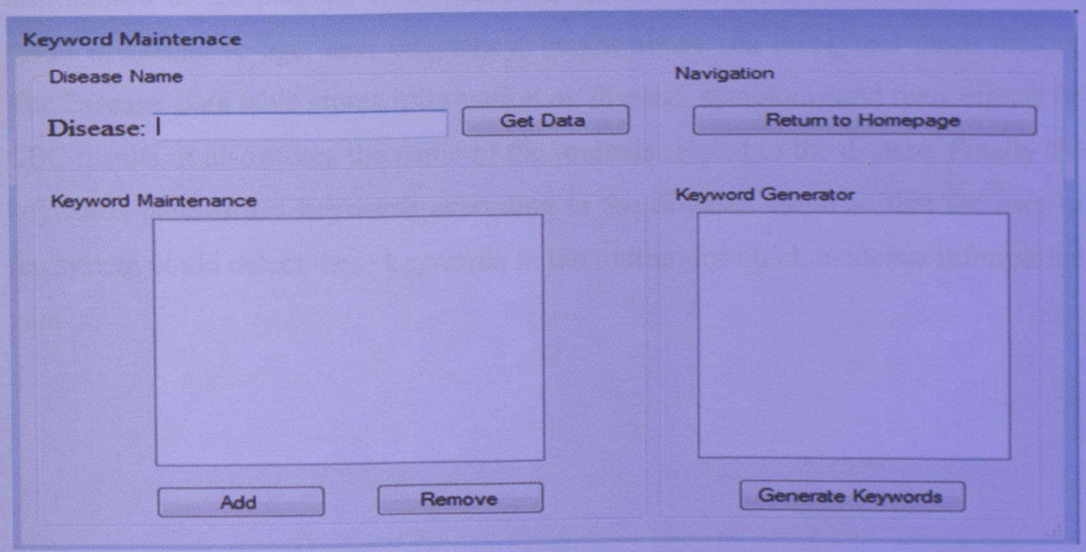


Figure 14: Keywords Maintenance

The form above allows the user of the system to update keywords based on the diseases names. This is due to different diseases having different keywords to search for in their respective journals. User clicks 'Get Data' and the list of keywords which are already tied to the disease name will appear. The user can add and remove keywords as they please after that. The 'generate keywords' button uses Term Frequency-Inverse Sentence Frequency to create a list of possible keywords based on available documents already tied to the diseases.

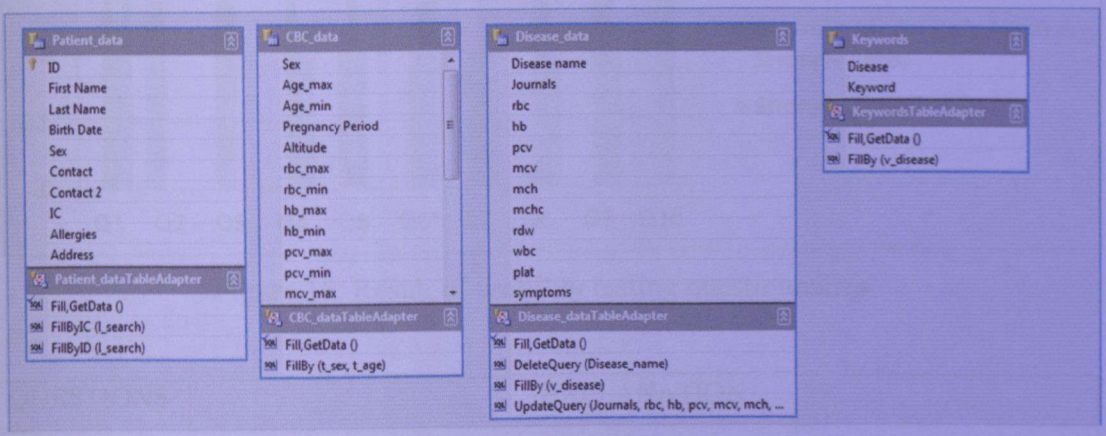


Figure 15: Database of the Clinical DSS

The figure above shows the dataset of the CDSS. It consists of four tables namely: Patient_data, CBC_data, Disease_data, and keywords. The patient data stores information of the patients while the CBC_data stores the normal ranges of CBC result according to age, sex, pregnancy, height above sea level, and more factors. The Disease_data table stores information on disease, symptoms and their effects on CBC results. It also stores the name of the journals related to the disease. Finally the keywords table stores keywords according to the diseases name so that the user of the system could detect these keywords in the journal for quick evidence information gain.

