Decision Support for the Management of Essential Hypertension

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Declaration

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Abstract

The thesis presents a decision support system targeted at the needs of health care professionals in primary care. The architecture of the new decision support system is based on a model of the management of a patient with essential hypertension, that itself is based on the observation of the interactions between medical practitioner and patient and the recognition and formalisation of the steps in that process.

The need for a new decision support system is driven by two independent factors. Firstly rapid advances in medical knowledge have created enormous pressures on practitioners, who have a real need to maintain and update their medical knowledge. Secondly rapid advances in computer technology, particularly in the 1990s with the introduction of new design features into desk top computers has created opportunities for system designers to introduce a wide range of facilities into user interfaces, which in turn, provide medical practitioners with tools that are both useful and easy to use. In effect it is the combination of a medical need and user friendly technology that now enables an embedded decision support system to be demonstrated.

The work that is reported in the thesis has three main features, which have been implemented into a prototype demonstrator:

Firstly, a model of the management of a patient with essential hypertension is described which enables decision support to reflect the decision making needs of the clinician and to interface transparently with their normal working practice.

Secondly, the system architecture which enables a range of decision support components to be embedded within the normal consultation environment is described. This approach has enabled convenience, ease of access and ease of use of decision support facilities, to be demonstrated.

Thirdly, clinical guidelines have been utilised to form the foundation of the systems knowledge base. In using these guidelines it has been noted that they have been developed by several international teams of medical experts to guide doctors in their diagnosis and treatment of patients with essential hypertension.

The thesis concludes with the results of the system evaluation. The evaluations have enabled the methods and techniques that have been used to design and develop the new system to be tested, and for the advice generated by the system to be compared with current medical opinions.

1. Chapter One : Introduction to the Thesis

1.1 Background and Motivation

Medical Informatics is a relatively new field of study that has emerged from the increasing use of computers in both hospitals and general practice. Research into computer based medical applications has been pursued almost from the day the first computers were commercially available, but it is only relatively recently that specific applications, including computerised CT scanners, laboratory instruments and ECG interpreting systems, have been adopted by medical practitioners for use in routine clinical practice. Despite the success of a small number of computer based medical applications, the uptake of computer technology to assist in medical decision making has been slow. This is because the very nature of medical knowledge is not easily computable, particularly as a great many crucial patient decisions are made on the basis of judgements from a wealth of, often conflicting, data sources. However the increasing complexity, rate of change and depth of medical knowledge has created a demand from the medical profession for decision support systems.

The clinical domain of hypertension has been chosen to demonstrate how a decision support system could be developed for use in the primary care environment. Hypertension is a higher than normal blood pressure, which effects approximately 20% of adults aged over 40 years, and is the most reliable factor for predicting subsequent stroke and coronary heart disease, which accounted for nearly 40% of all deaths in the UK in 1990. Evidence from clinical trials has shown that drug treatment to lower blood pressure substantially reduces the risk of cardiovascular disease, particularly strokes and heart attacks. However only half the eligible patients receive treatment and in only half of these does treatment achieve a satisfactory blood pressure reduction. Consequently hypertension is one of the most common chronic problems in the Western world, and given its high incidence and the lifelong treatment and monitoring it requires, it consumes significant health care resources; thus ensuring optimal treatment and management is an important issue both for maximising quality of care to a large number of patients and ensuring cost effectiveness.

These issues provide the motivation for a research study into the application of decision support to the medical condition of hypertension.

1.2 Hypothesis, Aim and Objectives

1.2.1 Hypothesis

Given the background summarised in section 1.1, the hypothesis that will be tested in this research is that by developing a user centred approach to analysis and design, a decision support system can be developed which satisfies the need of users, who will demonstrate their willingness to incorporate the system into routine clinical practice.

1.2.2 Aim

The aim of this research is to address some of the barriers which prevent widespread use of decision support in current clinical practice, and demonstrate how these may be overcome by the development of a decision support system that satisfies the following criteria :

- It is **reliable**, in that it produces consistent and reproducable results.
- It is **effective**, in that it meets decision making needs and provides safe and appropriate advice.
- It is **easy to use**, in that it is integrated within doctors' normal working practice and its design features facilitate ease of access and ease of use.

In order to identify a realistic set of research objectives to satisfy these aims, the scope of the project is confined to decision support for the treatment and management of a patient with essential hypertension in primary care. The target user group is the general practitioner.

1.2.3 Objectives

The following objectives have been developed to satisfy the aims of the research:

- To analyse the issues preventing the widespread use of decision support in primary care and to develop a user centred application environment.

- To analyse the decision making needs of the clinician in the diagnosis, treatment and management of a patient with hypertension, and to model this process to enable decision support facilities to be embedded into normal working practice, and to compliment the natural interaction between clinician and patient.

- To make recommendations for the design of a decision support system in primary care which recognises the need for:-

  a) a flexible, event driven architecture that maps users' operational needs but which allows the medical practitioner to make the final judgement.

  b) a user interface which sustains and supports a smooth continuum between medical practitioner and patient.

  c) a verified and referenced knowledge base that clearly identifies the source of recommendations.

- To develop a prototype clinical decision support system for the treatment and management of hypertension, that takes advantage of the data processing and presentational capabilities of modern technology, in order to demonstrate some of the recommendations.

- To evaluate the prototype system to demonstrate that:-

  a) the system is reliable in that it produces consistent and reproducable results.

  b) the system is effective in that the knowledge bases are comprehensive enough to cope with a wide range of different cases, and the advice generated is medically safe and appropriate.

c) the system is easy to use and the format in which the advice is presented is acceptable to the user.

1.3 Chapter Summaries

In this thesis the issues summarised above are presented in eight chapters, which contain the following material:

Chapter one is the introduction and contains the structure of the thesis.

Chapter two presents a generic overview of medical decision support and a detailed review of eight decision support systems which have been designed to assist the clinician in the management of hypertension. This analysis provides the basis for a specification of the design features that have been incorporated into the conceptual model that has underpinned the development of the *embedded decision support* system, (E.D.S).

Chapter three presents the core ideas of a model representing the decision making process which provides the basis for the design of the *embedded decision support* system. The model also takes into consideration the need for a user friendly human computer interface. The chapter provides a summary of the evaluation process which is an essential feature of the development of a decision support system.

Chapter four contains a detailed discussion of the medical condition hypertension, and discusses the origins of the knowledge base. It is readily appreciated that the knowledge base is a crucial component of the decision support system in that it has to be repeatable, reliable, and verifiable. Previously poor knowledge bases have been a significant factor that have inhibited the application of decision support in medical practice. This chapter describes the solution adopted in the E.D.S. system.

Chapter five is concerned with implementation issues and the detailed design features that have been incorporated into the *embedded decision support* system. A particular

feature of modern system development is the availability of the Microsoft windows environment, which provides a platform for the application of various design tools. The prototype has been developed in LPA Prolog, which has a range of features that make it a suitable implementation language.

Chapter six presents the results of the evaluation of the prototype system. The system has been tested with a range of case studies, provided by several different consultants and general practitioners, which have provided evidence that the advice generated by the system is reliable, effective and appropriate. The prototype system has also been demonstrated to, and used by, several general practitioners who have confirmed that the system is easy to use and the generated advice is both safe and appropriate.

Chapter seven presents a review of the key issues the thesis sort to address and a discussion of the evidence provided by the results of the evaluations described in chapter six.

Chapter eight presents the conclusions of the thesis which describe the extent to which the objectives have been met, outlines the contributions to knowledge and contains the proposals for future work.

2. Chapter Two: Medical Decision Support

2.1 Introduction

In this chapter a generic overview of the subject of medical decision support will be presented. This includes a widely accepted definition of medical decision support; a summary of the historic development of medical decision support systems; the identification of some of the factors which have influenced the development of medical decision support systems; a review of eight decision support systems which have used hypertension as their application domain, and an analysis of those factors which have restricted the effective implementation of decision support in the clinical environment. This review provides the basis for the specification of those features which have been incorporated into the design of the embedded decision support system, and establishes that the focus of the work reported in this thesis is driven by the recognition of medical need.

2.2 Review of Medical Decision Support

2.2.1 Definition of Decision Support

Clinical decisions involve diagnosis, therapy and monitoring. The aim of a decision support system is to make appropriate information available to the decision maker at a time that can influence the decision making process (Benson and Neame, 1994).

A widely accepted definition by Shortliffe (1987) suggests that a clinical decision support system is any computer program designed to help health care professionals make clinical decisions. Thus any computer system that deals with clinical data or medical knowledge can be considered to provide decision support. Shortliffe (1987) suggests that clinical decision support systems can be divided into three categories:

1. Tools for information management. For example, hospital information systems and bibliographic retrieval systems. These tools provide data and knowledge as requested by the user, in this case a clinician, but they generally do not help them to apply that information to a particular decision task. Interpretation of the data and the appropriate decision is the task of the clinician.

2. Tools for focusing attention. For example, clinical laboratory systems and pharmacy systems. These systems flag abnormal values, or warn of possible drug interactions. Such programs are designed to remind the user of diagnoses or problems that might otherwise have been overlooked.

3. Tools for patient specific consultation. These systems provide patient specific assessments and generate advice on likely diagnoses or appropriate therapies.

The relevance of these distinctions is often debated, for example, Linnarson (1993) argues that these categories are not distinct and an effective decision support system will integrate all three components, to provide the clinician with a comprehensive support environment. The key issues are that a decision support tool :-

- must have some degree of reasoning embedded in the system.

- must not seek to usurp the authority of the medical practitioner who has to carry the final responsibility.

- must satisfy the primary purpose of a decision aid, which is to complement the medical practitioners skills.

In this context Heathfield and Wyatt (1993) suggest there are five major issues to consider for successful implementation of decision support systems.

Firstly it is important to formalise the real requirements of potential end users. If a clinical decision support system aims to address a real clinical problem then developers must first attempt to establish a genuine need for the system, by determining the nature

and quality of decisions currently made and their impact on patients, health care workers and the health service.

Secondly system developers must ensure that the system closely matches the end-users' requirements. This can be achieved by user involvement at all stages of the design and development process. One method to achieve this, and concurrently assess the appropriateness of the proposed solution is through rapid prototyping. This technique provides insight into what functions are required of the system. However after documenting amendments the prototype system should be destroyed and the ideas re-implemented in a more appropriate programming language.

Thirdly a model of the problem should be developed. This creates an understanding of the application domain and enables the key problem areas to be identified, and also has the indirect benefit of improving communication between designers and intended users.

Fourthly an appropriate choice of methods, mechanisms and tools should be made. The model of the clinical problem can also be used to facilitate the choice of development tool to build the decision support system which responds to the defined problems. This results in a system which is truly problem and not software driven, which is believed to result in a system more acceptable to users.

Fifthly the system should be evaluated. For a system to be accepted into routine clinical use, clinicians must be convinced of the systems safety, accuracy, effectiveness and usability. It is also important to assess the systems impact on users, patients and the healthcare system.

Finally there must be professionalism in implementation, maintenance and support. The effort involved in developing, maintaining and supporting a decision support system is often underestimated, for example, a system must have suitable documentation and instructions on use, there must be effective backup services to answer users queries, and plans for updating the system must be made.

This general approach has been used as the framework for the design and development of the embedded decision support system which is described in detail in chapter three.

2.2.2 Historical Perspective

The potential for computers to assist in medical decision making was first recognised in the late 1950s (Ledley and Lusted, 1959). By 1964 experimental prototypes were shown to be effective (Warner et al. 1964). Two examples of early computerised decision support systems were de Dombal system for the diagnosis of abdominal pain (de Dombal et al. 1972) based on bayesian probability theory, which was used in an accident and emergency department, and Shortliffe's system MYCIN (Shortliffe, 1976) for the selection of antibiotic therapy based on a system of production rules, which although evaluated, was not used in the clinical environment. Since that time many applications have been developed in most medical domains (Miller, 1994). During the 1980s and 1990s several other developments have contributed to and influenced the development of clinical decision support systems:-

- Development and widespread use of clinical information systems
- Increasing growth and complexity of medical knowledge
- Increasing demand and cost of health care.
- Increasing legal pressures on health care professionals
- Changes in the structure of the health care system

These will be considered in more detail in section 2.2.3. However despite the apparent accuracy of these systems, and the potential demand from the medical community, few decision support systems are in routine clinical use. This was highlighted in a survey by Cramp and Goodyear (1989), which showed that of 25 European organisations who were then involved in the development of diagnostic systems, only three systems were

in use outside their site of origin. This observation is supported by Shortliffe and Clancy (1984), who reviewed the progress those involved in the development of decision support systems had made over a ten year period, and found that few systems had progressed beyond the stage of system development. Some of the reasons for the lack of routine use of clinical decision support systems are outlined in section 2.4, but a key factor is the lack of professional accreditation of the knowledge base. In general the reason why few systems are in general use outside their site of origin relates to the personal nature of medical expertise. Many decision support systems have based their knowledge structure on the opinions of experts through knowledge elicitation techniques, but in general there is no scientific proof, that is analogous to the laws of physics, that clearly lays down unequivocal knowledge boundaries, with the consequence that there has been an area of uncertainty surrounding medical decision support systems. A key feature of the work reported in this thesis is that the knowledge base provides justified evidence to support recommended findings, and the evaluation has shown that this approach will support acceptance of the technology into practice.

2.2.3 Factors Influencing the Development of Clinical Decision Support Systems

2.2.3.1 Clinical Information Systems

The development of personal computers that can store, process and manipulate information, coupled with the generation of easy to use software, has led to the acceptance and use of computers in industry, society and commerce. Doctors are making extensive use of computer tools such as word processors, spread sheets and graphics packages. Computerised C.T. scanners, laboratory instruments and E.C.G. interpreting systems are also in widespread use. Users have demonstrated that they are willing to invest substantial time and effort into learning how to use these tools *if they perceive that there are real advantages to be gained from their use*. This has stimulated interest in developing software tools to meet the specific needs of health care professionals.

One example of the successful implementation of computer technology into practice is the clinical information system. Use of such systems by general practitioners in the United Kingdom has grown dramatically since a Department of Health project introduced the first paperless consultation records at a general practice in Ottery St Mary, near Exeter in 1976. Today, about 6000 GPs (2 per cent) no longer keep hand-written notes and the Department of Health has undertaken to change the law to allow computer based records to be legal as the principal record of care. It is likely that the use of computerised patient records will continue to increase during the next few years and it has been predicted that in the future most GPs will be using computerised patient records. The background to this uptake of computer technology is summarised below (Benson and Neame, 1994) and it is recognised that the Ottery St Mary project has been a cornerstone for medical acceptability of this technology in medical practice:

1. During the 1970s the Department of Health sponsored an experimental computer project at Ottery St Mary near Exeter, which produced the first fully computerised 'paperless' general practice.

2. In 1981 as a result of the Ottery St Mary project, a computer version of the prescription form became available. This led to the spread of computer based repeat prescribing systems.

3. In 1982, a government initiative 'Micros for GPs' was launched, which provided 150 practices with heavily subsidised systems. This generated a great deal of political and professional interest in GP computing, which provided the foundation for future developments.

4. In 1987, two GP system suppliers launched similar no-cost computer schemes. In return for anonymous data about doctors drug prescribing, morbidity and side-effects, practices were provided with a computer system almost free of charge. Each company expected to recoup its costs by selling data to the pharmaceutical industry for post-marketing surveillance, clinical trials and market research. Nearly 2,000 practices (20 per cent of all practices) participated in these schemes, which resulted in the first widespread use of computers at the point of care.

5. In 1989 the Department of Health introduced direct reimbursement of some computer system costs. Fund-holding practices received up to 100 per cent reimbursement. However practices already participating in the no-cost schemes were not eligible. In 1991, the no-cost schemes collapsed.

6. In 1990 the GP Contract introduced a further financial incentive for GPs to maintain good information systems. GPs received extra payment if they met stringent targets for preventative medical procedures such as immunisations and screening. The combination of direct reimbursement and the demands of the new contract led to a boom in the installation of GP computer systems during 1990-91.

7. In 1991, the principle of software accreditation was introduced for fund-holding software. This principle was extended to GP-FHSA links in 1993, and from 1994 all GP systems required third-party accreditation as a precondition for reimbursement. One objective was to bring all systems up to the same standard and to facilitate links between the FHSA, hospitals and community services.

To explore the use of computers the NHS GP Computing Survey (1993) was conducted which covered all practices in England and Wales during April-May 1993. Results from the survey confirmed that GP computer systems are heavily used. The average time spent using the computer each week by each user is shown in table 2.1.

User	**Hours per Week**
Receptionist	16.8
GP	16.1
Secretary	15.5
Practice Manager	13.6
Practice Nurse	10.9

Table 2.1 Average Time Spent Using the Computer

Another feature highlighted by the survey was that systems were used by doctors and nurses for clinical purposes, not just by clerical staff for administrative and financial tasks. The main uses of the computer are shown in table 2.2.

Task	Use of Computer for Each Task (%)
patient registration	98
repeat prescribing	94
clinical records (full or part)	90
call and recall	84
annual practice report	80
audit	77
acute prescribing	58
referral letters	51
word processing	48
spreadsheets	30
full clinical records	29
protocols of care	29
payroll	29
accounts	25
graphics	15
desk top publishing	14
statistics	11

Table 2.2 Computer Use in General Practice

On average, computerised practices use the computer for more than ten of the tasks listed above, which illustrates the extensive use of software applications within computerised practices.

One reason for the success of the computerised medical record project and the widespread use of clinical information systems was that it was perceived to have met a genuine medical need. The medical record presents a chronological record of the events that happened to the patient over time. The record itself is comprised of various types of information from many different sources, such as: the patients history, examination and progress notes, which are written by each health care practitioner who sees the patient; letters between GPs and hospital consultants; investigation reports from laboratories and diagnostic imaging departments; medication charts and nursing records. Benson and Neame (1994) identified three functions of the medical record:-

1. To facilitate patient care. The provision of high quality health care depends on the availability of information. By documenting observations, diagnostic conclusions and management plans the medical record acts as an external memory aid and as a means of communication between health care professionals (for example, studies in the general practice sector have shown that 70 per cent of the information in patient record originates from outside the practice), which helps ensure continuity of care. It also enables data to be viewed over time to allow the course of the patients problems and diseases to be tracked.

2. To serve as a legal and financial record. The medical record is a legal document in that it contains evidence which can be used to determine whether a patient received appropriate care in a given situation. The medical record also documents all diagnostic tests, treatments and nursing care a patient received, which can be subsequently used to make appropriate payment claims. The medical record provides evidence for quality assurance measures, professional standards reviews, and accreditation schemes.

3. To aid clinical research. The medical record can provide a source of new knowledge. Much epidemiological research is based on retrospective analysis of large sets of patient records, for example, to identify links between risk factors and diseases. These techniques are referred to as data mining.

Traditionally doctors have hand written patient records. This has led to several problems, which are believed to have had a detrimental impact on patient care:-

- Physical damage to paper, resulting in loss of information.

- Inaccessible, misplaced or lost records. Paper based records can only be used by one person at a time which inhibits parallel care processes.

- Incomplete data recording.

- Redundant information. This results from copying the same data to different locations, for example : doctors record medication plans in the progress notes, and rewrite them on the prescription pad. Technicians paste laboratory reports into the notes, and doctors copy selected results into their progress notes and repeat them again on discharge summaries. This is a time consuming process and increases the risk of introducing errors into the data.

- Lack of co-ordination between health care professionals which leads to lots of different 'sets' of notes. For example, general practitioners, nurses, outpatient departments and hospital consultants all have unique sets of notes.

- Inconsistent data.

- Illegible handwriting leads to misunderstanding.

- Imprecise use of terminology, leads to misunderstanding.

- Lack of understanding of terminology, because different medical specialities use different 'standard' notations.

- Disorganised, with no predefined structure or format, making it difficult to find relevant information and apply it to the current clinical problem.

- Inflexible display of information, this is a particular problem when trying to detect trends in large quantities of measurements (e.g. blood pressures).

- Difficulty in generating summaries.

- May contain misleading information if results are inserted into the wrong patient record.

It follows that clinical information systems which incorporate electronic patient records can provide a mechanism for doctors to assemble, integrate, sort, retrieve and review key facts already known about the patient, as well as to bring together material from remote sources. Benefits to the clinician can be divided into two categories, quality and cost (Benson and Neame, 1994):-

Quality of care benefits

- Improved quality of patient information. Data are typed and therefore legible; reports are better organised and automatic summaries can be generated.

- The patient record can be structured to meet each user's immediate needs, without redundant data recording.

- Complex data can be presented in the form of graphs or charts which improves interpretation; there is potential to introduce monitoring facilities (e.g. flags, warnings, protocols) to ensure the completeness, consistency and validity of the data recorded.

- Improved access to patient information. Patient information can be accessed instantly; records can be accessed remotely; different members of the health care team can access and update different parts of the record simultaneously.

- Information can be integrated over time and between settings of care.

- There is the opportunity to introduce facilities to assist in medical decision making.

Cost of care benefits

- Reducing redundant tests and services due to unavailability of test results.

- Saving administrative costs by generating reports automatically and through electronic submission of claims.

- Enhancing productivity by reducing the time needed to find missing records or wait for records already in use, avoiding redundant data entry and reducing the time needed to enter or review data in records.

- Reducing risks to the patient (and thus unnecessary costs of care) arising out of : decisions that are delayed due to inability to find or access information; repeating invasive tests or procedures (all procedures carry some risk of morbidity or mortality however small those risks may be); minimising the probability of adverse effects or interactions arising from drugs prescribed by practitioners unaware of the full clinical situation.

- Reducing legal exposure arising out of medical records that are inadequate, incomplete or unable to be found when required.

- Opportunity for clinical research and management, by aggregating data from many patients to report general trends.

The development and use of clinical information systems through the 1980s and 1990s has led to many computer literate general practitioners in the United Kingdom. Linnarson (1993) commented that only when clinicians are routinely using computers to store and retrieve patient data, and when the same systems can give patient specific advice based on those data, will decision support systems become widely accepted. The continued use and growth of clinical information systems by general practitioners in the United Kingdom can only facilitate the implementation of computer based clinical

decision support systems into practice. In this context it is essential that decision support systems are incorporated within the general IT facility as embedded patient management tools that provide intelligent support to the medical practitioner.

2.2.3.2 Increasing Growth and Complexity of Medical Knowledge

While many changes have been driven by computer technology, another very important factor which has proved to be an incentive for the developers of decision support systems, is the increasing demand from the medical profession for effective information management. Increases in medical knowledge combined with problems in meeting informational needs, disseminating research finding, and facilitating use of new knowledge in clinical practice, have provided good reasons for developing the use of computers to provide easy to access, up to date, patient specific advice on a range of diagnostic, management and treatment issues. These issues can be categorised in three areas:

Firstly the continued growth of knowledge in the biomedical sciences makes it increasingly difficult for clinicians to keep up to date in best care practices, resulting in a widening gap between the knowledge a doctor should have and what can be learned, retained and applied in a particular situation. A study by Williamson and colleagues (1989), found that most medical practitioners feel that the volume of literature is unmanageable. The increase in the number of biomedical journal titles since 1870 has been exponential, doubling approximately every 19 years (Wyatt, 1991b). As diagnostic and therapeutic choices proliferate (for example, it has been estimated that there are approximately 6800 single drug entities, 3300 combination products and 14200 different dosage forms), clinical care becomes more complex and results in problems for clinicians to access and use all relevant pieces of information when treating patients with a wide range of disorders (Piergies, 1987).

Secondly despite this information overload there is much evidence that doctors informational needs are not being met. An observational study by Covell and colleagues (1985) found that out of 47 doctors working in a clinic setting, 269 questions were

raised about the management of 409 patients. One third of the questions related to missing data; one third of the questions required access to medical knowledge and apparently remained unsolved because of lack of time or the inconvenience or cost of seeking the answer; two thirds of the questions were related to specialities outside the doctors own expertise. When questioned about the information sources used to meet their informational needs, the doctors stated they used printed material (textbooks and journals) for one third of all queries and consulted colleagues for two thirds of all queries. However when observed, the doctors consulted printed material in one quarter of queries and colleagues in half of all queries. This evidence is broadly compatible by a survey by Stinson (1980) who found that doctors consulted the medical literature most frequently, (a personal collection of books and papers; unsolicited publications; hospital or medical school library) secondly through discussion with colleagues; and finally through attending medical meetings.

Studies such as these indicated that colleagues and local experts contribute substantially to a qualified doctors knowledge. Advantages of this source of information include convenience and the advice being tailored to the specific problem. However consulting colleagues also has disadvantages:- it is only possible to seek advice from one expert at a time; it is expected that the advice will be remembered to avoid asking the same question at a later date; colleagues are not always available; colleagues may resent excessive consultation; some individuals and institutions stigmatise those who publicly seek information. The other frequently cited source of information is the published medical literature, however problems with this source of information include:- it is not patient specific; there is often no direct answer to patient management questions; textbooks contain out of date material, as current volumes are at best written two years before they are generally available and up to fifteen years may elapse before a genuine medical advance is recorded in a textbook (Wyatt, 1991b); It is often difficult to find the information required from the vast amount of detail; there is the additional problem of assessing the quality of published papers and extracting clinically relevant advice.

While these traditional techniques of managing information remain valuable, the computer is offering new methods of storing and processing information, such as:-

- On line bibliographic retrieval systems.

- PCs to maintain personal information, reprint files and provide connections to the Internet.

- Information systems to capture, communicate and preserve the medical record.

- Consultation systems to provide assistance when colleagues are inaccessible or unavailable.

- Office administration systems.

- Systems to assist in the direct management of patient care.

Thirdly, the problem of disseminating research findings and facilitating the use of new advances in clinical practice. Many studies have been conducted to assess doctors awareness of current best practice. A study by Williamson and colleagues (1989), found that over one third of specialists were unaware of the value of glycosylated haemoglobin in assessment of diabetic control and half did not know the dangers of digoxin in elderly patients with uncomplicated heart failure, despite evidence being published and discussed in medical journals. A study by Evans and colleagues (1986), found that the strongest predictor of the drugs used to manage hypertension was the doctors year of qualification. A study by Bucknall and colleagues (1986) found that general practitioners management of hypertension and of transient ischaemic attacks did not closely reflect the results of clinical trials.

A further problem, is that even if doctors are aware of current evidence, they may not apply it in practice. Stross (1989) conducted a study of 84 general practitioners and found that while 75% knew about a disease modifying agent shown to be effective in

the management of rheumatoid arthritis, only 14% of them had prescribed it in the previous year.

These studies highlight the problems of crossing the clinical research to practice gap. This has stimulated interest in the development of clinical decision support systems which contain a knowledge base of up to date best practice guidelines, generate patient specific advice and can thus facilitate high quality health care decisions which are based on current evidence of best practice.

2.2.3.3 Increasing Demand and Cost of Health Care.

There has been an increasing demand for healthcare services in recent years due to the development of new and more effective treatments; increased expectations for health; emphasis on preventative medicine and health promotion; and the increase in the elderly population all of which have resulted in increased pressure on individual practitioners to meet the needs of patients.

In addition to this demand there is the pressure on health care professionals to effectively manage health care resources. Paying agencies are starting to place limits on those services for which they will pay, and the maximum claims they will accept. Providers are expected to work within these guidelines, if they do not, then without appropriate authorisation the cost of care will not be reimbursed. This has lead to practitioners needing information to assess the clinical utility and reliability of tests, procedures and therapies in order to make optimal clinical and financial decisions.

It is now clear that decision support systems need to be developed so that they provide support for health care professionals by providing timely information and advice.

2.2.3.4 Increasing Legal Pressures on Health Care Professionals

The increasing frequency of litigation in every part of society, means that every decision and action is subject to scrutiny as to whether it was adequate, timely and appropriate in

the context, especially where an untoward outcome results. A study by Piergies (1987) showed that 18% of patient admissions to hospital were caused by inappropriate prescription drug use and 14% of hospital days were spent caring for cases of toxicity, 6-8% of which were classified as severe. Analysis of these figures led to the conclusion that 70% of these drug related adverse effects were predictable and therefore preventable if clinicians had used all available data correctly. Evidence such as this defines the need to develop tools to assist the clinician to effectively store and manipulate medical information to provide safe and effective health care.

Patients are increasingly successful in suing doctors for ineffective or inappropriate care. This is resulting in clinicians having to be more accountable for the care they provide. In this context, clinical decision support systems would be able to provide a basis for evidence of the knowledge and process used in clinical decision making.

2.2.3.5 Changes in the Structure of the Health Care System

Changes in the organisation of health care, has resulted in doctors becoming managers of small businesses as well as providers of health care services, thus there is an agenda of self interest. Decision support systems can be used to optimise both medical and financial decisions.

2.3 Application of Decision Support Systems to Hypertension

2.3.1 Framework for Literature Review

It has been shown in section 2.2 that clinical information systems are being incorporated into GP practice. This section reviews eight decision support systems which have been designed to assist the clinician in the management of hypertension. The aim of this literature review is to identify the strengths and weaknesses of existing systems in order to focus on the area of most need when viewed from the perspective of the user clinician.

In order to review each system in a consistent manner and to enable comparisons between different systems to be made an evaluation methodology was developed from the work of Shortliffe and Perreault (1990) and Carson and colleagues (1990). Each decision support system was analysed and its contribution to the following categories identified:

- **Description of the clinical problem**

  Identification of the clinical need.

  Why was the system designed ?

- **Intended function of the system**

  Aims and objectives of the system.

  Definition of the user.

  Consultation style (consult/critique).

  Mode of giving advice (active/passive).

- **Decision-science methodology**

  Algorithm: statistical method, model, decision tree, rule-based, neural network.

- **Technical description**

  Description of the system.

  Knowledge representation.

  Updating the system.

- **Human computer interaction**

  Data input / data output. How are the data entered and by whom; how are the results of the system displayed to the user?

- **System status**

  At what stage of development is the system: experimental, prototype, in clinical use?

  Has the system been evaluated?

- **Implementation**

  Hardware, operating system, shell, language etc.

- **Comments**

  Advantages and disadvantages.

In the following review this structure has been used to analyse the strengths, weaknesses and achievements of a range of decision support systems applied to the hypertension domain.

2.3.2 HTN-APT

HTN-APT: Computer aid in hypertension management.
Siepmann J.P. (MD) and Bachman J.W.(MD) (1987). Section of Family Medicine, Rochester, Minnesota.

- **Description of the clinical problem**

Hypertension was the chosen application because of its high prevalence in western society. The authors suggested that there was a lack of therapeutic individualisation in the treatment of hypertensive patients; secondly that the stepped care plan recommended by the World Health Organisation did not facilitate individualised patient care; thirdly that the availability of vast amounts of drug and treatment data often forced physicians to become familiar with only those drugs that seemed to have a general applicability to patients, leading to some patients receiving sub-optimal treatment. These issues provided the evidence of clinical need which justified the development of a decision support system.

- **Intended function of the system**

The aim of the system, for use by a doctor, was to produce a drug based treatment regime for an individual hypertensive patient. The system was user initiated.

- **Decision science methodology**

The system used a model of the decision process which a physician might use to make a therapeutic recommendation. This was achieved by a logical process where positive and negative aspects of a decision were weighted. Recommendations were based on the highest final score.

- **Technical description**

The knowledge base was derived from the medical literature and contained the drug data. Each drug had a corresponding number between +4 and -4, which indicated its appropriateness for thirty different patient factors (e.g. age, sex, concurrent disease).This number was referred to as the value of appropriateness (VOA). Two other values, between 1 and 9, were also associated with the data. These were referred to as the drug field weight (DFW) which was a measure to vary the emphasis on different drugs depending on the relevant patient factors (e.g. Nifedipine had a higher score than Frusemide when the patient's blood pressure was significantly elevated) and the patient field weight (PFW), which was a value to vary the emphasis on the relevant patient factors (e.g. a history of asthma was considered to be more significant, and therefore had a higher weight, than the patient's sex). There was no suggestion of medical intervention during the initial construction of the knowledge base. The weights appeared to have been generated from an analysis of the literature. To generate a treatment recommendation, relevant VOA's, DFW's and PFW's were accessed from the knowledge base. Their product was added to the running total for each drug. The drug regimens were then put in rank order, and those above a confidence threshold were recommended.

The system also offered a critiquing facility in which the user entered their drug of choice and the system calculated a value, as described above, to indicate its appropriateness.

Updating the Knowledge Base. Because of the use of weights associated with the data, which are the basis of the decision making process, the knowledge base can be easily updated, by adding new data with associated weights, or altering the existing weights.

The system takes minutes to generate its recommendation.

- **Human computer interaction**

At the start of the program, a main menu offers the user 5 options :- enter new patient data; update patient data; review patient's hypertensive history; access drug information; request treatment recommendations or critiques.

Input: the paper does not explicitly describe how the doctors enter patient data.

Output: the drugs, relevant patient factors, individual weights and their totals are displayed. A list of the recommended drugs are also displayed. The doctor is able to choose between different acceptable treatments.

- **System status**

The system has been evaluated by eight family physicians who were each given a different set of twenty cases. The doctors made their own treatment recommendations which were then compared to the systems results. From 157 responses, the computer was rated to give the same or better treatment advice in 92% of the cases.

- **Implementation**

The program was written in compiled basic for the International Business Machines Series of personal computers.

- **Comments**

1)Treatment recommendations are limited to drugs only, other aspects of the management of a patient with hypertension are not supported.

2)There is no indication of how the weights associated with each drug have been validated.

3)There is a large emphasis on database facilities and only one intelligent component, the treatment advice component.

4)The system took minutes to generate its advice.

2.3.3 Antihypertensive Therapy for the Elderly

Antihypertensive therapy for the elderly: an expert system to assist therapeutic decisions. Gondek K. Lamy P.P. Speedie S.M. Jeffrey P.L. (1988). University of Maryland at Baltimore, Baltimore, Maryland.

- **Description of the clinical problem**

Hypertension in the elderly population was chosen as the application domain because of its high prevalence (64%) and poor control (25% of patients do not receive satisfactory blood pressure control), (WHO, 1986); secondly there are multiple complicating

conditions which increase the knowledge required to determine effective antihypertensive therapy; thirdly doctors are faced with large quantities of new data, which makes it difficult to keep their knowledge up to date, for example it has been estimated that over the period 1986-1989, over 2,000 articles have been published under the subject heading hypertension.

- **Intended function of the system**

The aim of the system, for use by a general practitioner, was to provide individualised patient advice for pharmacological and non-pharmacological antihypertensive treatment.

- **Decision science methodology**

A rule based system, consisting of over 200 rules.

- **Technical description**

The knowledge base was constructed from the literature on geriatrics, cardiology and pharmacology, and was validated by a cardiologist. It was structured in the form of rules (IF, THEN statements) and parameters(e.g. age, sex, race). The patient data was entered by the doctor into a computer generated questionnaire, which contained all the information required by the system to make a therapeutic recommendation. Frequent unspecified responses (e.g. incomplete patient data) resulted in the inability of the system to reach a conclusion. The system generated its advice in approximately 2-4 minutes.

- **Human computer interaction**

Input: the doctor entered patient data in a computer generated questionnaire consisting of questions, multiple choice selections and checklists. The data entered consisted of specific items of patient data, laboratory values and measurements, concomitant diseases, concurrent medications, activities of daily living, cognitive function, nutritional status, prior treatment and control.

Output: the system suggested both non-pharmacological therapy, such as modification of risk factors (e.g. decreasing smoking, decreasing alcohol consumption, modifying diet); and pharmacological therapy, including diuretics, ace inhibitors, beta blockers, calcium channel blockers and vasodilators. The system also suggested suitable combination therapies, an alternative choice of the agent; cautions for use; potential drug interactions;

potential adverse drug reactions; estimation of relative cost, based on average wholesale price.

- **System status**

The system had been evaluated in a family practice on a sample of 90 elderly patients. Experts agreed with the computer suggested therapy in 82% of the cases. The system was being modified and updated and future evaluations were planned in a geriatric clinic.

- **Implementation**

The program was implemented in IBM's Expert System Environment (ESE) on the IBM 4341.

- **Comments**

1)The knowledge base was validated by a single cardiologist only. A panel of experts from different disciplines would be advantageous.

2)The system underwent a small clinical trial, although further studies have been planned.

3)The system requires complete patient data to reach a conclusion; there is little tolerance for incomplete data.

4)The system took 2-4 minutes to generates its advice.

2.3.4 Decision Support in Primary Care

Integrated decision support within a primary care clinical information system. Hopkins R.J. (1993). General Practitioner, Exmouth, Devon

- **Description of the clinical problem**

The motivation for the design of a decision support system was to aid patient care and contain costs. Analysis of the available software led to the following problems being identified:- lack of flexibility; lack of interaction with the existing medical record leading to repetitive data entry; complex user interface; detrimental impact on the consultation process and the patient-doctor relationship. The design of a new system aimed to overcome some of these issues.

- **Intended function of the system**

1)To aid both the diagnostic and therapeutic processes and aid long term monitoring.

2)To provide an easily accessible tool from within the medical record at the time of consultation.

3)To be interactive with the full contents of the existing medical record.

4)To be both manually and automatically initiated

5)To have minimal impact on the consultation process.

- **Decision science methodology**

A rule based system

- **Technical description**

The system consists of a diagnostic component, an aetiological component and a management component:

1)The diagnostic shell determined whether the patient fitted the established criterion for the diagnosis of hypertension. This was specified as three blood pressure measurements on three separate occasions within a six month period, outside the normal range.

2)The aetiological shell interrogated the patient's medical record for information to determine whether there was a secondary cause for the elevated blood pressure. If the required data was not present the system reminded the doctor to perform investigations or update the patient history.

3)The management shell. There was no indication from the report that the system generated patient specific therapeutic recommendations. However the system presented the doctor with the established rationale and protocol for the treatment of the hypertensive patient and checked the medical notes for clinical and pharmacological interactions and contra-indications to the prescribed treatment. Because the system was fully interactive with the computerised medical record it was able to check for possible interactions which may otherwise have been overlooked because of the routine nature of the management of chronic disease. The system also generated appointments.

There is no indication in the report how the knowledge base was created or validated.

- **Human computer interaction**

Input: no specific data entry was required for the hypertension system because the program was fully integrated with the computerised medical record.

Output: the output of the system took the form of written reminders. Each reminder included a rationale.

- **System status**

The hypertension application had been in use in a general practice for a 2 year period. However, the system had been designed by a partner in the practice and it was not in use outside the site of development.

- **Implementation**

The hypertension decision support tool was written within the ABIES clinical information system. This system has a data entry tool, MICKIE, which can be used for data entry and processing. This makes it possible for the hypertension shell to interact with the user, the data within the shell (i.e. the knowledge base / rules) and data within the ABIES system (i.e. the medical record).

- **Comments**

1)The advantage of this system is that it does not require specific data entry; it is fully interactive with the existing medical record.

2)The system generates reminders to ensure all relevant patient data are present and up to date (e.g. monitoring tests etc.)

3)The system detects possible contra-indications to the doctor's management plan, but it does not offer any therapeutic recommendations. This is an area of potential major work to extend the role of the existing decision support tool.

2.3.5 A Neural Network Expert System

A neural network expert system for diagnosing and treating hypertension. Poli R. et al. (1991). University of Florence.

- **Description of the clinical problem**

The justification for the development of this system was based on an analysis of the problems faced by developers of clinical decision support systems. Firstly it was suggested that most clinical decisions are based on experience, inferences and pathophysiological knowledge. This extensive range of information limits the performance of algorithmic approaches to many clinical tasks. Secondly it was suggested that the depth and breadth of clinical knowledge is an obstacle to the creation of a symbolic knowledge base. From this analysis the requirements for a clinical decision support system were made, and included low cost; user friendliness; short processing time; fault tolerance (incorrect input data); reliability; ability to tolerate incomplete data.

- **Intended function of the system**

The aim of the system was to provide treatment advice for the management of a hypertensive patient. The treatment was restricted to four drugs, a beta blocker (Enalapril), an ace-inhibitor (Acebutolol), a calcium channel blocker (Nifedipine) and a diuretic (Chlortalidon). The system advised times of administration and dosages of the drug regime, which could be a single drug or a combination.

- **Decision science methodology**

The system used a neural network.

- **Technical description**

Advantages of a neural network include: experienced based learning, fault tolerance, noise rejection, graceful degradation. The system took less than 1 second to generate its recommendations. The system has three main modules:

1) Reference generating module. This compared a patient's 24 hour blood pressure time series with the time series typical for normal subjects of the same sex and age. It represented significant blood pressure excesses.

2) Drug compatibility module. This analyses the clinical report and determines the patient's degree of compatibility with each considered drug.

3)Therapy selecting module. Input to this module consists of the output from the reference generating module, the output from the drug compatibility module and other clinical data. The module determined the dosage of each of the 4 drugs to be prescribed at specific times during the day. If the patient was not hypertensive the dosage of each of the 4 drugs was zero.