4.4 User Evaluation

4.4.1 Results for Usability Testing

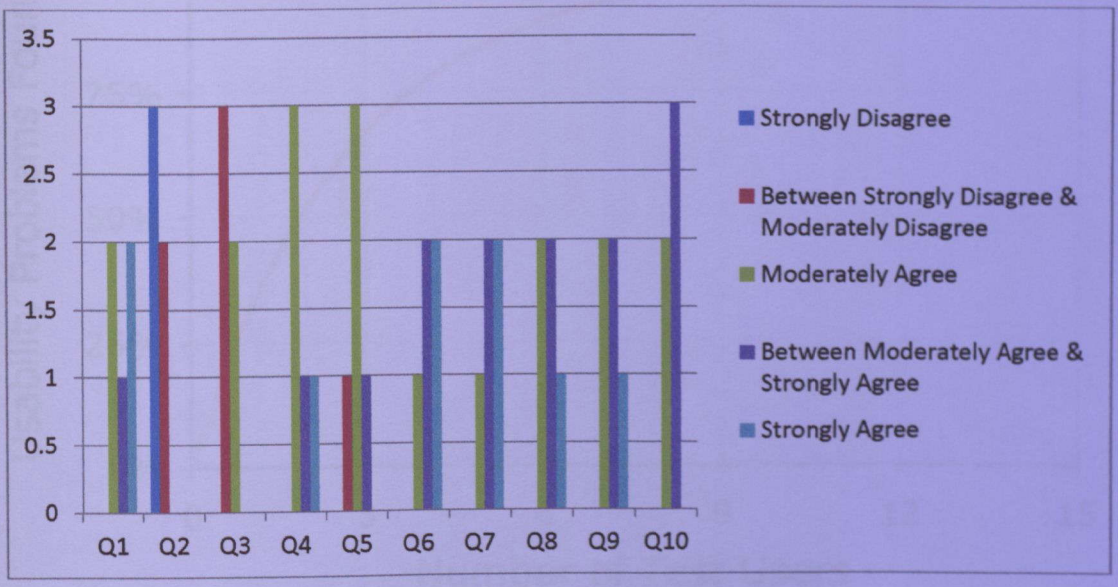


Figure 16: Result of usability testing questionnaires

QUESTIONS	EXPLANATION
1	System is easy to use
2	Need support of technical person
3	Need to learn a lot about the system before being able to use it
4	Information provided easy to understand
5	Information is effective in helping to make a decision
6	Information is organized properly
7	Interface of the system is pleasant
8	Like using the interface of the system
9	Various functions of the system are well integrated
10	Overall satisfaction of the system

Based on the results of the questionnaire directed to general practitioners, clinic receptionist, and some medical students, majority of them are satisfied with the system. Some doctors question the use of CBC results for diagnosing but later agree that it could be used as a base for further tests to finalize diagnosis. Overall, the system seems to be user friendly and is accepted as easy to be used by most of the people who answered the questionnaire. A doctor gave an opinion that a quick tutorial for the system is needed to increase its usability.

Only 5 people were involved in answering the usability questionnaire.

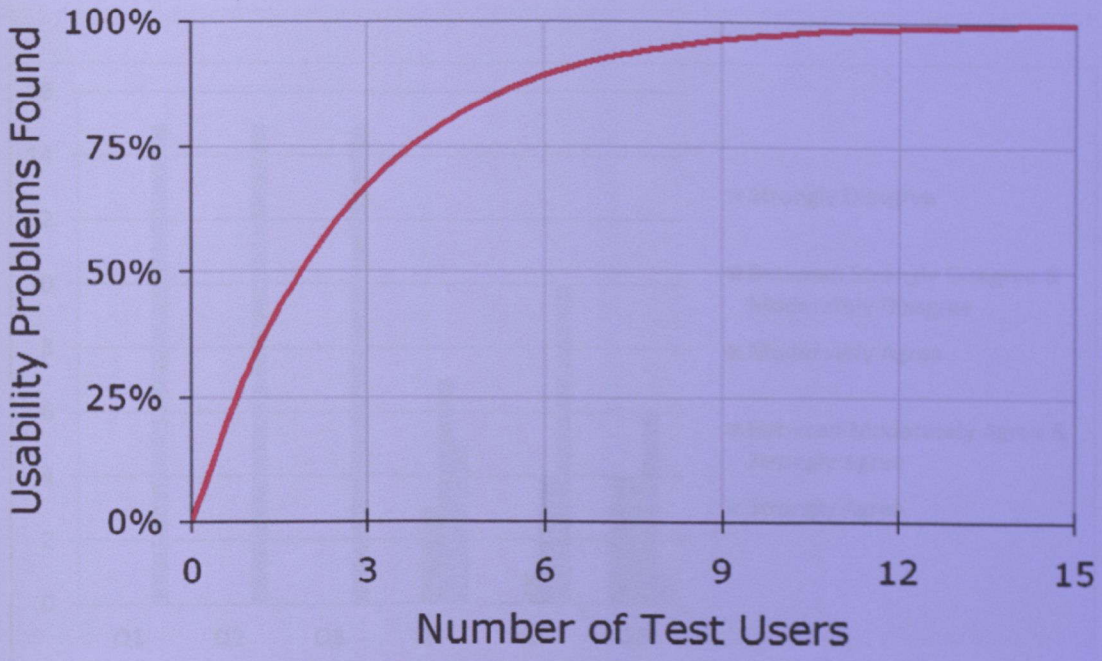


Figure 17: Graph for number of test users

The reason for the small number of test users was because of the graph shown above. (Jakob Nielsen, 2000) Based on the graph, the insights shoot up as soon as data collected from a single test user. It could be seen that almost one third of the problems were already detected. The difference between zero and even a little bit of data is astounding.

When the second test user comes in, it could be seen that the second user would do some of the same things as the first user causing an overlap of problems identified. The second test would add some new insight but less than the first person. The third user will do many things that you already observed with the first user or with the second user and even some things that you have already seen twice. Therefore, the third user would generate some new insights but less than the first and second user.

As you add more and more users, you learn less and less because you will keep seeing the same things again and again. By repeatedly observing the same insights again, temptation to revisit the design of the system for no proper reasons will occur. Therefore, the testing stopped at the fifth user where enough insights were already collected.