- **Human computer interaction**

Data input: There was no evidence from the report of a user interface suitable for use by a clinician. The data input required included, a 24 hour blood pressure time series and clinical data such as the patient's age and sex.

Data output: Drug treatment advice was presented as four, 24-item arrays, whose values specify the hourly dosages of each of the 4 drugs considered by the system.

- **System status**

This was an experimental system. The system had been tested on patient data. 35 subjects, of whom 10 were not hypertensive and 25 had been diagnosed as having hypertension. The system results were compared to a specialist's recommendations. 82% of the system's prescribed treatment was deemed correct or acceptable.

- **Implementation**

It is not clear from the report what software tool / language was used to implement the artificial neural network.

- **Comments**

1)At present the system does not describe to the user how it reached its conclusions.

2)Once the neural network has been trained, the system cannot be modified without additional learning.

3)There is no indication in the report how the knowledge base, used to train the network, was validated or from where it was derived.

4)The system is very fast, taking less than 1 second to reach its conclusions.

5)The system can cope with incomplete data.

6)It is unclear from the report how suitable is the user interface for use by a clinician.

7)Use of a 24 hour time series blood pressure graph, is not practical for the general practitioner, but is likely to be available in high dependency settings.

2.3.6 Artel

Artel: An expert system in hypertension for the general practitioner. Lavril M. and colleagues (1988). Hospital Broussais, Paris.

- **Description of the clinical problem**

The report does not specify a justification for the project. Requirements for the system were based on an evaluation survey performed among general practitioners.

- **Intended function of the system**

The system was designed for use by the general practitioner, and was fully integrated with an existing computerised medical record / information system. Its objectives were to assist the physician by maintaining a minimum standardised medical record, suggesting possible diagnoses, investigations and therapeutic strategies, and preventing management errors by automatic warnings of contraindications.

- **Decision science methodology**

The system used a semantic network for knowledge representation and two types of production rules for inferencing, exact rules for exact reasoning and uncertain rules for approximate reasoning.

- **Technical description**

The knowledge base, represented in a semantic network, contained information on simple facts, syndromes, diagnoses, investigations and therapies. Reasoning was expressed by two kinds of production rules (the system contains approximately 650 of such rules); exact rules for exact reasoning, based on conventional propositional logic and uncertain rules for approximate reasoning, in which the accumulation of evidence for or against a decision permited final conclusions to be reached. The expert system accessed patient data from the computerised medical record, thus reducing the need for repetitive data entry. The expert

system offered several facilities:- Hypotheses for diagnosis; proposals for investigations; suggestions of medications; general health advice; automatic warnings for contra-indications.

- **Human computer interaction**

The expert system could be accessed either at the end of an updating procedure, at the end of viewing a previous consultation or from the main menu. Treatment recommendations were user-initiated.

Data input: the patient data required by the expert system, were accessed from the medical record, and as such no specific data entry was required for the hypertension module.
Data output: the system provided automatic reminders to the user concerning possible contra-indications to treatments, or reminders to carry out routine examinations and investigations.

- **System status**

The version of the system reported in the paper was considered to be a prototype. The diagnostic capacity of the system had been evaluated on 100 test cases. Agreement between a panel of experts and the computer system occurred in 88% of the essential hypertension cases and 92% of the 50 secondary hypertensive cases. A second evaluation was performed on an additional 80 cases. In this test the expert system was presented with incomplete information. As regards the investigations proposed by the system and the specialists, agreement was achieved in 58% to 89% of cases. For the diagnostic suggestions, agreement was reached in 65% to 91%. There had been no evaluation of the treatment recommendations provided by the system.

- **Implementation**

The system described here is a version of the ARTEMIS programme. It is made available through the French MINITEL telecommunications network.

- **Comments**

1)The major advantage of this system is its integration with the computerised medical record, thus eliminating the need for repetitive data entry.

2)Automatic alarms preventing management errors and reminders to carry out investigations or tests.

3)User initiated diagnosis, to reduce the risk of missed causes of hypertension

4)User initiated treatment recommendations.

5)Further evaluations are required, particularly to test the therapeutic recommendations of the system.

2.3.7 A Computerised Protocol for Hypertension

An interactive computerised protocol for the management of hypertension. Evans A.R. et al. (1985). Dept Community Medicine, University of Sheffield Medical School and IBM, Winchester.

- **Description of the clinical problem**

The increased emphasis on community care which has led to increased demands on general practitioners to manage chronic disease, was the justification for the development of this system. The authors suggested that a treatment protocol would improve the delivery of care and they made the assumption that this would result in increased patient compliance with treatment advice and thus improved health. They also suggested that a computer based protocol would be both effective and acceptable to physician and patient.

- **Intended function of the system**

The system aimed to facilitate complete data collection, which was believed to lead to improved patient management. It was an advisory system and the clinical decision making was the responsibility of the doctor.

- **Decision science methodology**

The emphasis of the system was on the collection of complete patient data, via the computerised questionnaire. However the prompts and reminders were generated from a series of rules.

- **Technical description**

The hypertensive protocol consists of a set of four screens:- History and Examination screens in which the doctor entered patient data to complete a questionnaire. If data were omitted, the system assumed this was a negative response to the question. A third screen for trend data, in which a blood pressure graph of the previous six measurements was displayed. Finally a therapy screen. This evaluated the data collected and listed some general findings, e.g. patient's blood pressure, weight, age; advice on therapy changes for certain findings (based on rules defined by the system); suggestions and justifications for further investigations and tests; suggestions for a date for the next appointment.

- **Human computer interaction**

Input: The doctor entered patient data on computer generated questionnaires.

Output: This was presented as two screens, firstly a graph of blood pressure showing the trend over the previous six visits, and secondly a therapy advice screen.

- **System status**

The system has been evaluated by two general practices, involving a total of 11 doctors. Results from this evaluation suggest that:

1) The doctor's compliance with the protocol was poor, suggesting that doctors do not like such a rigid approach to patient management.

2) On average only 74% of the questions presented in the computer protocol were answered, suggesting 25% of the questions were considered inappropriate.

3) A major complaint was the protocol significantly increase the length of the consultation.

4) The advice generated by the therapy module was not considered of particular value by the doctors concerned.

- **Implementation**

It is not clear from the report what software tool / language was used to implement the system. The hardware used was an IBM 3270 display station.

- **Comments**

The fundamental assumption on which this system was based was that adhering to a questionnaire to facilitate complete data collection would improve patient care. The subsequent evaluation of the system showed that the participating doctors did not appreciate this kind of support.

2.3.8 HT-ATTENDING

HT-ATTENDING. Miller P.L. and Black H.R. (1984). Yale University School of Medicine, New Haven, Connecticut.

- **Description of the clinical problem**

The justifications for the development of the system included:- hypertension is a chronic problem and commonly encountered; there is a large array of different drugs and treatment regimens, each with potential risks and benefits to individual patients; new agents and management strategies are frequently developed which leads to difficulties for the practising physician to keep up to date.

- **Intended function of the system**

The system provided a critique of the physician's approach to the pharmacological management of essential hypertension. The authors assumed that this would help to avoid inadvertent management errors, would inform the physician about relevant new drugs and treatment regimens, and would focus attention on topical issues. The system was user initiated.

- **Decision science methodology**

A rule based system.

- **Technical description**

A prose critique of the physicians pharmacological management plan was generated using a tool called PROSENET. This is based on the augmented transitional network (ATN) formalism which has been widely used in natural language processing. Each prosenet network consists of states and arcs (arcs are associated with prose fragments). Whenever

an arc is traversed, the prose fragment is output as part of the critique. The path taken through the network is governed by action routines. These are rule based programs associated with each arc which perform certain tests, (e.g. assessing the relevance of the prose to the specific patient data) and then activate or inactivate the arc, thereby controlling the path taken.

Information about individual drugs was stored in a hierarchy. Associated with each drug was a "frame" of information, which contained all possible comments which might be made if the drug was selected.

Total interaction time, including data input and generation of the prose critique has been estimated to be approximately 3-4 minutes.

- **Human computer interaction**

Data input: the physician entered patient data, including the patient's current blood pressure, sex, age, underlying medical problems, concurrent medications and present antihypertensive regimen. (These are the data called upon in the action routines).
Data output: A prose critique which discussed the risks and benefits of the proposed antihypertensive medication.

- **System status**

This was an experimental system. A small informal clinical test was carried out in which 13 cases were contributed by different clinicians in a primary care clinic. In several situations, the clinicians suggested they would probably have changed their prescribed treatment based on information proposed in the critique.

- **Implementation**

The system has been written in the LISP programming language. The PROSENET prose generation tool has also been used.

- **Comments**

1)This system has the advantage of providing reasons and explanations with each piece of advice.

2)It has been suggested that providing a critique of a physician's management plan will be widely accepted because the doctor remains the primary decision maker. This approach could also be used to develop a teaching tool. The system would allow the user to decide on a suitable management plan and then offer a critical evaluation of that plan.

3)The idea of a critique could be incorporated into a wider application in which there is also a function for the system to generate its own treatment recommendation, to respond to situations in which the clinician wants advice on a suitable treatment regimen for a specific patient.

4)A potential problem with this system is the lengthy prose report the program generates, which a busy clinician may not have the time or motivation to read.

5)This system is not integrated with a medical record and therefore data entry is another potential problem.

2.3.9 HYPERCRITIC

HYPERCRITIC: A critiquing system for hypertension. Mossevels B.M.Th and Van der Lei J. (1990). Erasmus University, Rotterdam.

- **Description of the clinical problem**

The system was designed in response to the view that critiquing the management decisions of a physician is an appropriate approach to decision support and that integrating a decision support facility within the medical record is essential for its successful implementation into the clinical environment.

- **Intended function of the system**

The purpose of HYPERCRITIC is to offer the general practitioner comments on their treatment of hypertension. HYPERCRITIC is a critiquing system. It is activated by the presence of a diagnosis of hypertension in the medical records, and is therefore not user initiated. This results in no specific data entry by the clinician, thus the system does not influence the consultation process, nor the doctor-patient relationship.

- **Decision science methodology**

A rule based system.

- **Technical description**

HYPERCRITIC is activated by the presence of a diagnosis of hypertension in the medical record, thus it is not user initiated.

HYPERCRITIC has four components:

1)Representation of the medical record. The system translates a portion of the ELIAS medical record into its own internal representation.

2)Task structure. The set of rules and procedures which combine the knowledge stored in the fact base to the information in the patient record, to produce a response.

3)Medical fact base. The knowledge base, which was not independent of the task structure. This presents significant problems when the knowledge base is updated.

4)Text generation. This uses the Augmented Transition Network for prose generation.

The system generates four types of critiques:

1)Preparation. Checks if the GP has performed the necessary tests / examinations for the actions he or she performs. e.g. minimum diagnostic workup, baseline measurements.

2)Selection. Checks if actions of the GP are appropriate. e.g. contra-indications, dosages, interactions.

3)Monitoring. Checks if the actions of the GP require monitoring. e.g. blood tests etc.

4)Responding. Checks the medical record to if any side effects of treatment have been recorded. reports on length of time between visits.

The results of the critique are presented to the GP in a prose format. On average the system produces a median of 19 comments per patient, a minimum of 7 comments and a maximum of 70 comments.

- **Human computer interaction**

Data input: No specific data input are required because the system uses the ELIAS automated medical record for its patient data.

Data output: This is in the form of a prose critique.

- **System status**

The system was evaluated in a clinical trial, in which 20 cases were submitted to 8 physicians who were asked to critique the recorded management regimens. Their responses were compared to the comments generated by HYPERCRITIC when given the same patient data. The results showed that of the comments generated by HYPERCRITIC, 55% were deemed acceptable (6 or more of the doctors agreed with the comments), 25% were deemed debatable (4-5 of the doctors agreed with the comments) and 20% were rejected (1-2-3 of the doctors agreed with the comments).

- **Implementation**

HYPERCRITIC has been implemented using an object orientated environment on a Xerox 1186 LISP machine running Common LISP.

- **Comments**

1)Integration with the existing medical record, removing the need for specific data entry is a major advantage of this system.

2)There is a potential problem that if too many comments are automatically generated, the doctor may become overwhelmed and ignore major treatment errors indicated by the system.

3)The knowledge base is an integral part of the task structure; this results in problems when the knowledge base needs to be updated.

2.3.10 Key Findings from the Application Review

From the evaluation of eight decision support systems that have been developed for the hypertension application domain, the following conclusions have been reached. Firstly the positive aspects of existing systems will be presented.

Data Entry. Three systems, Hopkins (1993), Lavril and colleagues (1988) and Mossevel and van der Lei (1990), were integrated with an existing clinical information system, thus repetitive data entry was avoided. Hopkins' (1993) system also offered the choice of using

a questionnaire to facilitate data entry. Poli's system (1991) which used an artificial neural network coped with incomplete data entry.

Decision Support Facilities. Six of the eight systems provided drug treatment advice but the system of Gondek and colleagues (1988) also provided non-pharmacological treatment recommendations and suggested cautions for use, potential drug interactions and side-effects. However, the latter were general to the drug and not patient specific. The systems of Lavril and colleagues (1988) and Hopkins (1993) had management facilities which checked the existing patient record and informed the user if investigations were required, if the patient history needed updating or if there was clinical evidence of secondary hypertension. The systems of Hopkins (1993) and Mossevels and van der Lei (1990) also informed the user if there were contra-indications to the prescribed treatment.

Explanation. The systems of Miller and Black (1984) and Mossevel and van der Lei (1990) provided explanations for each piece of advice provided.

Speed. Poli's system (1991), generated its advice in less than one second using an artificial neural network.

Evaluation. All of the systems presented in this chapter had undergone some form of evaluation and had been shown to give accurate advice compared with doctor's opinions.

All these positive attributes will be incorporated into the design of the embedded decision support system. The problems highlighted by the analysis of existing systems will be now be discussed.

Data Entry. The lack of integration within an existing medical record continues to be a major problem to successful implementation and occurs in five of the eight systems reviewed. Thus data entry remains an issue of concern to decision support designers as shown by the rejection of the system of Evans and colleagues (1985) which used a questionnaire as the sole method of data entry. However Hopkins (1993), showed that a questionnaire could be a useful tool in addition to other forms of data entry, particularly

if it was designed by the user. Complete data entry for the system to reach a conclusion is a problem raised by the system of Gondek and colleagues (1988).

Decision Support Facilities. The fragmented approach to decision support is apparent in all the systems, which tend to focus on one or two parts of the clinical management process. For example, the systems of Miller and Black (1984), Seipman and Bachman (1987) and Poli (1991) offer drug recommendations only and that of Evans and colleagues (1985) focuses on data entry. Six of the eight systems offer drug advice although there is often a limited range of drugs in the knowledge base, this is particularly evident in the systems of Seipman and Bachman (1987) and Poli (1991). Automatic warnings of treatment contraindications or management reminders can become irritating and therefore ignored by doctors as indicated by the Mossevel and van der Lei system.

Knowledge Base. None of the systems describe a model of the clinical domain of hypertension as the foundation for their knowledge bases. This results in incomplete and unreliable knowledge bases which are difficult to validate. Problems updating the knowledge base are shown by the systems of Poli (1991) and Mossevels and van der Lei (1990) as the knowledge base is an integral part of the inference mechanism.

Explanation. Lack of explanation for advice is another common problem. However evaluations indicate that advice and explanations written in lengthy prose as the systems of Miller and Black (1984) and Mossevel and van der Lei (1990) are not liked by doctors.

Speed. Time taken to generate advice continues to be a barrier to successful implementation. This is particularly evident in the systems of Siepmann and Bachman (1987), Gondek and colleagues (1988) and Miller and Black (1984), which all take minutes to generate their conclusions.

All these criticisms of existing systems are considered in the design of the Embedded Decision Support system. The key feature of this critique is the lack of a comprehensive methodology to sustain the design and integration of the various component parts of the

decision support systems that have been developed. The work reported in this thesis is based on a conceptual model of the therapeutic process, which is used as the basis for the design.

2.4 Factors Restricting the Application of Decision Support

Despite the development of sophisticated computer technology and the apparent demand from the medical community, few decision support systems are in routine clinical use. Many reasons for this failure have been given and in this section some of these issues are explored.

1. It has been suggested that researchers developing decision support systems have failed to explicitly state their aims, this has led to misinterpretation of the goals of decision support resulting in mistrust from the medical profession. If a project is using a medical domain as an example to test a novel computer based technique, this should be made explicit and a clear distinction should be made from those projects which are aiming to address clinical problems with computer based solutions. Both pieces of research are important, but they are different, and care should be taken not to confuse them (Heathfield and Wyatt, 1993).

2. Focus on the technical side of development to the detriment of the other issues. By focusing on software tools and computer artifacts, e.g. data structures / algorithms, used to build the decision support system, insufficient attention is paid to the clinical problem and the potential users. Heathfield and Wyatt (1993) comments that those cognitive processes which cause clinicians greatest difficulty are often those which are most effectively performed by computers, however they are not necessarily computationally complex, and are thus ignored.

3. Decision support has been treated as a theoretical subject and practical issues of implementation have not been adequately considered. Many of those involved in building clinical decision support systems are based in research environments. Therefore the goal of developing a decision support system is a report, thesis or research

paper and rarely a fully operational system. Thus the organisational issues of user acceptability; system performance and software documentation and maintenance issues are ignored. Failure to attach sufficient importance to these tasks is believed to contribute to many system failures at the implementation stage.

4. Lack of communication between system developers and clinicians. This has lead to failure to identify those aspects of decision making where support is genuinely required. A study by Kassirer and Gorry (1978) showed that clinicians are highly skilled in their ability to focus sharply on a small number of diagnostic alternatives given only a few items of patient data, however a large research effort has been directed towards diagnostic decision support systems, resulting in a computer based reproduction of a clinicians natural ability. Such systems do not meet any perceived need and are therefore rarely used in the working clinical environment. A study by Haynes (1990) supports this mismatch between the support a clinician requires and the focus of research interest by the decision support community. Haynes compared the main topic of 346 MEDLINE searches (MEDLINE is an online bibliographical retrieval system) with the problems addressed by 47 clinical decision support systems, and found that there was a large mismatch. 41% of MEDLINE searches were for advice on therapies, while 19% of decision support systems were built to address this issue; conversely 6% of MEDLINE searches were for advice on diagnosis, while 53% of decision support systems were built to address this issue.

5. Failure to formalise the real requirements of potential end users, resulting in use of the clinical domain as an interesting example, but not a realistic one. The low rate of utilisation of clinical decision support systems by clinicians can be contrasted with their extensive use of other computer tools such as word processors, spread sheets and graphic packages, computerised CT scanners, ECG interpreting systems and laboratory instruments. Users appear to be willing to invest substantial effort into learning these tools if they perceive that there are real advantages to be gained from their use. Heathfield and Wyatt (1993), argue that one of the reasons why existing decision support systems have largely gone unnoticed by the medical profession is that they are not useful or usable by clinicians.

6. Failure to integrate decision support systems with existing information systems. This highlights the problem that developers do not effectively consider the working environment of potential end users. Thus systems are not designed to interface transparently with the doctors normal working practice, and are therefore likely to be rejected.

7. Resistance to decision support from the medical profession. Shortliffe (1989) conducted a study in which the attitudes of doctors to the use of computers in professional practice was explored. Overall there was a lack of interest and in some cases open hostility regarding the use of computers in professional practice, specific concerns included:

- Fear of loss of rapport : doctors were concerned that the computer would have a detrimental impact on doctor - patient interaction. Despite the widespread use of computers in society as a modern method for information access and data management, doctors appear to believe that patients confidence in the doctor will be reduced by use of a computer.

- Fear of loss of control : doctors were concerned that the computer would replace their role as autonomous decision maker and provider of health care. This is believed to be one of the key issues inhibiting use of computer based systems by health care professionals. A parallel problem is the failure of the medical profession to adopt best practice guidelines. Although these often appear in a familiar format in journals and originate from opinion leaders within the profession, few are routinely used. It appears that any attempt to aid clinical decision making whether or not it originates from the profession is seen as a threat to physician autonomy and is rejected (Heathfield and Wyatt, 1993).

- Inertia : there is a reluctance from an essentially conservative profession to adopt new innovations, particularly when there may be an initial outlay of time, effort and finance to learn new skills. Related to this issue is the attitude that medical computing is essentially a research domain and although potentially promising is currently still experimental.

- Non acceptance of machine capabilities : The doctors involved in the study held the opinion that if a problem was too difficult for them to solve then they could not expect the computer to contribute to its solution. This reflects a general reluctance to acknowledge that computers can reliably assist doctors with complex decision making tasks.