4.4.2 Results for Non-functional Testing

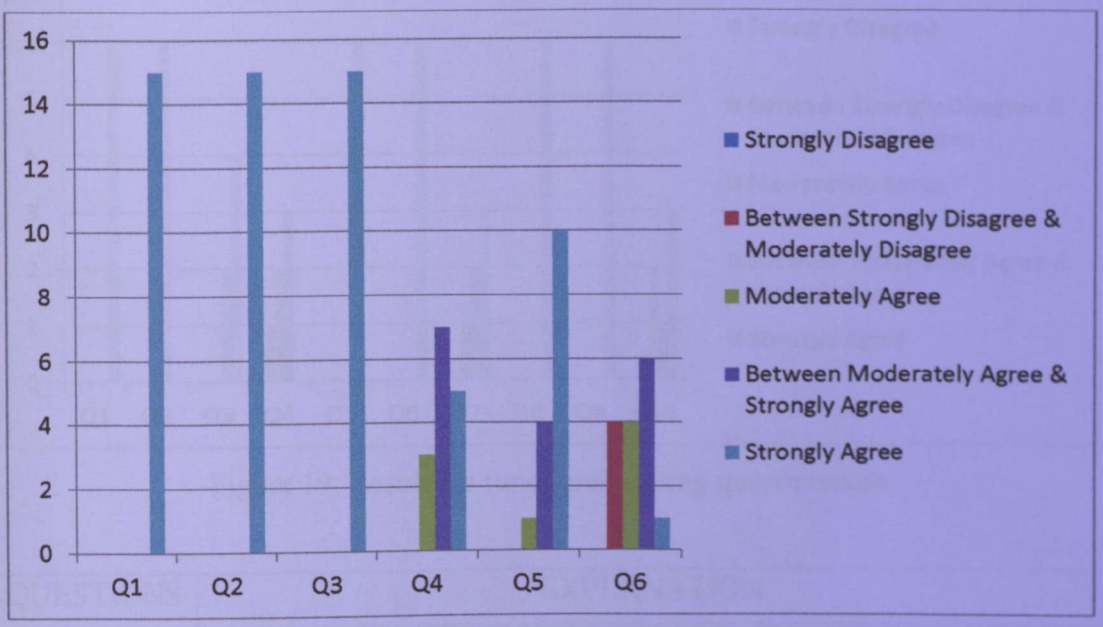


Figure 18: Result of nonfunctional testing questionnaires

QUESTIONS	EXPLANATION
1	System can operate on windows environment
2	System uses Microsoft Visual Studio
3	System uses Microsoft Office Access
4	System database can be updated real time
5	Flow of data from each process in system is good.
6	Change log required to track changes in databases

Based on the answers of 15 candidates, the nonfunctional requirement of this system has been fulfilled. This system can be successfully run in a windows environment without problem and uses Visual Basic as its code editor. Microsoft access is used as the system database and all agreed that the database could be updated real time. The flow of important information from each process is prominent. However, the 4 out of 15 disagreed that the change log could track the changes in database for the system only stores one change log at a time.

4.4.3 Results for Functional Testing

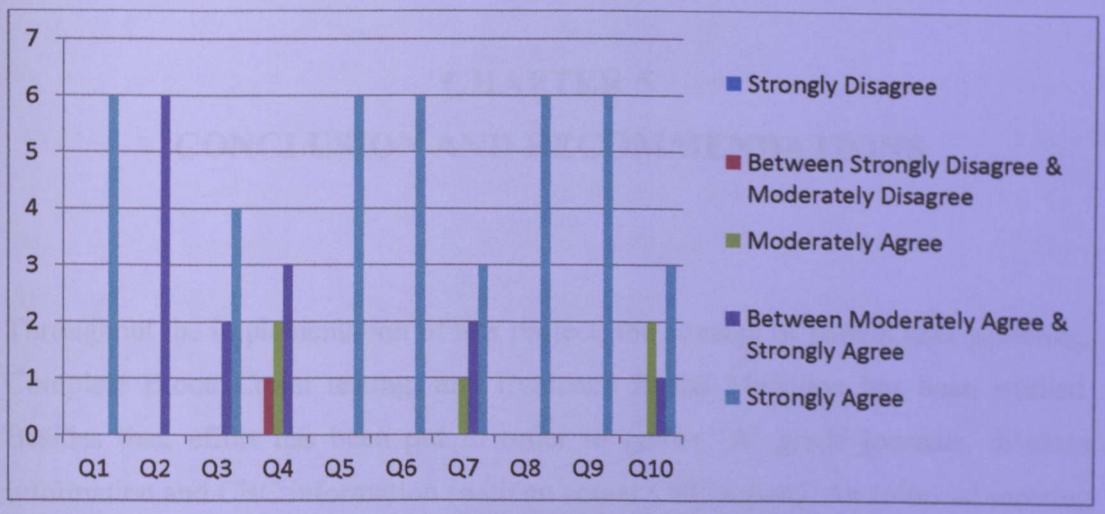


Figure 19: Result for functional testing questionnaire

QUESTIONS	EXPLANATION
1	System allows smooth patient registration and updates
2	Patient information can be viewed easily
3	System accepts realistic CBC report results
4	System can provide a list of probable diseases based on CBC results and patient information
5	System can calculate MCV. MCH, and MCHC based on CBC results
6	System successfully provides journals related to chosen disease
7	System allows smooth and easy browsing of journal contents
8	System allows database back up
9	System allows proper database maintenance
10	System capable of capturing tacit knowledge in journal content filtering from experienced general practitioners

Overall, the system does its function satisfactorily. A doctor questions the use of low, normal, and high blood counts in determining probable diseases. He suggests to be more detailed as to determine how high or how low is the blood count. Since no one strongly agrees that an accurate list of diseases could be produced, more work has to be done on that part. Information required for decision making is concluded to be easily viewed and understood. Finally, 3 out of 6 agree that the system was able to capture tacit knowledge in evidence searching.

CHAPTER 5
CONCLUSION AND RECOMMENDATIONS

Throughout the implementation of this project, the concept of patient data gathering, Complete Blood Count testing, and Evidence Based Medicine has been studied. Besides that, effort has been put in order to gather 'A' grade journals, diseases information and CBC information (with an actual CBC report). An informal meeting with a general practitioner was also conducted to get more information. It is confirmed through many articles, studies, and the general practitioner's opinion that the CBC results are often used as a first step of diagnosing a patient with hematological problems. Often, a CBC test is done and the general practitioner will continue other tests to further diagnose the patient. A decision support system at that basic level could assist a general practitioner greatly. Therefore, studies on the normal ranges of the CBC test results and the many hematological diseases which could be tied to the CBC results were done. EBM is also a current concept of diagnosing and prescribing patients now. It is the use of properly filtered evidence by experts in making medical decisions. These evidence usually comes from past tests/experiments, journals, and other relevant knowledge in written format. However, Evidence Based Medicine is hard to conduct because poorly maintained repository and the huge amount of evidences available. Therefore, EBM was studied with the purpose to find out how a GUI could help the general practitioner in using the EBM concept. In conclusion, the proposed system of hematological clinical decision support system is viable in this current society and all the efforts and studies done in the implementation of this project is in accordance to the objectives set in Chapter 1. It is hoped that after conducting the series of research and studies in the related areas, a hematological clinical decision support system that applies the use of CBC results and the EBM concept can finally be developed. Thus, all activities that have been accomplished so far are relevant to the objectives of this project.

Meanwhile, further recommendations and improvement to the system has been suggested for the future expansion of this project to make it more viable and useful. An improvement to the CBC result conclusion could be made by replacing the 'low', 'normal', and 'high' values of the cell count with more precise values that can show its intensity. For example, 'low' could be paired with number ranges of 1 to 5 showing the intensity of how 'low' is the cell count. This can allow for more accurate diagnosis of diseases. The system could also be further improved by collecting additional data from patients like drugs currently being used (has effect on the CBC normal ranges). The system could also be further improved by having a login form to protect the patient data for it is private. Finally, the system could also be improved by allowing it to accept other evidences from other sources instead of just PDF journals from the repository. These extra evidences from other sources could help the general practitioners make a more accurate decision. Including differential and absolute count of the different types of WBC as factors in determining diseases is also a good recommendation to help the system create a more accurate list of probable diseases.

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APPENDICES

APPENDIX A:

Example Patient Data Forms.

1)

UNIFOUR PAIN TREATMENT CENTER
PATIENT DATA FORM

Please complete this form prior to your appointment. Please be as accurate as possible. The information is confidential and will be available to your health care team and their staff only.
PLEASE BRING THIS FORM WITH YOU ON YOUR NEXT VISIT.