- Suspicion of Artificial Intelligence : There is an essentially emotional rejection of the field of artificial intelligence, and a belief that it has no place in the practice of medicine. There is also concern about the source and quality of the information in the knowledge base of an expert system. The doctors involved in Shortliffe's study expressed the opinion that systems whose knowledge bases contained information extracted from medical experts were too subjective and biased to be of value. One doctor was quoted as saying.....

  > "expert systems suffer from the fact that, in my view, the experts aren't expert and I wouldn't listen to their judgement in person" (Shortliffe, 1989 p3)

- Fear of legal liability : Lack of legal guidelines concerning the use of medical decision aids have constrained not only doctors acceptance of decision aids but also the commercial development of such systems. The dilemma exists that it is possible to be sued both *for* using the decision aid if its advice has a detrimental effect on the patient, and *for not* using the decision aid if the patient does not receive the best possible treatment.

- Problem of data entry : data entry is a major barrier to the effective use of computers in clinical practice. Most doctors do not type, and for the computer to manipulate the data it has to be recorded in a form that the computer can interpret, this implies some form of coding or classification (e.g. read / ICD codes). Although this has great benefits in terms of decision support an initial outlay of effort is required to enter in the appropriate codes. Another problem is how to enter pictures and diagrams in the form of sketches / x-rays / MRI scans etc.

- Belief they are too old to learn about computer technology. Comments from older members of the profession reflect the view that they are too old to learn about computers. However, it is interesting that younger doctors are equally reluctant to embrace computer technology as their older peers.

The design and implementation of modern computer based decision support systems must take advantage of the advances in technology and yet continue to satisfy the needs of users. Overwhelmingly there is a need to design systems which address real needs, are easy to use, useful and save time or money and enhance patient care. Shortliffe summarises these requirements in the following way.

" Make it simple and intuitive, like a telephone, and don't expect me to need to know how it works in order to make it work, and then there is a chance that I will embrace what you have to offer - if it addresses a real need in my practice " (Shortliffe, 1989 p4)

Shortliffe uses the example of a telephone, which is now an integral part of modern society, however it is interesting to note that there was considerable reluctance to use this piece of machinery when it was first introduced.

2.5 Summary

In this chapter a definition of medical decision support has been presented. The background to the development of decision support systems has been summarised and the factors influencing the development of such systems has been discussed. Eight decision support applications using the clinical domain of hypertension have been reviewed and the key points highlighted. Finally the factors restricting the effective implementation of decision support in the clinical environment have been discussed.

This chapter provides the basis for the research project which focuses on the analysis of user needs to develop a clinical decision support system which is reliable, effective and easy to use. In the following chapter a model of the management of

essential hypertension is presented which forms the foundation for the development of the embedded decision support system.

3. Chapter Three : New Model for Embedded Decision Support

3.1 Introduction

In chapter two it was suggested that by developing a model of the application domain, the needs of users could be defined. In this chapter the use of models to formalise the therapeutic process is described. The role of human computer interaction in this process is outlined, and the development of a model for the management of essential hypertension, which provides the basis for defining the decision making facilities in the embedded decision support (E.D.S.) system, is presented. The architecture of the E.D.S. system is described, and the central issues to evaluating decision support systems are explored. The key idea is to ensure that decision support facilities are integrated into the doctors normal working practice and reflect their decision making needs.

3.2 Introduction to Models of the Therapeutic Process

A model can be described as a representation of an environment or situation in which the elements and their interactions are defined (Deutsch et al. 1994). This definition implies that any situation can be considered as a collection of elements that are related to each other to form a whole. Each element has a set of characteristics or properties some of which are capable of change. Relationships between elements include flows of material, energy or information. The purpose of modelling is to describe, predict or explain the behaviour of complex dynamic situations. This facilitates communication between those interested in the given situation and enables simulations to be carried out to observe the effect of changes to the components or their relations. Models are built from observation of the given situation, from experimental data or from principles that describe general laws underpinning physical, chemical and biological phenomena. Many different disciplines use models, for example, architects make scaled models of their buildings to visualise the impact on the environment; engineers draw diagrams to represent static components (e.g. capacitors and resistors) and use mathematical models

to predict dynamic performance. However in the case of the therapeutic process, currently there is no means of describing the relationships between medical practitioners and patients using an algorithm that is analogous to the engineer describing an electronic circuit with a differential equation. Modelling the therapeutic process is based on the observation of the interactions between medical practitioner and patient, and the recognition and formalisation of the steps in that process. Models of the therapeutic process are therefore based on the information flows that occur in the medical consultation process.

Many people have analysed the process associated with treating a patient, and the decisions that are involved in that process (Deutsch et al. 1994; Shortliffe and Perreault, 1990; Kassier and Gorry, 1978). In general the therapeutic process is made up of a number of information collection and information processing steps to determine:-

- the cause of the patient's problems (Diagnosis).
- to anticipate the progression of the patient's illness (Prognosis).
- to select a suitable technique (e.g. drugs, surgery, lifestyle changes, physical therapy) to eliminate the cause of the disease or reduce its effects (Treatment).

These steps are often represented as a feedback loop, in which the output of each stage of the process provides input for subsequent decisions (see Fig 3.1). The key stages in the therapeutic process include:-

- obtaining information about the patient.
- interpreting these data in the light of current diagnostic hypotheses and therapy.
- generating, refining and evaluating diagnostic hypotheses.
- evaluating current treatment, if any.

- deciding on management actions which may involve further testing and or therapeutic intervention.

If the therapeutic objectives are met and the patient recovers, or if the patient dies, the process stops, otherwise it returns to stage one.

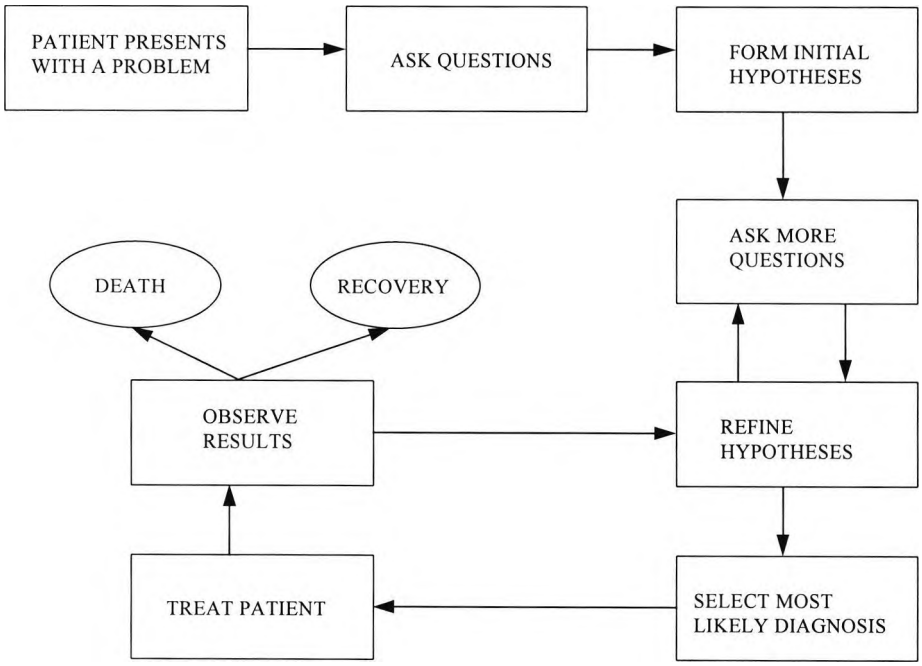

Figure 3.1 Medical Decision Making as a Feedback Loop

Information collected about the patient is used to determine the cause of their problems and includes:-

- demographic data, including age, sex, height, weight and other characteristics.

- symptoms. This is information reported by the patient and includes their feelings, thoughts, opinions, sensations (e.g. pain), and observations about their body (e.g. blood in urine).

- physical signs. These are observations made by the doctor during examination, e.g. cardiac murmurs, wheeze etc.

- vital signs. These are temperature, pulse rate, respiratory rate and arterial blood pressure.

- paraclinical findings. These include laboratory rest results and all examinations not conducted by the doctor. For example, X-ray and histological findings.

- other relevant information. This includes the patients past history, environmental factors, lifestyle.

Once the information has been collected about the patient it is necessary to interpret it to produce recommendations for suitable interventions to alleviate the patients problems. This is a cognitive process in which the clinicians medical knowledge is applied to the observed or measured patient data, according to their decision making strategy. Current knowledge about this strategy is limited, as doctors cannot reliably express how they make clinical decisions, thus most of what is known has resulted from retrospective analyses of the management different patients received. A review by Deutsch and colleagues (1994) suggested that clinical decisions are made by a combination of tradition, custom, prescribed rules, compassion, intuition and common sense. Another reason why it is difficult to formalise clinical decision making is the inherent uncertainty in clinical data and the subjective nature of its interpretation, for example:-

- subjective nature of symptoms reported by the patient (e.g. severity of pain).

- different threshold in perceiving a clinical sign as significant (e.g. identifying a cardiac murmur, or classifying a wheeze as mild, moderate or severe).

- miscalibration or measurement errors leading to errors in laboratory results.

- subjective nature of interpreting some laboratory test results (e.g. histology or X-ray images).

- inherent uncertainty in medical knowledge, for example, diseases have a probability of being associated with certain signs and symptoms.

Clinical decisions must also balance the benefits of the proposed interventions against the risks of causing harm to the patient, including: possible side effects of the intervention; complications arising from the intervention; invasiveness of intervention; financial cost; time, which is of particular relevance in a life threatening situation.

Thus by observing the medical decision making process and formalising it in a model, the decisions that are involved in the analysis of patients problems (diagnosis) and in the delivery of treatments to alleviate those problems can be identified. Such models can form the basis for the development of medical decision support systems by :-

- providing a framework for the decision making strategy, which is responsible for combining medical knowledge with patient specific information.

- providing a framework for the development of the knowledge base. In the E.D.S. system general medical facts are used in conjunction with clinical guidelines and other published documentation for the treatment of essential hypertension, many of which have been accredited by recognised professional organisations (e.g. The World Health Organisation, The British Society for Hypertension and The Royal College of General Practitioners), to create a referenced and verifiable knowledge base. This is discussed in detail in chapter four.

- identifying those aspects of decision making where support is genuinely required. In the embedded decision support system, each stage of the decision making process is supported by an appropriate decision support facility.

This ensures that the decision support system is embedded within the doctors normal working practice, reflects their decision making needs and makes use of a knowledge base defined by the medical profession.

3.3 Human Computer Interaction

Consideration of the issues in human computer interaction is an important aspect of the system definition phase of the design process, and it is an area which has often been neglected by the designers of decision support systems. Shortliffe (1987) stressed the importance of designing systems that not only met users requirements but also fitted smoothly into their everyday routines. Human computer interaction (HCI) is concerned with the design of computer systems that are safe, effective, efficient, easy and enjoyable to use, often referred to collectively as usability, as well as functional. This requires an understanding of the user; the task they have to perform; the environment in which they work; the computer system in terms of technical and logistical feasibility. Each of these components influence the nature of the interaction between user and computer system, and they will now be considered in more detail (Open University 1990; Wyatt and Spiegelhalter, 1990).

3.3.1 User

In order to design appropriate systems, knowledge of the user (or group of users) is required. Key factors which should be taken into consideration include: the user's physical attributes, such as height, weight, reach, left or right handed, dexterity, visual acuity, general health and fitness; the user's knowledge and experience, both concerning the task they want to do, and of computer systems generally; the user's psychological attributes including, personality, learning ability, memory, motivation, concentration and attention span, attitudes to work and computer system, prejudices and fears; the user's socio-cultural background, their educational attainment, age, gender, race and ethnic background.

3.3.2 Task

It is important to achieve a clinically relevant definition of the decision problem or task. This may involve a medical audit or other structured data collection in addition to

problem definitions from experts or prospective users. This information can also act as a baseline study and may assist in the definition of measures in later evaluation stages. Specific characteristics of the task that need to be considered include :

- whether the task is repetitive
- to what extent the task varies from one occasion to the next
- whether the task will be carried out regularly, infrequently or only once
- complexity of the task
- what kinds of skills / knowledge are required to perform the task
- whether time is critical
- whether the user will do the task alone or with others
- whether the user will normally be switching between this and several other tasks.

3.3.3 Environment

It is important to consider the environment in which the computer system is to be used and its potential effects on the culture of that organisation. In order to achieve this it is necessary to have an understanding of the structure and working practices of the organisation; the potential problems resulting from changes to work practices including training requirement, changes in traditional roles and job design and internal political issues; the social aspects of computer use, e.g. attitudes to computer use. Successful implementation is also influenced by environmental factors including noise, heating, lighting and ventilation; practical issues of seating and equipment layout; and providing measures to prevent detrimental health effects such as physical and psychological stress, headaches, eye strain and muscular-skeletal disorders.

3.3.4 Constraints

Constraints to system design can be categorised as technical or logistical. Technical constraints refer to the availability of hardware and software, memory size, compatible input and output devices, software tools to create a user interface. Logistical constraints refer to budgets, costs, time scales, staff, building structure, pressure from sanctioning authority, for example, to increase output and quality and decrease cost, error rates and labour requirements.

However, Wyatt (1992) comments that even if a decision support system has been designed correctly, according to currently understood guidelines, it will not necessarily perform correctly. It has already been noted that the discipline of medical decision support system design is not underpinned by rigorous theoretical models which allow simulations to predict performance, consequently in order to achieve a complete definition of these four components it is often necessary to build prototype systems and obtain users comments on how they could be improved. This phase of the design process is an iterative build, test, refine cycle with recommendations stimulating further development. The aim is to ensure that the decision support system is built to fulfil a genuine role and that user needs are clearly defined.

3.4 Model for Embedded Decision Support System

The therapeutic model used in the embedded decision support system is shown in Fig 3.2. The model was developed as a result of the compiled evidence from four sources.

The first was from personal experience nursing in a variety of health care settings both in hospitals and the community. By observing and participating in medical decision making it was possible to build up an understanding of how different practitioners make decisions, the factors which influence that process and the impact of those decisions on patients. It was also possible to gain insight into the structure and organisation of the different components of the health care service. In particular the roles of different members of the health care team, their priorities, and their attitudes to changes in work

practices. Because these insights were gained while performing an accepted clinical role, it is believed that any changes staff made to practice due to the pressure of being observed would have been minimal.

The second was by a combination of informal discussions and formal interviews with general practitioners working in different health authorities and who had different experiences and backgrounds. The aim of these interviews was to discuss the approach each practitioner took to the management of a patient with essential hypertension; to identify the key problems they faced; and to gain further understanding of their working practices, psychological and professional needs.

The third was by attending clinical study days and seminars which were organised by local health authorities to contribute to their Postgraduate Medical Education schemes. These occasions which attracted in excess of fifty clinicians, aimed to update and extend their knowledge of the diagnosis, treatment and management of hypertension. They also provided the opportunity for clinicians to discuss specific clinical problems with both colleagues and experts in the field of hypertension. This provided an ideal opportunity to identify those aspects of patient management which posed problems for practising clinicians and to observe the different opinions expressed by their colleagues.

Finally by reading the medical literature, including medical and pharmacological textbooks, clinical guidelines and other research papers which addressed the issues and proposed solutions to the diagnosis, treatment and management of hypertension.

These sources enabled the key issues in the diagnosis, treatment and management of hypertension to be identified. The factors which influenced each stage of the decision making process were identified and formalised in a model (see Fig 3.2).

The model begins with the interaction between patient and doctor (see Fig 3.3). This is a complex process as the patient not only brings details of their current problem, but also several other factors including:

- past medical history.

- personal information (e.g. age, sex, ethnicity).

- social history (e.g. education, income, employment, home environment).

- family history of illness.

- behavioural factors (e.g. diet, exercise, smoking).

- psychological factors (e.g. attitude to doctors, expectations of the role of the doctor, attitude to health and illness).

The doctor brings his knowledge and experience to the process and may also consult books, journals, colleagues or other decision aids for advice. The environment in which the consultation takes place, the time available for the consultation, and the doctors interpersonal skills will also effect this process. From this interaction the patient's current problem, in the context of their current lifestyle is identified.

This leads the doctor to form an initial set of possible causes or diagnoses, which are refined during further information gathering, until the most likely diagnosis is reached (see Fig 3.4). The type of information gathered may include:

- past medical history.

- current illnesses.

- current medications.

- family tendency to disease. Causes of death of parents and grandparents where appropriate.

- social history (e.g. education, income, employment and home environment).

- behavioural factors (e.g. diet, exercise and smoking history).

- a review of the major body systems (e.g. respiratory, cardiovascular, renal) to assess the patients overall state of health.

- further investigations, including physical examination, diagnostic tests (e.g. ECGs), radiological investigations (e.g. X-rays, MRI), laboratory tests (e.g. blood and urine specimens) and periods of observation may also be carried out.

The decision to treat the patient's problem then has to be made (see Fig 3.5). This is achieved by considering the advantages and disadvantages of initiating treatment for the specific patient. This includes an assessment of the individuals:

- medical needs

- social situation, which includes their home environment, employment and support from friends and relatives.

- behavioural factors, for example their diet, exercise and smoking habits.

- psychological factors, including their attitudes to health and illness, and an assessment of their level of compliance with advice.

In terms of hypertension, the decision to initiate treatment can be defined as a balance of the individuals potential for cardiovascular disease risk reduction, as compared with their current risk; the opportunity to reduce cardiovascular risk with lifestyle changes, for example with diet, exercise and stopping smoking; their current state of health; the potential for side effects of medication; the potential for poor compliance with treatment advice; and the psychological effects of labelling a patient with a chronic disease. All these factors contribute to the decision to initiate treatment for a patient with raised blood pressure.

If a decision is made to initiate treatment, the doctor considers the range of possible treatments suitable for the patient's diagnosis (see Fig 3.6), this set of treatments is determined by the doctors personal knowledge and experience, from consulting books and research papers or from consultation with colleagues. From this set, those treatments which are contraindicated for the specific patient based on their individual needs are ruled out. Also considered are any specific recommendations for treatment. Factors which influence this decision include the patients:-

- concurrent illnesses.
- concurrent medications.
- possible adverse side-effects.
- known allergies.
- personal factors including; age, sex, ethnicity.
- personal preferences.

From this basis a choice of treatment is made. The patient's response to the treatment is then monitored, so modifications can be made to the treatment or diagnosis if required. In chronic disease management, the patient may remain in this cycle of treatment and observation, for a considerable length of time.