Patient Information:

Full Name: _____ Date of Birth: _____

Address: _____ Home Phone: ( ) _____

_____ Work Phone: ( ) _____

May we contact you at work? Yes ( ) No ( )

Email (optional): _____ Cell: ( ) _____

Social Security Number: _____ Sex: Male ( ) Female ( ) **Age:** _____

Contact person in case of emergency: Name: _____
Home Phone: _____
Cell / Work Phone: _____

Spouse's Social Security Number: _____
Spouse's Employer: _____ Spouse's Date of Birth: _____

Approximate distance from your house to our office: _____ miles
How long is your expected travel time to our office? _____
Name, address, and phone of your pharmacy: _____
_____

Insurance Information: ***Please Bring All Insurance Cards With You***

Insurance Company: _____

Certificate No.: _____ Group No.: _____

Insured Name: _____

Relationship to you: ( ) self ( ) spouse ( ) other _____

Additional Insurance: _____

Certificate No.: _____ Group No.: _____

Insured Name: _____

Relationship to you: ( ) self ( ) spouse ( ) other _____

RN Initials: _____

Frye Regional Medical Center
UNIFOUR PAIN TREATMENT CENTER
PATIENT DATA FORM
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2)

SETH P. LEVINE, M.D., F.A.C.S ABRAHAM KNOLL, M.D.

ASSOCIATES IN UROLOGY NORTH JERSEY, P.A.

Diplomates American Board of Urology

DATE_____ PATIENT DATA FORM

LAST NAME_____FIRST NAME_____MI____

BIRTHDATE_____ AGE_____ M / F SOC.SEC. # _____

ADDRESS_____CITY_____STATE_____ZIP_____

TELEPHONE: HOME_____WORK_____

DO YOU RECEIVE ANTIBIOTICS PRIOR TO DENTAL TREATMENT FOR JOINT REPLACEMENT OR

MITRAL VALVE PROLAPSE? YES_____ NO_____

REFERRING

MD_____OCCUPATION_____

MARITAL STATUS : SINGLE____ MARRIED___ WIDOWED___ DIVORCED___ SEPARATED____

SPOUSE'S NAME_____NUMBER OF CHILDREN_____

EMERGENCY CONTACT_____TELEPHONE _____

PHARMACY_____TELEPHONE _____

PRIMARY CARE MD_____

TELEPHONE_____

INSURANCE POLICY HOLDER_____DOB_____SOC.SEC.# _____

I HEREBY ASSIGN ALL MEDICAL AND/OR SURGICAL BENEFITS, INCLUDING MAJOR MEDICAL,MEDICARE, BLUE SHIELD, HMO AND COMMERCIAL INSURANCE TO ASSOCIATES IN UROLOGYNO. JERSEY, PA. I UNDERSTAND THAT I AM RESPONSIBLE FOR ALL NON-COVERED CHARGES FOR PARTICIPATING INSURANCES AND ALL CHARGES FOR NON-PARTICIPATING INSURANCES.

I HEREBY AUTHORIZE THE RELEASE OF ANY INFORMATION NECESSARY TO SECURE PAYMENT

ON MY BEHALF. I AM AWARE THAT I AM RESPONSIBLE TO NOTIFY THIS OFFICE OF ANY CHANGE IN MY INSURANCE CARRIER (S), COVERAGE OR CO-PAY.

DO YOU HAVE A DRUG (P.A.A.D.) CARE? Y N DO YOU HAVE A PRESCRIPTION PLAN? Y N

DATE_____SIGNATURE_____

I _____ (HIC#_____), REQUEST THAT PAYMENT

OF AUTHORIZED MEDICARE BENEFITS BE MADE EITHER TO ME OR ON MY BEHALF TO ASSOCIATES IN UROLOGY NORTH JERSEY, P.A. FOR ANY SERVICES FURNISHED ME BY PHYSICIAN OR SUPPLIER. I AUTHORIZE ANY HOLDER OF MEDICAL INFORMATION ABOUT ME TO

RELEASE TO THE CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) AND ITS AGENTS ANY BENEFITS PAYABLE FOR RELATED SERVICES.

DATE_____SIGNATURE_____

I HEREBY ACKNOWLEDGE THAT I HAVE BEEN PRESENTED WITH A COPY OF ASSOCIATES IN UROLOGY NO. JERSEY, P.A.'S NOTICE OF PRIVACY PROTECTION.

DATE_____SIGNATURE_____

ASSOCIATES IN UROLOGY NORTH JERSEY, PA

NAME_____**SS#**_____**DATE**_____

REASON FOR VISIT:_____

MEDICAL CONDITIONS (PLEASE LIST):

HOSPITALIZATIONS YES___NO___ IF YES WHEN, WHERE AND FOR WHAT CONDITION

SURGICAL PROCEDURES (PLEASE LIST) WHEN PHYSICIAN WHERE TREATED

MEDICATIONS (INCLUDE OVER THECOUNTER)_____

ALLERGIES_____

SMOKE___HOW MUCH_____QUIT WHEN_____ ALCOHOL___HOW MUCH_____QUIT WHEN_____

DO YOU HAVE A FAMILY HISTORY OF ANY OF THE FOLLOWING:

CANCER_____DIABETES_____HEART DISEASE_____HIGH BLOOD PRESSURE_____KIDNEY DISEASE_____

INDICATE THE HEALTH STATUS OF FAMILY, IF DECEASED GIVE AGE AND CAUSE OF THE DEATH:

MOTHER_____

FATHER_____

BROTHERS_____

SISTERS_____

PLEASE COMPLETE THE OTHER SIDE OF THIS FORM

APPENDIX B:

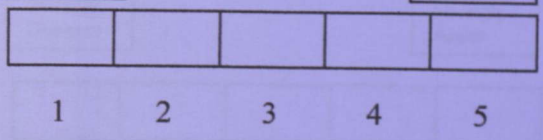
Sample of Functional Requirements Questionnaire

Hematological Clinical Decision Support System Functional Requirements Questionnaire

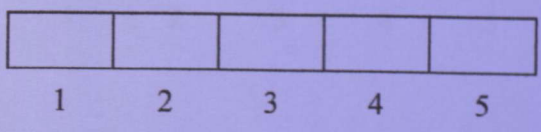
Please respond to all questions bellow by ticking the appropriate level of agreement next to the questions.

Strongly Disagree — Strongly Agree

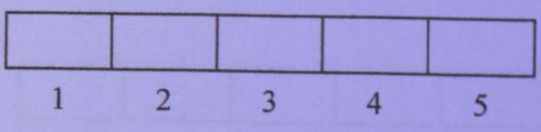
1. System allows smooth patient registration.



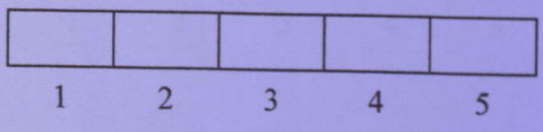
2. Patient information can be viewed easily.



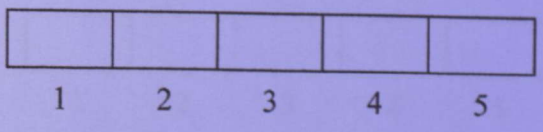
3. System accepts realistic CBC results.



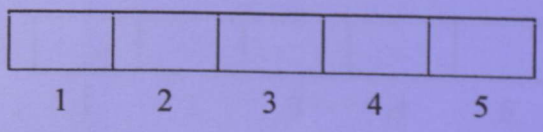
4. System able to provide list of accurate probable diseases based on CBC results.



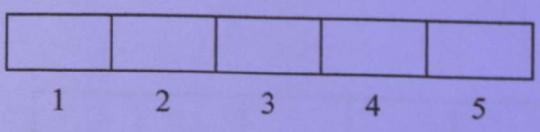
5. System can calculate MCV, MCH, and MCHC.



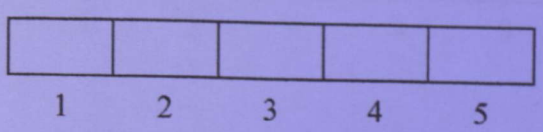
6. System able to provide journals related to chosen disease.