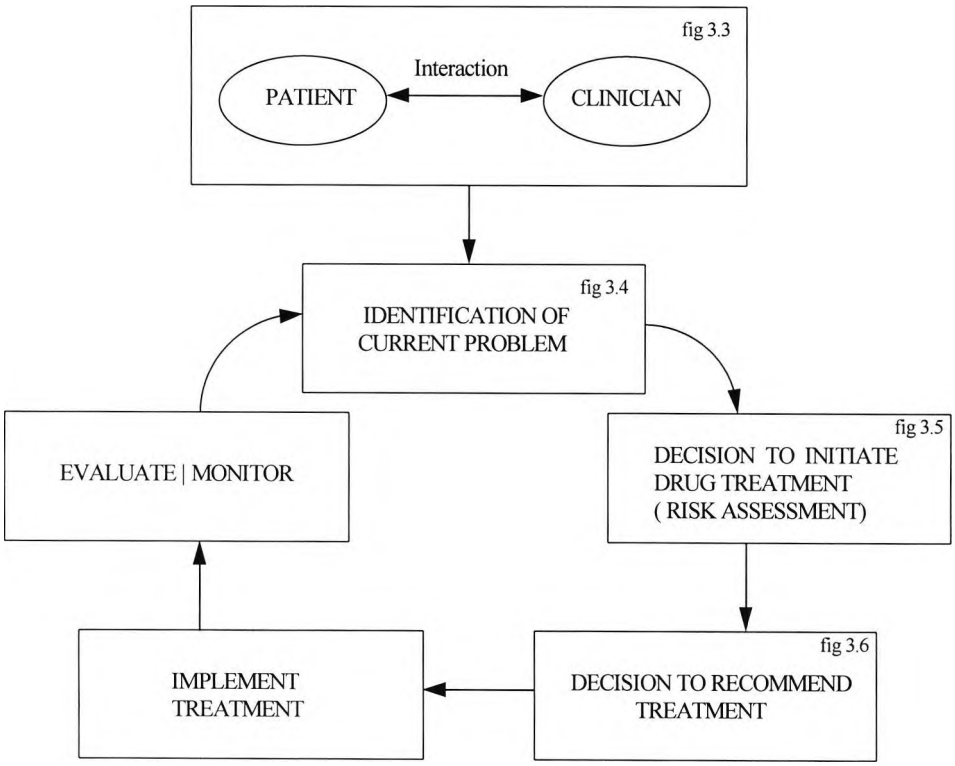

Figure 3.2 Model of the Therapeutic Process

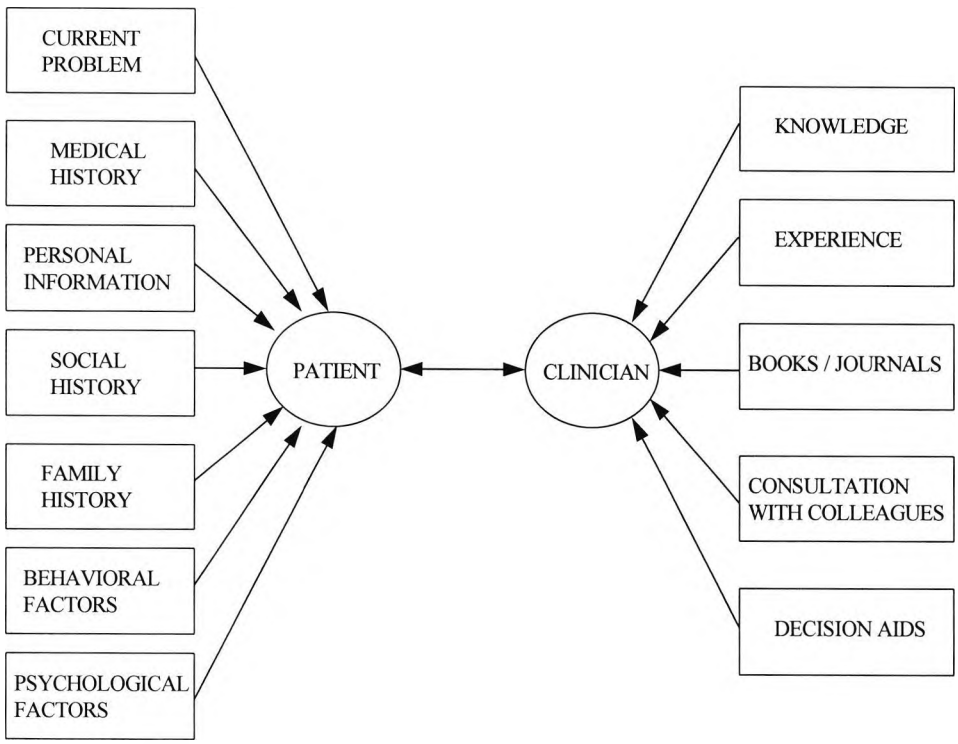

Figure 3.3 Patient - Clinician Interaction

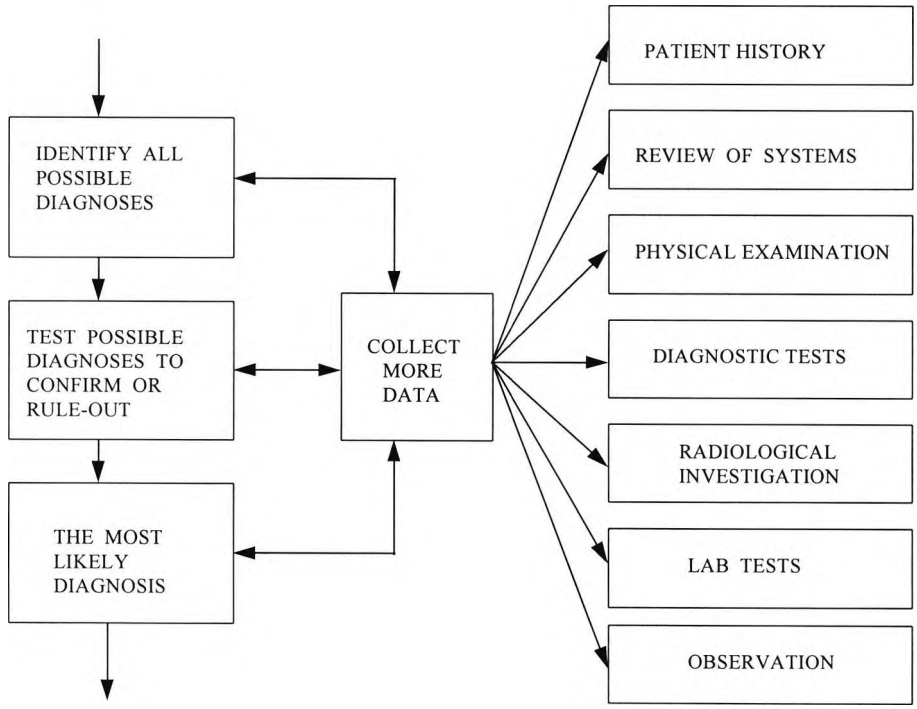

Figure 3.4 Identification of the Current Problem

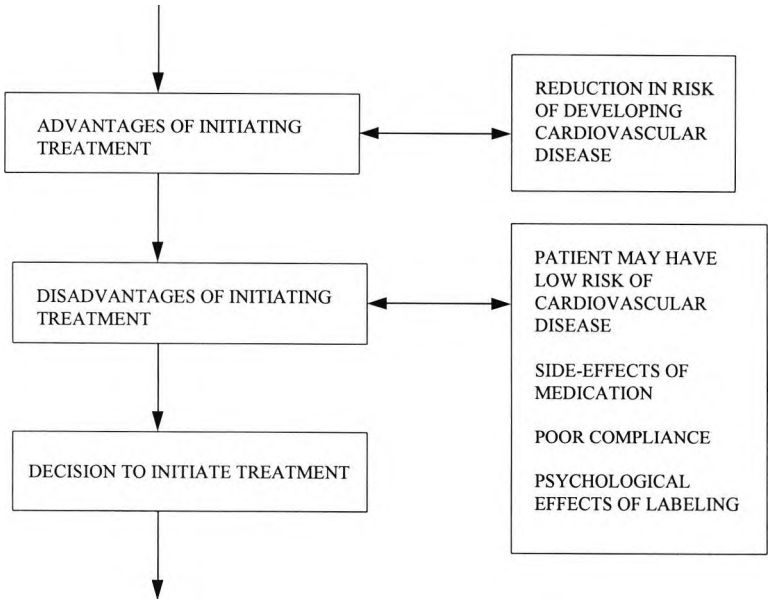

Figure 3.5 Decision to Initiate Drug Treatment

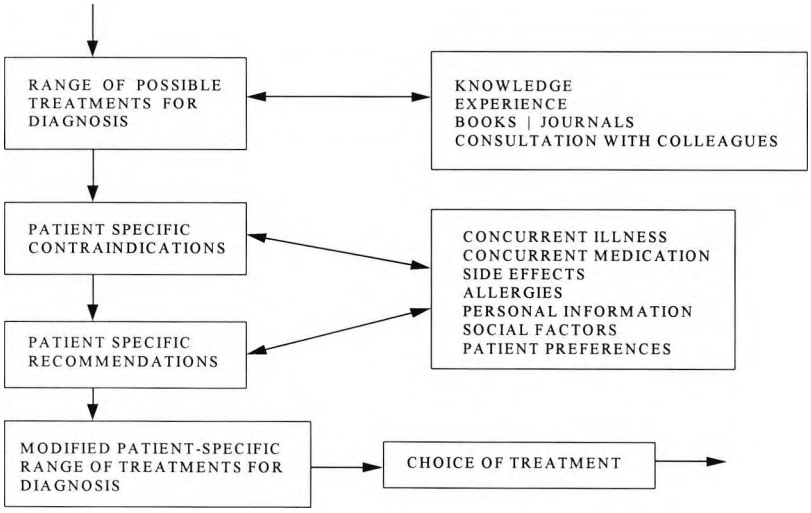

Figure 3.6 Decision What Treatment to Recommend

3.5 Definition of Decision Support Facilities

The model of the therapeutic process described in section 3.4, is used to define the decision support facilities in the embedded decision support system. Each stage of the decision making process is supported by an appropriate decision support facility (see Fig 3.7) which are described in the following sections.

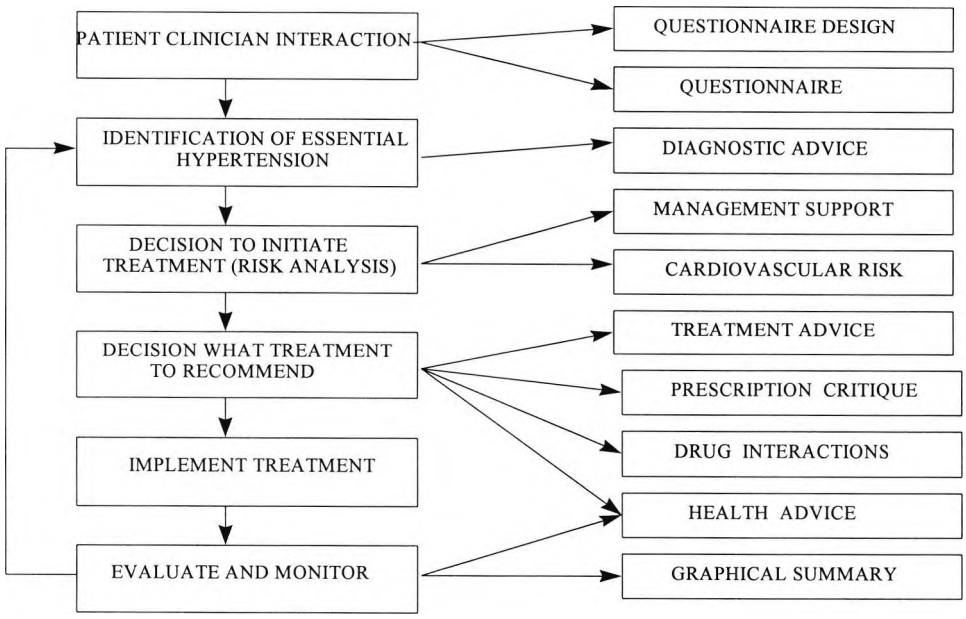

Figure 3.7 Mapping Between Model and Decision Support Facilities

3.5.1 Patient Clinician Interaction

The first stage of the model is the interaction between patient and clinician. In the E.D.S. system this process is supported by two decision support modules, questionnaire design and a questionnaire. Their aim is to facilitate complete data collection.

The questionnaire design module offers the user the facility to design their own questionnaires to facilitate data collection for the management of hypertension. The user may wish to design several questionnaires to guide information gathering on initial visits and on follow up visits. The aim of this module is to promote user involvement, reflect individual preferences, and to prevent the computer system dictating the needs of users.

Ideally the questionnaire module will have been previously designed by the clinician using the questionnaire design module, and thus reflect their individual needs, however default questionnaires would be provided. The questionnaire module provides a summary of the information relevant to hypertension that is already known about the patient, and highlights those areas where data is missing. All additional data recorded in the questionnaire automatically updates the patient record in the clinical information system.

3.5.2 Identification of Essential Hypertension

The second stage of the model is the identification of essential hypertension. In the E.D.S. system this process is supported by a diagnostic advice module. One of the important features of a decision support system is that it can review patient information and thereby indicate data which suggests secondary hypertension. This prevents symptoms being missed due to the routine nature of the treatment of chronic disease.

3.5.3 Decision to Initiate Treatment

The third stage of the model is the decision to initiate treatment. In the E.D.S. system this process is supported by two decision support modules, management support and cardiovascular risk.

The management module, provides the user with guidance on how to manage a patient from the point when a raised blood pressure measurement is recorded until drug treatment is initiated. This involves a prolonged period of observation, carrying out diagnostic tests, ensuring that secondary causes of raised blood pressure are eliminated and performing cardiovascular risk assessments.

The cardiovascular risk module, provides the user with an objective tool to assess individual patients risk of cardiovascular disease, which can be used in the decision to initiate treatment. It is an interactive tool which can be used to demonstrate the effect of changing various cardiovascular risk factors. This can be used to encourage patient compliance with treatment advice.

3.5.4 Decision What Treatment to Recommend

The fourth stage of the model is the decision what treatment to recommend. In the E.D.S. system this process is supported by four decision support modules, treatment advice, prescription critique, drug interactions and health advice. The aim of these modules is to provide a comprehensive support environment for the doctor.

The treatment advice module provides patient specific advice on drug treatment options for essential hypertension. Both drug recommendations and contraindications are provided, and the advice is supported by reasons. Each reason is supported by references to indicate who supports the advice.

The prescription critique module provides a patient specific appraisal of the users choice of drug treatment. The user enters which drug they have prescribed for the patient and

the system provides reasons for and against that choice of medication. Each reason is supported by references. The aim of the module is to draw the user's attention to potential problems with their choice of drug therapy.

The drug interactions module provides an automatic check that the prescribed antihypertensive treatment does not interact with any other prescribed medication. This reduces the risk of potential adverse effects to the patient.

The health advice module provides patient education material on a range of lifestyle issues, such as smoking, diet and exercise. The importance of making lifestyle changes to reduce overall cardiovascular risk is an important aspect of the management of essential hypertension. However it is also clear that compliance with such advice is poor, and this provides the need for appropriate patient education material to support the patient through such changes.

3.5.5 Evaluation and Monitoring

The final stage of the model is evaluation and ongoing monitoring of the patients condition. In the E.D.S. system this process is supported by two decision support modules, graphical summary and health advice. The aim of these modules is to provide ongoing support for the doctor.

The management of essential hypertension requires ongoing monitoring of the patients blood pressure. This results in large quantities of data from which trends have to be identified. It is known that pictorial information in the form of graphs and charts is an effective communication medium between computer and user. Consequently the graphical summary module provides a graphical display of the patients blood pressure over time, and indicates what medication has been prescribed in relation to the blood pressure graph. This facilitates the doctor to evaluate the effectiveness of different treatments.

The health advice module has been described in section 3.5.4.

3.6 Architecture of the Embedded Decision Support System

The embedded decision support system is a flexible, event driven architecture which integrates decision support facilities with clinical information systems which are routinely used by medical practitioners (see Fig 3.8). This enables decision support facilities to be easily accessible at the point of need and makes use of patient data already stored in the medical record. The architecture provides decision support for a range of medical domains. Hypertension is the clinical example to demonstrate how the generic computer assisted management system could be implemented in primary care. The hypertension module comprises of ten decision support facilities which have been defined by the model of the doctors decision making process and have been described in the previous section.

The architecture begins with users, whether they are doctors, nurses, secretaries or patients, interacting with a clinical information system which contains a database of patient records. Clinical information systems currently perform a number of data management functions including patient registration, appointments, patient records, annual practice report, accounts etc., however the proposed architecture extends their role to include computer aided patient management modules. Computer aided patient management modules could be developed for any number of clinical conditions, including asthma, diabetes or cancer. Each module contains a set of decision support facilities, relevant to the clinical condition.

Features of the system architecture include:

- the modules and their decision support facilities are presented as self contained units
- the modules and their decision support facilities are user initiated
- users can access the decision support facilities in any order
- the decision support facilities are available for use at all times

The style of design is often refered to as event driven and has been chosen because it does not constrain or dominate the doctors normal working practice.

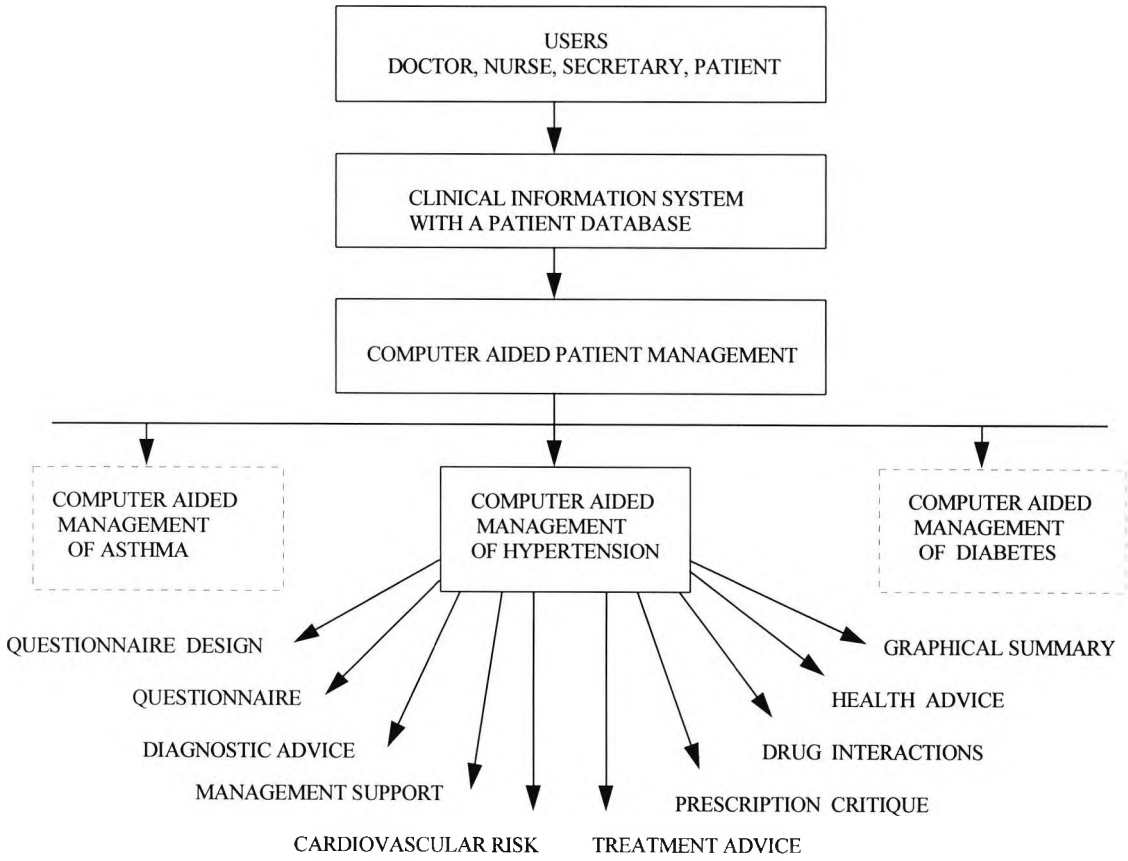

Figure 3.8 Architecture of the Embedded Decision Support System

3.7 Introduction to Evaluation

At the design and specification stage it is important to consider the framework for the evaluation of the decision support system. Consequently in this section the principles of an evaluation procedure for the embedded decision support (E.D.S.) system that has been described in this chapter will be reviewed. The purpose of evaluating new systems will be discussed, the problems previously encountered by developers of such systems will be reviewed and the key issues in the evaluation process will be highlighted.

3.7.1 Background to the Evaluation of Decision Support Systems

Wyatt (1992) defines evaluation as objective measurement against design criteria or expectations. This definition assumes that systems and users possess attributes that all observers will agree upon, and minimises the importance of variation between observers.

There are many reasons for performing evaluations of medical decision aids, and these can be divided into three categories : ethical, legal and intellectual (Wyatt and Spiegelhalter, 1990; Wyatt, 1992)

Ethical : The ethical basis of medicine is to improve patients health without causing harm and to use limited health care resources wisely. A medical expert system which is designed to have an impact on patient care should therefore be effective, safe and its impact on resources understood. It should also justify its use in preference to other aids.

Legal : Expert system technology is likely to be subject to litigation in a similar way as members of the medical profession, suppliers of pharmaceuticals and other medical technologies. It is not yet clear whether the courts will consider an expert system to be a product or a service. In the former case strict product liability laws dictate a product must be safe and effective and provide users with accurate information to enable them to exercise their own professional judgement when making decisions. In the latter case any advice generated by the system must reach the standard expected of an 'informed and

sensible body of opinion'. This can only be determined by an independent evaluation which needs then to be published in a peer-review journal.

Intellectual / Academic : An evaluation is necessary to:-

- determine the principles of the underlying science of medical informatics.
- promote the application of these systems to clinical medicine.
- determine which techniques or methods are effective.
- determine which technical advances lead to progress.
- determine which domains are the most fruitful to pursue.
- determine why certain approaches failed.
- learn from mistakes.
- avoid unnecessary repetition
- highlight which areas need further research.

However underpinning all of these issues is the need to address concerns about the safety and efficacy of medical decision support systems, which currently represent a major barrier to clinical acceptance.

3.7.2 Problems Evaluating Medical Decision Aids

There are many problems associated with evaluating medical decision aids, and it has been estimated that only about 10% of the many medical knowledge based systems that have been described over the years have been tested in laboratory conditions and even

fewer have undergone clinical trials (Lundsgaarde, 1987). Possible reasons for this include:

Technical not clinical solution : systems were built to investigate tools and techniques and were not intended for clinical use.