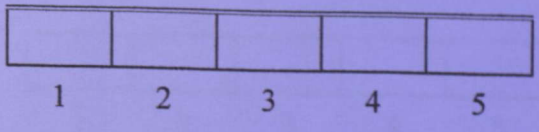
7. System allows smooth and easy journal content browsing



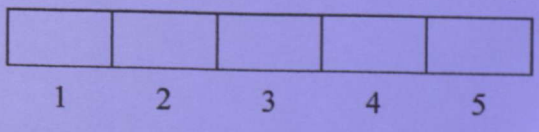
8. System allows database back up.



9. System has proper database maintenance



10. Capable of capturing tacit knowledge in journal content searching via keywords



APPENDIX C:

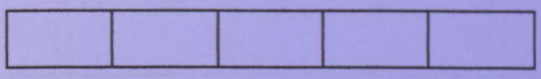
Sample of Non-functional Requirements Questionnaire

Hematological Clinical Decision Support System Nonfunctional Requirements Questionnaire

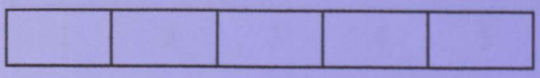
Please respond to all questions bellow by ticking the appropriate level of agreement next to the questions.

Strongly Disagree — Strongly Agree

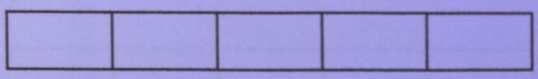
1. The system can operate in windows environment



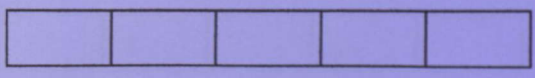
2. The system uses Microsoft Visual Studio



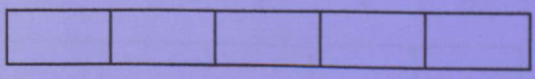
3. The system uses Microsoft Office Access



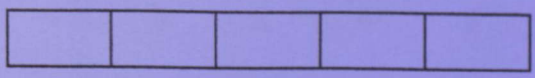
4. The system database can be updated real time.



5. User login should be required to access system



6. Database change log should be required



APPENDIX D:

Sample of Usability Questionnaire

Hematological Clinical Decision Support System Usability Questionnaire

Please respond to all questions bellow by ticking the appropriate level of agreement next to the questions.

	Strongly Disagree				Strongly Agree
1. I think this system is easy to use.	1	2	3	4	5
2. I think I need the technical support to use the system.	1	2	3	4	5
3. I need to learn a lot on how to use the system before being able to use it properly.	1	2	3	4	5
4. The information provided by the system is easy to understand.	1	2	3	4	5
5. The information provided really helps in making decisions.	1	2	3	4	5
6. The interface of the system is pleasant.	1	2	3	4	5
7. The information is organized clearly.	1	2	3	4	5
8. I like using the Graphical User Interface.	1	2	3	4	5
9. I think the various processes of the system are well integrated.	1	2	3	4	5
10. Overall, I am satisfied with the system.	1	2	3	4	5

APPENDIX E:

Gantt charts

FINAL YEAR 1st SEMESTER (September 2011)

No.	Detail/ Week	1	2	3	4	5	6		7	8	9	10	11	12	13	14
1	Project title selection and start							Mid-semester break								
2.	Preliminary research work															
3.	Preliminary report submission															
4.	Study on fundamental concepts related to the project															
5.	Study on CBC testing															
6.	Project defense and progress evaluation															
7.	Study on EBM approach for handling diseases															
9.	Preparation of interim report															
10.	Submission of interim report															
11.	Oral presentation															

FINAL YEAR 2st SEMESTER (September 2012)

No.	Detail/ Week	1	2	3	4	5	6	7		8	9	10	11	12	13	14
1	Project Development								Mid-semester break							
2.	Researching on journals and diseases															
3.	Progress report submission															
4.	Study on reading PDF files using Visual Basic															
5.	Studies on CBC testing and Patient data required															
6.	Pre-EDX															
7.	Study on EBM approach for handling diseases															
9.	Submission of draft report															
10.	Submission of technical paper and dissertation															
11.	Oral presentation															