Limited resources : there are many people potentially involved in an evaluation study, each with their own set of questions. Usually only a subset of these can be answered with the available resources.

Difficulty measuring change : Decision support systems act on patients and healthcare systems indirectly, by improving the decision made by clinicians. However measuring changes in clinical decisions is difficult because many different types of decisions are made, often using incomplete or fuzzy data, much of which is not recorded in the clinical notes.

Multiple effects : medical decision support systems are designed to give explicit advice about patient management or prognosis to a health care professional. However they do not only influence the health care process by this means. Studies have shown that there are several additional ways in which decision aids have an effect:-

- encouraging more complete data collection.
- encouraging better organised data collection.
- improving interpretation of clinical data through abstraction or charting.
- providing users with passive reference material.
- providing feedback on performance.
- educational effects.

- the Hawthorne effect, when the performance of a decision taker improves because it is being studied.

- the placebo effect, this is the potential effect on patients of receiving extra attention.

Lack of gold standards : There are few 'gold standards' for diagnoses and management decisions, because of the complexity of the human body and because it is unethical to subject patients to all possible tests.

Difficulty in designing and implementing clinical trials : To predict the results of implementing a decision aid in a new setting, evaluation studies must replicate the kinds of patients, users and decisions encountered in that setting, thus trials should be general and transferable.

High standards : High standards of proof are required than for other changes to clinical practice because clinicians are sceptical of innovative technology and fearful of the legal implications.

Long time-scale : computer hardware, software, and AI techniques are evolving rapidly so the time-scale of an evaluation study may be longer than that of decision aid development.

3.7.3 Evaluation Framework

To overcome some of these problems, evaluation frameworks have been developed to guide system developers through the design and management of evaluation studies. However, the literature on this subject is spread across several disciplines and although individually helpful, no coherent strategy emerges for the evaluation of medical decision aids. Wyatt and Spiegelhalter (1990) addressed this issue and developed a structured method for the evaluation of medical decision support systems from an analysis of the literature on the subjects of evaluation, medical technology and clinical trials. Several key issues have been identified from Wyatt's methodology and these have been used as

the basis for the evaluation of the embedded decision support system which is reported in chapter six.

3.7.3.1 Safety Testing

The aim of a safety test is to provide evidence that the decision support system is both safe and has the potential to benefit patients, before it is introduced into the clinical environment. This involves measuring how well the decision aid functions compared to the current decision takers and expert judges. At this stage of the evaluation, whatever the final intention, the system is viewed as a 'decision taker', in that its conclusions are judged directly. Wyatt and Spiegelhalter (1990) identifies five issues which are central to this process, and they have been taken into consideration in the evaluation of the E.D.S. system.

a) Collecting sufficient amounts of unbiased, representative test data.

It is important that there is an adequate set of test cases to measure the accuracy of the decision aid. However the question remains how many test cases are required to achieve this. Wasson and colleagues (1985) suggested that a test set should contain 5 NA cases, where N is the number of data items required for input to the decision aid, and A is the number of different items of advice the decision aid can generate. It is important that test cases should not have previously been used to train, develop or tune the decision aid as this will result in decision aid accuracy appearing spuriously high. Finally the test cases should be representative of those for whom the decision aid will actually be used.

b) Measuring the current decision makers' performance

Every medical intervention carries some risk, which must be judged in comparison to the risks of doing nothing or of providing an alternative intervention. It is hard to decide whether a decision aid is an improvement unless the performance of the current decision takers is also measured (de Dombal et al. 1974). If doctors decisions are to become more accurate following introduction of a decision aid, its error rate must be lower than

theirs. A study of doctors current decision making provides input into the design process for the decision aid; a reference against which decision aid performance can be compared; and an opportunity to assess the potential of the decision aid to improve these decisions. Wyatt (1992) suggests the following measures for assessing decision making:-

- the accuracy of the decision compared to an accepted value.

- the time taken to reach a decision, or the accuracy of decisions when a fixed time is allowed.
- the subject's estimated certainty of their decisions.

- the calibration of their stated certainty estimates.

- the number of items of case data requested by subjects before the correct decisions are made.

- the appropriateness of subject's stated next action in the case.

- the effect on accuracy of some distracting task, such as subtracting sevens from one hundred.

c) Obtaining the judges' verdict (gold standards) about each test case

The aim, when evaluating advice giving systems is to answer the question, ' given the test data, which is the best decision ?' (Wyatt, 1992). However in medicine, uncertainty is an inherent problem,

'There is often no such thing as the correct answer to a clinical problem' (Shortliffe, 1987)

To overcome this problem, usually a panel of one or more judges are appointed to review the case data and decide on the most appropriate action, this is known as the

verdict or gold standard. It is rare that these are true gold standards, they are usually the best estimate, given the patient data and judges available.

d) Choosing appropriate measures of accuracy

In many evaluations the only measurement made of accuracy is the percentage of agreements between the decision aid and the judge. The problem with this approach is that it gives no indication of what accuracy could have been achieved by chance, and the differences between errors are ignored; for example, some errors are life threatening, while others represent merely a difference of opinion. To overcome this problem, results should be fully reported and the use of classification tables to derive such measures as false positive / negative rates, sensitivity and specificity should be considered where appropriate.

e) Eliminating bias in measuring decision aid's output

There are three main causes of bias in measuring decision aid's output.

- Firstly if measurements are conducted by decision aid developers, there may be bias in favour of the decision aid, either by entering input data in cases with missing data, or in judging whether the decision aid matches the gold standard in subjective cases. To overcome this source of bias those performing evaluations should be independent of developers; wording of decision aid advice should exactly match that of accepted standards; the procedure for handling cases with missing or ambiguous data is clear.

- Secondly, if the decision aid is modified during testing to cater for a novel case, but accuracy is quoted for the whole series, without re-running the full evaluation, inaccuracies may result because the modification may now cause the decision aid to fail on some previous cases. To overcome this source of bias evaluators should be independent of developers; the contents of the test set should be decided in advance; the decision aid must be 'frozen' for the duration of the test, and its advice recorded for every case.

- Thirdly if the decision aid produces a list of possible diagnoses or treatments, the evaluator may be tempted to record a correct result even if the accepted value is at the bottom of the list. To overcome this source of bias evaluators must define in advance when the decision aid is to be considered correct.

3.7.3.2 Outcome Testing

Once the system has been shown to be safe it is necessary to conduct an outcome test to determine:-

- how the decision aid functions with real users entering data.

- the number and kinds of problems encountered.

- whether the decision aid has the intended effect on the users' decisions and on their declared actions.

- whether the decision aid is likely to retain these effects when placed in a real clinical environment.

The choice of outcome measures depends on the specific role of the decision aid. In the E.D.S system evaluation a structured interview was developed to assess users reaction to the system design, specifically ease of access and ease of use. These criteria were chosen to reflect a view that medical decision support systems will not succeed unless they are wanted, usable in the clinical environment and draw conclusions that seem reasonable to the user. This may seem obvious, but many systems have failed because they were too cumbersome to use, asked too many questions in an unintuitive order, took up more time than was available and produced answers that were clearly wrong but for which they had no explanation (Wyatt and Spiegelhalter, 1990; Wyatt, 1992). For a decision support system to be successful it must be acceptable to clinicians and hence its 'usability' is a key aspect for study and evaluation. This approach is supported by Shortliffe and Perreault (1990) who comments that developers of medical computer

systems have paid insufficient attention to the quality of the interface between users and computers.

3.7.3.3 Field Testing

In a field evaluation users install the decision support aid in their normal environment and manage cases with or without access to the decision aid at a time when it could help them; their actual decisions and actions, and the impact of these on patients are measured. The aim is to determine:-

- Whether decision makers actually use the decision aid in a clinical setting.
- Whether the decision aids advice actually alters the clinicians decisions.
- Whether the altered decisions are reflected in changes in patient management.
- Whether changes in patient management change patient outcomes.

Which measures are of most significant will depend on the systems intended clinical role, its users and the motive behind the trial.

3.8 Summary

In this chapter the use of models to identify and formalise the medical decision making process was presented. The role of human computer interaction, and the importance of achieving an accurate definition of both user needs and the intended role of the decision support system was discussed. The model of the therapeutic process used in the embedded decision support system was presented, and the use of this model to define the decision support facilities was described. The architecture of the proposed system was presented and the key issues in the process of evaluating such systems were highlighted.

In the next chapter an introduction to the medical domain of hypertension and a detailed account of how the knowledge base of the embedded decision support system was developed will be presented.

4. Chapter Four : Medical Domain of Hypertension

4.1 Introduction

In this chapter a summary of the anatomy and physiology of the cardiovascular system will be presented in order to provide the context for the discussion of the medical domain of hypertension. A definition of hypertension will be presented and its possible causes discussed. Indications for the treatment of hypertension will be presented along with different management options. The problems faced by clinicians in the diagnosis and management of this condition will be highlighted. This provides the background for the discussion of how the knowledge base of the embedded decision support system was developed. Problems with existing knowledge bases are discussed and the solution adopted in this work, making use of clinical guidelines, is proposed. Details of the systems knowledge base are then presented.

4.2 The Cardiovascular System

4.2.1 Anatomy of the Cardiovascular System

The heart is the centre of the cardiovascular system. It is a hollow, muscular organ situated between the lungs to the left of the body's midline. The interior of the heart is divided into four chambers, the two upper chambers are known as the right and left atria, the two lower chambers as the right and left ventricle. The adult heart is shaped like a blunt cone about the size of a closed fist, weighs approximately 342 grams and beats over 100,000 times a day to pump 3,784 litres of blood through over 60,000 miles of blood vessels. The blood vessels form a network of tubes that carry blood away from the heart (arteries), transport it to the tissues of the body (capillaries), and then return it to the heart (veins). Large elastic arteries leave the heart and divide into smaller muscular vessels that branch out into the various regions of the body. These vessels divide into smaller and smaller arteries until they reach the tissues where they are

referred to as arterioles. As the arterioles enter tissues, they branch into countless microscopic vessels called capillaries. Through the walls of capillaries, substances are exchanged between the blood and the tissues cells (e.g. oxygen, carbon-dioxide, chemicals etc.). Before leaving the tissues groups of capillaries reunite to form small veins called venules. These, in turn, merge to form progressively larger tubes called veins which convey blood from the tissues back to the heart (Tortora and Anagnostakos, 1987).

4.2.2 Functions of the Blood

The blood has three main functions; It transports oxygen, carbon dioxide, nutrients, waste products, hormones, and enzymes, between the various cells in the body; It regulates pH, body temperature and water content of cells; It protects against blood loss through a clotting mechanism and protects the tissues against toxins and foreign microbes through a defence mechanism(Tortora and Anagnostakos, 1987).

4.2.3 Blood Flow through the Heart

Under normal conditions, blood flows from the veins into the atria. The right atrium receives deoxygenated blood from the head, body and heart muscle, the left atrium receives oxygenated blood from the lungs. When the atria contract blood is forced into the ventricles. Near the end of atrial contraction, the ventricles begin to contract forcing deoxygenated blood from the right ventricle into the lungs, and oxygenated blood from the left ventricle into the vessels of the arterial system. After the contraction, each of the heart chambers relax before the cycle is repeated. The term systole refers to the phase of contraction, the term diastole refers to the phase of relaxation (Tortora and Anagnostakos, 1987).

4.2.4 Blood Flow through the Vessels

Blood flows through the system of closed vessels because of different pressures in various parts of the system. It always flows from regions of high pressure to regions of lower pressure. In the adult the average pressure in the first artery leaving the heart (the aorta) is about 100mmHg. This pressure decreases rapidly through the arterial system and more slowly through the venous system. Because of the continuous drop in pressure, blood flows from the aorta (100mmHg) to the arteries (100-40mmHg) to the arterioles (40-25mmHg) to the capillaries (25-12mmHg) to the venules (12-8mmHg) to the veins (10-2mmHg) into the right atrium (0mmHg) (Tortora and Anagnostakos, 1987).

4.2.5 Definition of Blood Pressure

Blood pressure can be defined as the pressure exerted by the blood on the wall of any vessel. It is determined by the product of the cardiac output and the total peripheral resistance. In clinical use however, the term blood pressure refers to the pressure in the large arteries when the left ventricle contracts (systole) and the pressure remaining in those arteries when it relaxes (diastole) (Tortora and Anagnostakos,1987).

4.2.6 Blood Pressure Control

Blood pressure is influenced by several factors which enable it to respond to the changing needs of the body. These include the heart, which indirectly influences blood pressure by changes in rate and force of contraction; the autonomic nervous system which influences the muscular tone of the vessel walls - an increase in tone increases the peripheral resistance which increases the blood pressure; the pressure receptors in the vessel walls, which send impulses to the autonomic nervous system in response to pressure changes; the chemoreceptors which work in a similar way to pressure receptors but are sensitive to arterial blood levels of oxygen, carbon-dioxide and hydrogen ions; the higher brain centres, which have a significant influence on blood pressure, for example, anger causes the cerebral cortex to stimulate the autonomic nervous system to

produce more sympathetic impulses, which cause vasoconstriction of vessels and result in an increase in blood pressure; Chemicals which effect blood pressure by causing vasoconstriction of the vessels; Autoregulation, which is a local automatic adjustment of blood flow in a given region of the body in response to the particular needs of the tissue. If more oxygen and nutrients are required local blood vessels relax, decreasing resistance and pressure and thereby increasing blood flow (Tortora and Anagnostakos, 1987).

4.2.7 Measurement of Blood Pressure

Direct measurement of systolic blood pressure was first carried out by Stephen Hales in 1733 by cannulating the large arteries of mammals. However the need to open an artery prevented the use of this technique in human patients. In 1855 Veirordt suggested that a non-invasive technique could be developed to measure arterial pressure in a limb by a using a system of counterweights. This method proved ineffective and in 1860 Marey developed a sphygmographic method which, with further modifications by Mahomed and Dudgeon, was used throughout the remainder of the 19th century. Early measurements were extremely unreliable but Mahomed was able to report the presence of high blood pressure in the absence of renal disease, which had up to that time been considered as the sign for elevated blood pressure. The measurement of diastolic pressure remained a major problem until Nikolia Korotkoff described his auscultatory technique in 1905. This method of measuring blood pressure is still in use today (Swales et al. 1991). Two pieces of equipment are required, a sphygmomanometer, which consists of a cuff attached to two rubber tubes, one to a hand pump and the second to a column of mercury or pressure dial marked off in millimetres, and a stethoscope. The cuff is usually wrapped around the upper arm and is inflated until the pressure in the cuff exceeds the pressure in the brachial artery. At this point, the walls of the artery are compressed together and no blood can flow through. The cuff is gradually deflated until the pressure in the cuff is slightly less than the maximal pressure in the artery. At this point the artery opens and a sound can be heard through the stethoscope. This corresponds to systolic blood pressure, the force with which the blood is pushing against arterial walls during left ventricular contraction. As the cuff pressure is further

reduced, the sound suddenly becomes faint. This corresponds to diastolic blood pressure, the force of the blood in arteries during ventricular relaxation, which provides information about the resistance of blood vessels. The various sounds that are heard while recording blood pressure in this way are called Korotkoff Sounds. The blood pressure is recorded in millimetres of mercury and is conventionally written as systolic blood pressure / diastolic blood pressure mmHg (Swales et al. 1991).

4.3 Hypertension

The domain of hypertension has been chosen to demonstrate how clinical decision making is embedded within the prototype E.D.S. system. Population studies have shown that about 20% of adults aged over 40 have a blood pressure greater than 140/90 mmHg with a risk of stroke at least 100% higher than subjects of the same age with a blood pressure of 125/75 mmHg (MacMahon et al. 1990). Hypertension is the most reliable factor for predicting subsequent stroke and coronary heart disease, which accounted for nearly 40% of deaths in the United Kingdom in 1990. Evidence from clinical trials have shown that drug treatment to lower blood pressure substantially reduces the risk of cardiovascular disease, particularly strokes and heart attacks. However, only half the eligible patients receive treatment and in only half of these does treatment achieve a blood pressure less than 140/90 mmHg (Brown, 1997). Thus hypertension is one of the most common chronic problems in the Western world, and given its high incidence and the lifelong treatment and monitoring required, it consumes significant health care resources. Thus ensuring optimal treatment and management is an important issue both for maximising quality of care to a large number of patients, and ensuring cost effectiveness. It has already been suggested that one of the reasons why computer based decision support systems are not widely accepted is due to the fact that the advice they generate is not perceived as useful by clinician. It is therefore important to establish whether the diagnosis and treatment of hypertension poses problems for practising clinicians, thus establishing a clinical need for decision support in this domain.

4.3.1 Definition and Cause of Hypertension

Hypertension can be defined as a higher than normal pressure on the arterial side of the circulatory system, which by virtue of its physical effects increases the risk of developing certain cardiovascular disorders, e.g. stroke and coronary heart disease (Walton, 1994). Although there are several conditions, mostly associated with kidney or endocrine disease, which may cause elevated blood pressure, these account for only 3-4% of people diagnosed as hypertensive and are referred to as secondary hypertension. In 97% of cases the high pressure is of no known cause and is referred to as essential hypertension. The current view is that essential hypertension is the consequence of a number of genes (polygenic inheritance) reacting in a variable manner with environmental factors including age, weight, sex, stress, alcohol, excess dietary salt and a deficiency of potassium (Walton, 1994). The challenge for the clinician is to establish that an individual has no reversible cause for their elevated blood pressure, which by definition is the case in the minority of patients and therefore the possibility of being overlooked is increased. This is an area where a decision support system could be of value to the clinician.

4.3.2 Decision to Initiate Treatment

Knowledge of the effects of elevated blood pressure is based on large population studies, for example, the Framingham Study. This is a long term prospective study which was set up in 1949 in the town of Framingham, Massachusetts on a sample of over 5,000 individuals. Evidence from this, and other prospective epidemiological studies (Mac Mahon et al. 1990) have shown that hypertension is the most reliable factor for predicting subsequent stroke, and is a risk factor in the development of renal disease, coronary artery disease, congestive cardiac failure, intermittent claudication and various other forms of cardiovascular disease. Evidence from studies such as these, indicate that there is a continuum of cardiovascular risk associated with the level of blood pressure, the higher the blood pressure is, the higher the risk of both stroke and coronary events. However the dividing line between normotension and hypertension is arbitrary. The current definition from the World Health Organisation is that this line is

the level of blood pressure above which intervention has been shown to reduce the risk of cardiovascular disease (WHO, 1993). However the ambiguity of this definition has resulted in many professional organisations establishing guidelines for clinicians to follow when initiating treatment for essential hypertension. All the advice recommends prolonged periods of observation to ensure the blood pressure is persistently elevated, and advises considering the patients overall cardiovascular risk, but the level of blood pressure over which drug treatment is advised varies between 160/100 mmHg (The Royal College of General Practitioners, 1992); 160/90 mmHg (The World Health Organisation, 1993 and The British Hypertension Society, 1993); 140/90 mmHg (The Joint National Committee, 1993). Thus there is an opportunity for a decision support system to assist the clinician decide when a patients blood pressure warrants reduction by drug intervention.

4.3.3 Cardiovascular Risk

A decision to initiate treatment should not depend solely on the level of blood pressure. The risk of cardiovascular disease is also influenced by age, male gender, previous cardiovascular events, target organ damage such as left ventricular hypertrophy, smoking, diabetes, dyslipidaemia (high Total and LDL cholesterol, low HDL cholesterol), central obesity and sedentary lifestyle. The presence of these factors may be a more important determinant of risk than a mild increase in the level of blood pressure. The absolute benefit of antihypertensive treatment to the individual will be determined by their absolute risk of cardiovascular disease, those at higher risk experiencing the greatest benefits (Jackson et al. 1993). There has been a great deal of research interest in developing tools to help clinicians assess patients cardiovascular risk, for example: the Dundee coronary risk-disk for management of change in risk factors (Tunstall-Pedoe, 1991); the New Zealand guidelines for the management of raised blood pressure, which recommends that decisions to treat blood pressure should be based primarily on the estimated absolute risk of cardiovascular disease rather than on blood pressure alone (Jackson et al. 1993); and the American Heart Association which produced a cardiovascular risk equation to estimate individual patients cardiovascular risk (Anderson et al. 1991). All these tools assist the user to assess

individual patients cardiovascular risk by providing advice on the relative contributions of each factor in the total cardiovascular risk. The role of cardiovascular risk in the management of patients with hypertension, and the need for its objective assessment, provides the opportunity for a decision support system to incorporate a cardiovascular risk assessment tool.

4.3.4 Lifestyle Advice

It is widely accepted that hypertension should be managed in the context of the patients overall cardiovascular risk. Therefore advice on reducing other cardiovascular risk factors is an essential part of a treatment program. Clinical trials provide evidence that stopping smoking; weight reduction in overweight subjects; reducing cholesterol level; reducing alcohol consumption to no more than 20-30g ethanol per day; regular mild exercise (e.g. walking, jogging, cycling or swimming); reducing salt intake to no more than 5mg/day and stopping hormone therapy are effective in lowering blood pressure in at least some subjects and can reduce overall cardiovascular risk. However, lifestyle changes are difficult to apply, particularly in the long term, and the ability of non-pharmacological treatments in reducing mortality and morbidity has not been proved directly (WHO, 1993). It is also important to note that lifestyle changes may take several months to become fully effective and that patient compliance is often poor. It is therefore important to provide appropriate advice and ongoing support for patients to encourage perseverance with treatment advice. Thus a decision support system which contains a patient education facility could be of benefit to the clinician.

4.3.5 Drug Treatment

The drug treatment of raised blood pressure has changed substantially in the past forty years. In the 1950s the first drugs for lowering blood pressure were used primarily to treat individuals with malignant hypertension. This was often characterised by very high blood pressure, which was usually fatal if left untreated. Since the 1960s numerous clinical trials have shown that drug treatment of mild to moderate essential hypertension reduces the individuals risk of developing cardiovascular disease, particularly stroke,

coronary artery disease and renal disease (Collins et al. 1990; Fletcher and Bulpitt, 1992; MacMahon et al. 1990; Whelton, 1994). Reviews of randomised clinical trials (Alderman, 1990; Kaplan, 1990; WHO, 1993) indicate that a reduction of diastolic blood pressure of 5-6 mmHg, and a reduction of systolic blood pressure by 10mmHg reduces the relative risk of a stroke by 35-40% and of coronary heart disease by 15-20%. Randomised trials of antihypertensive treatment have shown the benefits of lowering blood pressure and although most of these trials have used diuretics and / or beta blockers, no evidence is yet available that benefits are due to any particular class of antihypertensive agent. The real evidence provided by these trials concerns the benefit of lowering blood pressure. The appropriate choice of a particular class of antihypertensive drug for a patient should be determined by assessing the individuals other characteristics, e.g. concurrent diseases and medications, side-effects and personal factors. There are seven classes of antihypertensive drugs, all of which have different mechanisms of actions and thus have advantages and disadvantages for different clinical scenarios. Each of the classes will be briefly described (Reid et al. 1989):

Thiazide diuretics lower blood pressure by a combination of increased excretion of renal sodium and water, thereby reducing blood volume, and a direct effect on the vascular smooth muscle, reducing peripheral vascular resistance. They are well absorbed from the gut and are excreted through the kidney thus making them ineffective in severe renal impairment. They are cheap, effective, easy to use and can be given once daily. The dose response curve with respect to blood pressure is flat, so increasing the dose beyond a certain threshold has little benefit. Common side effects include hypokalaemia, hyperuricaemia, hyperlipidaemia; hyperglycaemia, impotence, and rashes. Diuretics are of particular value in older patient, black patients, and those with mild heart failure. They should be avoided in patients with diabetes, gout and renal failure.

Beta blockers competitively inhibit the action of catecholamines at beta receptor sites. Blockade of beta-1 receptors has the effect of decreasing heart rate and contractility, resulting in a fall in cardiac output; blockade of beta-2 receptors has the effect of increasing vascular muscle tone, causing increased peripheral resistance, and preventing dilatation of bronchial smooth muscle which may result in bronchospasm in susceptible individuals. Additional effects include lowering renin release and thus reducing the

formation of angiotensin 2 formation and aldosterone release, and blockade of central beta receptors may cause nightmares, vivid dreams and rarely hallucinations. Some beta blockers effect both beta one and two receptors, whereas others are relatively cardioselective. Beta blockers lower blood pressure by reducing cardiac output and by having a central effect on the vasomotor centre. They have a flat dose response curve with respect to blood pressure. They are well absorbed from the gastrointestinal tract and can be excreted by the kidney, metablised in the liver or both. Common side effects include tiredness, fatigue and weakness; bronchospasm especially in asthmatics; bradycardia, heart block and congestive cardiac failure; cold hands and feet, Raynaud's syndrome and worsening claudication; vivid dreams, nightmares and hallucinations; impaired response to hypoglycaemia; hyperlipidaemia; hyperuricaemia. They are of particular value in younger patients and those with concurrent anxiety, angina, previous MI. They should be avoided in patients with a history of asthma, heart failure, heart block, peripheral vascular disease and diabetes.

Calcium antagonists are a chemically heterogeneous group, to which more drugs are being added. They inhibit the transport of calcium ions across cell membranes, thus interfering in the generation of action potentials and in muscle contraction. Blood pressure is reduced by vasodilation. Three calcium antagonists are currently available, nifedipine, verapamil and diltiazem. They differ in their affinity for cardiac conducting tissue (where they slow atrioventricular node conduction), cardiac muscle (reducing contractility) and vascular smooth muscle (peripheral vasodilation). All are well absorbed from the gastrointestinal tract and undergo first pass metabolism in the liver. Common side effects include flushing, headaches, ankle oedema and gum hyperplasia. They are of particular value in patients with asthma, angina and peripheral vascular disease. Verapamil and diltiazem are contraindicated in patients with heart block and should be used with care in patients taking digoxin or beta blockers because of the additive effect of these drugs.

Angiotensin converting enzyme (Ace) inhibitors lower blood pressure by reducing peripheral vascular resistance and by preventing reabsorption of sodium by aldosterone. This is achieved by inhibiting the action of angiotensin converting enzyme, a catalyst in the conversion of angiotensin 1 to angiotensin 2. Angiotensin 2 is a potent

vasocontrictor and stimulates aldosterone secretion which leads to sodium reabsorption. The fall in blood pressure is not associated with a reflex tachycardia. Common side effects include first dose hypotension, taste disturbance, cough, neutropenia, proteinuria. They are of particular value in patients with heart failure and peripheral vascular disease. They should be avoided in patients with renal failure and in renal artery stenosis.

Alpha blockers antagonise the stimulation of alpha-one receptors on peripheral vascular smooth muscle, resulting in decreased peripheral vascular resistance and reduced blood pressure. Blood pressure is reduced without causing reflex tachycardia. They are well absorbed orally, but have to be given two to three times a day. Common side effects include first dose hypotension and syncope, sedation, fluid retention and dry mouth. They are of particular value in patients with asthma, peripheral vascular disease and heart failure.

Centrally Acting drugs (Methyldopa) have a direct effect on the central nervous system which has a role in the control of blood pressure. They are no longer in common use as they have the major disadvantages of needing to be administered three times a day and produce a high incidence of side effects at large doses. They are excreted by the kidney. These drugs may be used in patients with asthma, heart failure, peripheral vascular disease and diabetes. They should be avoided in patients with depression, liver disease and the dose reduced in patients with renal failure.

Vasodilators such as hydralazine have been widely used in conjunction with beta blockers and diuretics in cases of resistant hypertension. Their use as monotherapy is limited by side effects, particularly headaches and flushing. Hydralazine is rapidly absorbed and distributed widely. It is metabolised by the liver. Common side effects include facial flushing and peripheral vasodilation; weight gain and oedema; headache; palpitations and tachycardia; drug induced lupus syndrome; toxicity.

A study by Brown (1997), showed that for most patients, optimal drug therapy was found by a process of trial and error. Evidence such as this suggests that the choice of drug therapy for an individual hypertensive patient poses a considerable challenge to the

clinician. In the absence of clear evidence recommending a drug of choice, the treatment a patient receives must be based on an evaluation of their individual needs. This is clearly an area where a decision support system could be of benefit to the clinician.

4.3.6 Summary

Most patients with essential hypertension are managed by the primary health care team (e.g. general practitioners, nurses, dieticians etc). Essential hypertension is not a condition which can be diagnosed on one visit as the blood pressure must be shown to be persistently elevated, and possible causes of secondary hypertension must be eliminated. Lifestyle changes are often indicated, e.g. giving up smoking, and changing diet and exercise habits, and these changes need to maintained in the long term. If drug treatment is initiated, the patient must continue to take the medication for the rest of their lives. This often presents problems with compliance as most people who are treated for essential hypertension do not usually have symptomatic disease and thus do not feel unwell. Thus there are several issues concerning the diagnosis and treatment of hypertension which lead to problems for clinicians. Firstly the cause of the elevated pressure. Secondly the blood pressure above which hypertension warrants treatment. Thirdly a cardiovascular risk assessment. Forthly the type of drugs to be used when treatment is justified. Fifthly the potential for poor compliance with treatment advice as patients are asked to take medication and make lifestyle changes for the rest of their lives even though they may not feel unwell. Finally the problems with managing patients who require consistent monitoring for long periods of time. These issues will be addressed by the decision support facilities within the embedded decision support system.

4.4 Knowledge Base for Hypertension

4.4.1 Introduction

In this section the development of the knowledge base of the E.D.S. system will be presented. Concerns expressed by the medical profession about the knowledge bases of decision support system will be discussed. Recent interest in the use of clinical guidelines by the medical profession will be outlined, and the role of such documents as the foundation of system knowledge bases will be presented.

4.4.2 Problem with Existing Knowledge Bases

In chapter two it was shown that one of the reasons commonly cited for the lack of routine use of decision support systems in clinical practice is concern about the quality of the information in their knowledge bases. Traditionally knowledge bases have been developed by interviewing domain experts and attempting to identify how they make professional decisions. The extracted knowledge is then encoded for use by the decision support system. However this method has three main problems:-

- Lack of effective communication between expert system developer and domain expert, resulting in misunderstanding.

- Experts cannot reliably express the knowledge they use to make clinical decisions. Studies by clinical psychologists (Slovic, 1971) suggest that experts do not know themselves how they solve clinical problems, and although they may be able to offer plausible explanations, these may not accurately reflect their true decision making behaviour.

- Inter and intra expert variability. Doctors frequently offer different responses to the same clinical question.

These problems threaten the quality of the knowledge bases used in decision support systems. Combined with these issues are concerns expressed by both experts and potential users. Experts feel threatened that their professional opinions may be challenged and secondly that they may be held responsible for the knowledge base and thus be exposed to legal actions, particularly in the event of poor patient outcomes; Potential users tend not to value the opinions of anonymous experts, whose backgrounds and experience are not explicitly demonstrated. The solution adopted in this work is the use of clinical guidelines as the foundation for decision support systems knowledge bases.

4.4.3 Clinical Guidelines

Clinical guidelines have been developed by both purchasers and providers of health care in response to the rapid changes occurring in the field of medicine in recent years, such as the increasing complexity of clinical decision making as a result of medical advances; heightened public awareness of, and participation in, decision making; and a more explicit debate about the use of limited resources (Thompson et al. 1995).

Many definitions of clinical guidelines have been given including,

".....a recommendation for patient management that identifies one or more strategies for treatment....." (Farmer, 1993 p313)

".....a flexible strategy reflecting firm scientific evidence ....." (Eddy, 1992 p27)

".....systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances ....." (Field and Lohr, 1992 p237)

However, the key issue is that guidelines contain information to assist doctors decision making.

Evidence suggests that clinical guidelines based on the systematically analysed results of research can improve clinical practice and patient outcomes (Feder, 1994; Brook, 1995). However, the patchy nature of evidence, even in the best researched subjects in clinical practice, means that currently most guidelines are hybrid documents, with recommendations based on varying degrees of evidence and consensus. Feder (1994) in a report offering advice about how to develop guidelines, suggested that guidelines should clearly label recommendations according to strength of supporting evidence.

Users of guidelines should also be aware that the advice a guideline contains will reflect the agenda of those involved in its development. For example, different objectives include (Barahona et al. 1995; Farmer, 1993):-

- to control costs of care.
- to reduce variations in care between doctors.
- to improve outcomes of care.
- to improve the quality of care.
- to decrease the risk of legal action resulting from poor quality care.
- to base medical decisions on the results of research data.

Users need to be aware of the objectives of the guideline; possible hidden agendas; the method by which the guideline was developed; the extent to which the guideline represents the views of one or more expert; whether the advice is based on research evidence; and whether or not that evidence has been validated, in order to assess whether the advice is reasonable.

However, given these provisions, guidelines can potentially provide autonomous documents of current best practice for use in the knowledge bases of decision support systems. Guidelines are based on a combination of research evidence and consensus

thus overcoming the problems of extracting knowledge from experts with the associated problems of inter and intra expert variability. In many cases guidelines are produced or endorsed by respected medical establishments (e.g. The World Health Organisation, The Royal College of General Practitioners), and are published in medical journals. Thus a knowledge base developed from these sources is based on independent, yet verifiable advice and would overcome some of the concerns expressed by doctors about the quality of information in the knowledge bases of decision support systems.

4.4.4 Embedded Decision Support Systems Knowledge Base

As it has been noted above, the E.D.S. systems knowledge base has been developed from clinical guidelines and other documents published in the medical literature. An introduction to each of the documents will be presented and the justification for inclusion of each report will be outlined.

1. The fifth report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure. 1993. Annuals of Internal Medicine vol 153 pp154-183

The Joint National Committee on Detection, Evaluation and Treatment of high blood pressure published its guideline in 1993. The guideline was developed by a large committee which comprised of four specialist subcommittees to report on the subjects of clinical evaluation and public health; pharmacological treatment; lifestyle modification; special populations and situations. It was published in the Archives of Internal Medicine in 1993. The aim of the report was to guide practising physicians and other health care professionals in their care of hypertensive patients. The guideline represents a combination of scientific evidence and consensus of opinions. These guidelines are extensively cited by other authors.

2. BMJ 1987. ABC of Hypertension. BMA, London.

In 1987 the British Medical Journal published a book, 'ABC of Hypertension', based on a series of articles. Its aim was to provide a safe mainstream approach to the management of hypertension. The information it contains has been incorporated into the knowledge base of the E.D.S. system because it was published by a well respected journal; has been reprinted ten times between 1987 and 1994, suggesting it has reached a wide audience; and provides a thorough overview of the field.

3. Swales J.D. 1994. Pharmacological treatment of hypertension. Lancet vol 344. pp308-285.

The Lancet, a well respected medical journal, published a series of articles on hypertension known as the 'Hypertension Octet' in 1994. One of the articles concerned drug treatment in the management of essential hypertension, and was written by Prof Swales, who was a member of the British Hypertension Society working party. This article provides a detailed review and analysis of the results of randomised clinical trials on drug treatment and also cites the three main guidelines on hypertension management from the World Health Organisation \ International Society of Hypertension; The British Hypertension Society and the Joint National Committee. It was included in the systems knowledge base because it was published in a respected medical journal; was written by an eminent professor in the field of hypertension; cited a wide range of clinical trials and three major hypertension guidelines; provided one of the most recent reviews of hypertension treatment.

4. Management guidelines in essential hypertension: report of the second working party of the British Hypertension Society. 1993. BMJ vol306. pp983-987

The British Hypertension Society guidelines on the management of essential hypertension were developed by a working party of the British Hypertension Society and was published in the British Medical Journal in 1993. The aim of the guideline was to provide an analysis of the evidence provided by recent clinical trials and to give

guidance on issues where lack of evidence led to uncertainty. These guidelines are extensively cited by other authors.

5. The 1993 Guidelines for the management of mild hypertension: memorandum from a World Health Organisation / International Society of Hypertension meeting. 1993. Journal of Hypertension vol 11 pp905-918.

The WHO/ISH guidelines on the management of mild hypertension were developed by the guidelines sub-committee of the World Health Organisation and International Society of Hypertension Mild Hypertension Liaison Committee. The guideline was published in the Journal of Hypertension in 1993 and was also presented and discussed at an international conference (The sixth WHO/ISH Meeting on Mild Hypertension, Chantilly, France, 28-31 March 1993). The aim of the guideline was to

"provide extensive, critical and well-balanced information on the benefits and limitations of the various diagnostic and therapeutic interventions, so that the physician may exert the most careful judgement in individual cases." (WHO, 1993 p905)

The guideline represents a combination of research evidence provided by large randomised trials, and the consensus of opinion where no data is available. These guidelines are extensively cited by other authors writing on the topic of hypertension.

6. Hackney Hypertension Guide 1994. The Hackney collaborative clinical guidelines project.

One of the criticisms of clinical practice guidelines is that they are written at international or national level and do not reflect the specific needs of local practitioners and their patients. This issue led to the exploration of what guidelines were available in the locality of the City of London. The 1993 Hackney Hypertension Guide was written by three local experts; a general practitioner; a renal physician; a health promotion manager. During development, the guidelines were discussed with local general practitioners and specialists, and their suggestions were incorporated where possible. The guideline was based on the 1993 British Hypertension Society guidelines and a

review of the most recent clinical trials. It also contained local information, concerning hospital services to which general practitioners may refer patients. Information such as this is extremely valuable to doctors but is only relevant at a local level.

7.Hoffbrand B. Ross M. 1992. Clinical Guidelines : Hypertension. The Royal College of General Practitioners.

The Royal College of General Practitioners published a set of guidelines edited by Haines and Hurwitz in 1992, which contained a guideline for the management of hypertension written by Hoffbrand and Ross. This guideline was based on the British Hypertension Society (1989) guideline; several reviews of randomised controlled trials; and other papers on aspects of the management of hypertension. Its aim was to provide a relevant, practical and easy to read guide for the clinician.

8. British Medical Association and Royal Pharmaceutical Society of Great Britain. 1997. British National Formulary. BMA, London.

The British National Formulary is a joint publication of the British Medical Association and the Royal Pharmaceutical Society of Great Britain. It is revised twice yearly and each edition supersedes all previous volumes. It contains information on most of the products available to prescribers in the U.K. and notes to help in the choice of appropriate treatments. The BNF is intended to be a pocket book for rapid reference, and thus does not provide all the information necessary for prescribing and dispensing. However it is included in the knowledge base of the decision support system because it is one of the most up to date sources of reference material and is widely used by the medical profession.

9. Anderson K.M. Wilson P.W.F. Odell P.M. Kannel W.B. 1991. AHA Medical/Scientific Statement. An updated Coronary Risk Profile. A statement for Health Professionals. Circulation. vol83. no1. pp356-362

One of the facilities provided by the E.D.S. system is a cardiovascular risk module. The equation the system uses to calculate individual patients cardiovascular risks is taken

from a paper published by the American Heart Association in a medical / scientific statement which appeared in the journal Circulation in 1991. Although many methods of calculating cardiovascular risk are currently available, this equation was chosen because the data bases from which the equations were derived were larger and more recent than other versions; more data for individuals older than 60 years was available; the influence of HDL cholesterol was incorporated in the equations, which reflects the current view that the ratio of total cholesterol to HDL cholesterol is a better measurement than serum cholesterol as a predictor of coronary heart disease.

4.4.5 Knowledge Bases for Decision Support Modules

In this section, a description of how the information was extracted from the documents to form the foundation of the knowledge base for the E.D.S. system will be presented. The system has four separate knowledge bases to support advice on drug treatment, drug interactions, initial management and cardiovascular risk.

4.4.5.1 Knowledge Base for the Management Module

The aim of this module is to guide the user through the initial stages of patient management from the point where a high blood pressure measurement is first recorded until drug treatment is initiated. This reflects the need to establish that the blood pressure is persistently raised; eliminate causes of secondary hypertension; encourage lifestyle changes to lower blood pressure without the use of drugs; assess the patients cardiovascular risk; assess whether drug treatment is necessary to lower the blood pressure.

Five documents offered advice on how to mange patients from the point where a high blood pressure measurement is first recorded until drug treatment is initiated. The British Hypertension Society guidelines which are cited by both the Royal College of General Practitioners guidelines and the Hackney Hypertension Guide, the Joint National Committee guideline and the World Health Organisation guideline all give broadly similiar advice recommending prolonged periods of observation to ensure the

blood pressure is persistently elevated and highlighting the need to take other cardiovascular risk factors into account before initiating treatment. However the advice from the World Health Organisation guideline was used in the knowledge base of the management module because it offered the most detailed information on how to manage a patient over time, and suggested what factors should be considered at each stage of the decision making process.

The World Health Organisation guidelines aim to be a practical guide to the initial management of a patient with raised blood pressure and the advice is based on evidence from community screening programs and clinical trials. The document gives separate advice depending on whether the diastolic or systolic blood pressure measurement is used as the defining variable for a diagnosis of essential hypertension. The justification for this approach is that diastolic blood pressure has been used as the criterion for inclusion in most randomised therapeutic trials, but that there is increasing evidence to suggest that cardiovascular risk correlates more strongly with systolic blood pressure, thus actions depending on each parameter are given. No advice is given on which is the measurement of choice and both diastolic and systolic blood pressure are combined in a flow chart to summarise the advice.

The World Health Organisation guideline restricts its advice to those individuals between the ages of 40-80 years and with blood pressures within the range of 140-180 mmHg systolic blood pressure and 90-105 mmHg diastolic blood pressure. Individuals below the age of 40 years warrant special attention to determine the cause of their elevated pressure, and those over 80 years generally do not gain great advantages of treatment to lower their blood pressure. However, specific cases should be considered on individual merit, and refered to a specialist where general practitioners require further guidance. Individuals with blood pressures below 140 mmHg systolic blood pressure and 90 mmHg diastolic blood pressure are not considered to warrant treatment to lower their blood pressure further. Individuals with blood pressures greater than 180 mmHg systolic blood pressure or 105 mmHg diastolic blood pressure are not considered to have mild or borderline hypertension and thus do not meet the criteria for this guideline. If at any time the patients blood pressure is at or above these levels, they are excluded from the guideline. Advice is offered to support the management of a patient

over the first 28 weeks of management from the time a blood pressure measurement is first recorded.

The guideline starts by suggesting that if a health care professional records an average blood pressure measurement in the range of 140-180 mmHg systolic blood pressure and / or 90-105 mmHg diastolic blood pressure then repeat measurements should be made on at least two further occasions over a four week period. During this time full diagnostic screening should be carried out to ensure the patient does not have any evidence of secondary causes of hypertension. After a four week period has elapsed from the initial measurement, if the average blood pressure is below 140 mmHg systolic blood pressure and 90 mmHg diastolic blood pressure then blood pressure measurements should be repeated at three monthly intervals for one year. If the average blood pressure is between 140-180 mmHg systolic blood pressure and / or 90-105 mmHg diastolic blood pressure, then non drug treatment should be initiated and blood pressure should be monitored over a further three month period. After a sixteen week period has elapsed from the initial measurement if the average blood pressure is between 140-160 mmHg systolic and /or 90-95 mmHg diastolic blood pressure then non drug treatment should be reinforced and the blood pressure should be monitored over a further three months. If the average blood pressure is between 160-180 mmHg systolic blood pressure and / or 95-100 mmHg diastolic blood pressure then non drug treatment should be reinforced and drug treatment should be considered based on cardiovascular risk. If the average blood pressure is either 100 mmHg or above diastolic blood pressure, or 160-180 mmHg systolic blood pressure and 95 mmHg or above diastolic then non drug treatment should be reinforced and drug treatment should be initiated. After a 28 week period has elapsed from the initial measurement, if the average blood pressure is between 140-160 mmHg systolic blood pressure and / or 90-95 mmHg diastolic blood pressure then drug treatment should be considered based on cardiovascular risk. If the average blood pressure is between 160-180 mmHg systolic blood pressure and / or 95-100 mmHg diastolic blood pressure then drug treatment should be initiated. A flow chart summarising this advice is shown in fig 4.1.

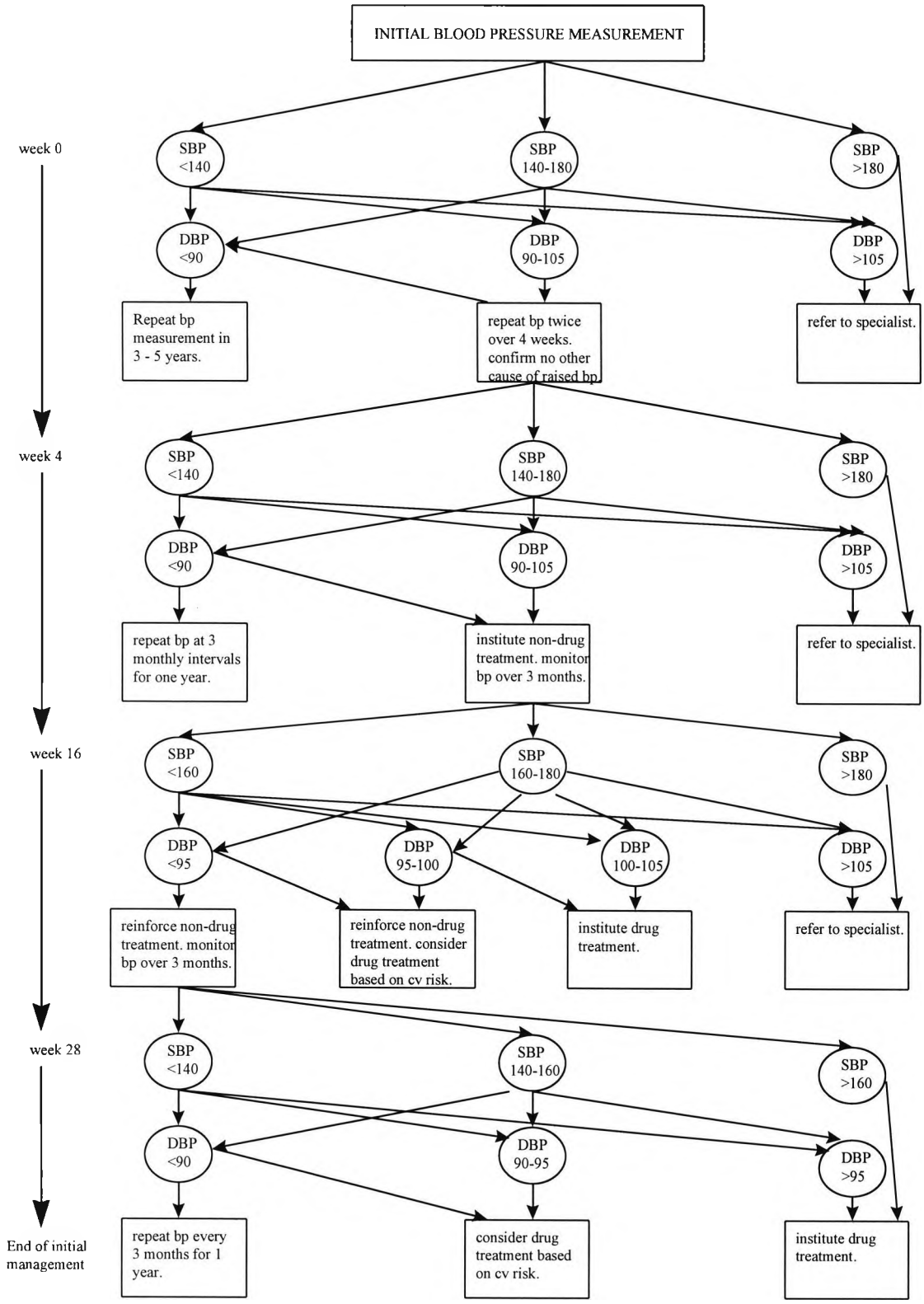

Figure 4.1 Management Advice from the WHO 1993

4.4.5.2 Knowledge Base for the Drug Treatment and Drug Critique Modules

The aim of these modules is to offer the user patient specific advice about appropriate antihypertensive drug treatments. Eight documents offered guidance on selecting appropriate drug treatment for essential hypertension. The recommendations were supported by a combination of evidence from clinical trials and the consensus of opinion where evidence was lacking. In each document, the class of antihypertensive drug, diuretics, refers to thiazide diuretics unless otherwise specified. The advice provided in the documents was compiled to produce a knowledge base for the drug treatment of essential hypertension (see table 4.1).

1. The guideline from the Joint National Committee (1993) reports that diuretics and beta blocker are the only classes of antihypertensive drugs that have been shown to reduce morbidity and mortality from cardiovascular disease in long-term controlled clinical trials. Based on this evidence they are recommended as first choice agents unless there are special indications for other drugs such as calcium antagonists, ace inhibitors and alpha blockers. Although these alternative drugs have potentially important benefits, and are all equally effective at reducing blood pressure, they have not been used in long term controlled trials to demonstrate their efficacy in reducing morbidity and mortality. Therefore they should be reserved for special indications or when diuretics and beta blockers have proved unacceptable or ineffective. Such special indications include:-

Cardiac. Angina or Ischaemic Heart Disease: beta blockers and calcium antagonists are recommended. Direct vasodilators should be avoided; Bradycardia or Heart Block or Sick Sinus Syndrome: beta blockers and calcium antagonists should be avoided; Cardiac Failure: control of blood pressure can improve myocardial fuction, prevent cardiac failure and reduce mortality. Ace inhibitors, when used alone or in combination with digitalis or diuretics in patients with congestive failure are effective in reducing mortality due to progressive congestive heart failure (SOLVD investigators, 1991; Cohn et al. 1991). Diuretics are also recommended. Beta blockers and calcium antagonists should be avoided; Left Ventricular Hypertrophy: this condition represents a major independent risk factor for cardiac death, MI, and other morbid events (Levy et al.

1990). All major drug classes, with the exception of direct acting vasodilators, may reduce left ventricular mass and wall thickness and are recommended; Peripheral vascular disease: beta blockers should be avoided as they may worsen peripheral vascular disease; Previous MI: beta blockers have been shown to reduce the risk of a subsequent MI and sudden death and are the drugs of choice (Yusuf et al. 1990). Direct vasodilators should be avoided.

Renal. Renal Artery Stenosis: ace inhibitors should be avoided as they can precipitate renal failure in hypertensive patients with bilateral renal artery stenosis or renal artery stenosis to a solitary kidney; Renal Disease: evidence from clinical trials demonstrates that controlling high blood pressure preserves renal function and prevents or slows the progression of renal failure. No specific antihypertensive agent has been shown to be particularly effective in this respect, they are all equally effective. Potassium supplements and potassium sparing diuretics should be avoided in the presence of even mild renal insufficiency. Ace inhibitors should be avoided as they can precipitate renal failure in hypertensive patients with pre-existing renal disease.

Respiratory. Asthma or COAD or Bronchitis or Emphysema: beta blockers may worsen bronchoconstriction and are contraindicated. All other antihypertensive agents may be used. However, in rare cases calcium antagonists can cause or aggravate hypoxemia by dilating the pulmonary arterial circulation and worsening the mismatch between regional ventilation and regional perfusion. Ace inhibitors can cause cough, and this may complicate chronic obstructive airways disease.

Diabetes. Patients with hypertension and diabetes mellitus are especially vunerable to cardiovascular complications. Ace inhibitors have been shown to reduce proteinuria and slow the progression of renal disease in patients with diabetic nephropathy (Mogensen, 1992), however there is a risk of hyperkalaemia and acute renal failure. Diuretics should be avoided as diuretic induced hypokalaemia may worsen glucose tolerance. Beta blockers should be avoided as they may worsen glucose tolerance and mask the symptoms of and prolong recovery from hypoglycaemia.

Dyslipidaemia. Alpha blockers may decrease serum cholesterol concentrations especially in the low density lipoprotein subfraction and therefore may offer some advantage. Ace inhibitors and calcium antagonists do not adversely effect on serum lipids or lipoproteins. Diuretics should be avoided as they can induce small increases in levels of total plasma cholesterol, triglycerides and low density lipoproteins. This effect is thought to decrease with long term therapy and dietary modifications may reduce or eliminate these effects. Beta blockers should also be avoided as they may increase levels of plasma triglycerides and reduce those of high density lipoproteins.

Other. Depression: centrally acting drugs should be avoided; Gout: diuretics should be avoided as they increase serum uric acid levels and may induce acute gout; Migraine: beta blockers are recommended as they may improve migraine headaches; Ethnicity: in general blacks are more responsive to diuretics and calcium antagonists than to beta blockers or ace inhibitors as monotherapy; Age: older persons are generally responsive to all classes of antihypertensive drugs. Diuretics are recommended for older persons. Beta blockers are recommended for younger persons.

2. The book 'A B C of Hypertension' notes that while the traditional approach to the treatment of hypertension has been the use of a diuretic or beta blocker, the development of ace inhibitors and calcium antagonists has broadened the choice of drug treatment options. Although diuretics and beta blockers remain popular, the newer drugs are effective, well tolerated and are suitable for use as first line agents. Specific recommendations and contraindications for use of the different agents include:-

Cardiac. Angina or Ischaemic Heart Disease: beta blockers and calcium antagonists are recommended as they both have anti-anginal actions; Bradycardia or Heart Block or Sick Sinus Syndrome: beta blockers and calcium antagonists should be avoided; Cardiac Failure: diuretics are recommended. Ace inhibitors are also recommended, in addition to vasodilation, the action of these drugs on the renin-angiotensin-aldosterone axis also helps reduce fluid retention. Alpha blockers and centrally acting drugs are also safe. Beta blockers should be avoided as they reduce cardiac output and may provoke or aggravate heart failue. Calcium antagonists should be avoided as they are also negative inotropes; Peripheral vascular disease: calcium antagonists, alpha blockers and centrally

acting drugs are recommended, ace inhibitors are recommended but care should be taken due to an association between peripheral vascular disease and renal artery stenosis. Beta blockers should be avoided; Previous MI: increasing evidence suggests that beta blockers post-MI may reduce the occurrence of a second infarct, and are therefore recommended.

Renal. Renal Artery Stenosis: ace inhibitors should be avoided in patients with renal artery stenosis; Renal Disease: good blood pressure control is essential for patients with renal failure to prevent further deterioration in renal function. Beta blockers, calcium antagonists, alpha blockers or centrally acting drugs are all considered to be safe. Ace inhibitors should be avoided as renal function may deteriorate. Thiazide diuretics should be avoided.

Respiratory. Asthma or COAD or bronchitis or emphysema: calcium antagonists are recommended as they may confer a degree of protection against bronchospasm. Ace inhibitors, diuretics, alpha blockers and centrally acting drugs may also be used. Beta blockers are contraindicated.

Diabetes. Diabetes Mellitus and hypertension often occur together. Elevated blood pressure accelerates the cardiovascular and renal complications associated with raised blood glucose concentration. Adequate treatment of co-existing hypertension delays the development of these complications. Recommended drugs include ace inhibitors, alpha blockers and centrally acting drugs. Calcium antagonists are recommended, but there is some suggestion that they may impair insulin release and therefore glucose tolerance, but current evidence does not substantiate this. Diuretics should be avoided as they may impair glucose tolerance. Beta blockers should be avoided as they may impair the metabolic response to hypoglycaemia.

Other. Depression: ace inhibitors are recommended as they cause fewer side effects on the central nervous system than other drugs. Diuretics and calcium antagonists are also safe. Centrally acting drugs should be avoided as these are well recognised causes of depression. Beta blockers should also be avoided as they may cause lethargy and fatigue, thus aggravating depression; Gout: diuretics should be avoided; Impotence:

calcium antagonists and ace inhibitors are recommended. Diuretics, beta blockers, and centrally acting drugs should be avoided as these may cause impotence as a side effect; Ethnicity: diuretics are recommended for black patients. Age: diuretics are recommended for older patients. Beta blockers are recommended for younger patients.

3. Swales, in his report in the Lancet (1994), cites four trials as the basis for his drug treatment recommendations; The 1992 MRC Trial of treatment in the elderly and 1991 SHEP Trial, which showed favourable coronary outcome with diuretic therapy in elderly populations; The 1988 MAPHY Study and 1987 MRC Trial which showed lower mortality from MI with beta blocker therapy. In his review of these trials Swales comments that while neither of these pieces of evidence is conclusive as an adequately designed prospective study, in the absence of other data, diuretics are recommended as initial therapy for elderly patients and beta blockers are recommended as initial therapy for younger patients. Due to lack of evidence from clinical trials newer classes of drugs would be reserved for patients in whom first line therapy with diuretics or beta blockers is either contraindicated or ineffective. Swales goes on to make the following recommendations concerning specific conditions:-

Cardiac. Cardiac Failure: beta blockers should be avoided; Previous MI: beta blockers are the first choice in patients who have sustained a myocardial infarction; Left Ventricular Dysfunction: ace inhibitors extend life and decrease the myocardial infarction rate in patients with left ventricular dysfunction (Yusuf et al. 1992).

Diabetes. Diabetes Mellitus: ace inhibitors have been shown to reduce proteinuria and slow the rate of decline in glomerular filtration rate in diabetic hypertensives, although the specificity of this observation in uncertain (Mogensen, 1992).

Other. Ethnicity: beta blockers and ace inhibitors are less effective as monotherapy in afro-Caribbean blacks.

4. The guideline from the British Hypertension Society (1993) reports that beta blockers and diuretics have been adequately and extensively tested in long term prospective outcome trials and have been shown to be effective in reducing mortality and morbidity

from cardiovascular disease. Newer classes of drugs (e.g. ace inhibitors, calcium antagonists and alpha blockers) have not been evaluated in long term outcome trials. Thus based on current evidence, the British Hypertension Society recommends that diuretics and beta blockers are used as first choice agents and other antihypertensive drugs as second line agents if indicated by concurrent disease or if first line agents are contraindicated, ineffective or when side effects occur. Indications for the use of specific drugs include:-

Cardiac. Angina or Ischaemic Heart Disease: diuretics, beta blockers, ace inhibitors, calcium antagonists and alpha blockers are all recommended; Cardiac Failure: diuretics, ace inhibitors and alpha blockers are recommended. Beta blockers and calcium antagonists should be avoided; Peripheral vascular disease: diuretics, calcium antagonists and alpha blockers are recommended. Ace inhibitors are recommended but should be used with caution due to an association between peripheral vascular disease and renal artery stenosis. Beta blockers should be avoided.

Renal. Renal Artery Stenosis: diuretics, beta blockers, calcium antagonists and alpha blockers are recommended. Ace inhibitors should be avoided due to an association with renal artery stenosis.

Diabetes. Diabetes Mellitus: ace inhibitors, calcium antagonists and alpha blockers are all recommended. Diuretics should be avoided as they may exacerbate diabetes. Beta blockers should also be avoided as awareness of hypoglycaemia may be dulled and glucose tolerance worsened.

Dyslipidaemia. Ace inhibitors, calcium antagonists and alpha blockers are all recommended. Beta blockers and diuretics should be avoided as they may exacerbate deranged lipid profile.

Respiratory. Asthma or COAD or bronchitis or emphysema: diuretics, ace inhibitors, calcium antagonists and alpha blockers are recommended. Beta blockers are contraindicated.

Other. Gout: beta blockers, ace inhibitors, calcium antagonists and alpha blockers are all recommended. Diuretics should be avoided; Impotence: diuretics and beta blockers should be avoided as they may cause impotence as a side effect.

5. The 1993 document from the World Health Organisation / International Society of Hypertension, reports that randomised trials of antihypertensive treatment have shown the benefits of lowering blood pressure, and although most of these trials have used diuretics and/or beta blockers no evidence is yet available that benefits are due to any particular class of antihypertensive agents rather than to the lowering of blood pressure. However, based on the available mortality and morbidity studies, recommendations for drug treatment include: firstly diuretics, which have been shown to be effective in the prevention of cardiovascular morbidity and mortality, especially fatal and non-fatal strokes, secondly, beta blockers which have been shown to reduce cardiovascular morbidity and mortality, and thirdly the newer agents, ace inhibitors, calcium antagonists and alpha blockers. The average blood pressure reduction in each category of drugs is similiar, but there are large variations in the reduction induced in the individual patient. The appropriate choice of a particular class of antihypertensive drugs for a patient should be determined by the other characteristics of the patient. Factors which should be taken into consideration include:-

Cardiac. Angina or Ischaemic Heart Disease: beta blockers are recommended; Cardiac Failure: ace inhibitors are recommended. Calcium antagonists and beta blockers should be avoided; Peripheral vascular disease: beta blockers should be avoided; Previous MI: beta blockers have been shown to prevent fatal and nonfatal coronary events in patients who have had a previous myocardial infarction, however, they have not been shown to have any consistent advantages over diuretics for the primary prevention of MI. Ace inhibitors and calcium antagonists are also recommended; Left Ventricular Dysfunction: calcium antagonists should be avoided; Atherosclerotic Arterial Disease: calcium antagonists are recommended as they may reduce the development of new plaques.

Renal. Renal Artery Stenosis: ace inhibitors should be avoided in renovascular disease as deterioration in renal function has been reported.

Diabetes. Diabetes Mellitus: ace inhibitors are recommended as they do not effect glucose homeostasis. Alpha blockers are recommended as they may have potential beneficial effects on glucose homeostasis. Diuretics should be avoided due to adverse effects on glucose tolerance. Beta blockers should be avoided.

Dyslipidaemia. Ace inhibitors are recommended as they do not effect serum lipids. Alpha blockers are recommended as they may have potential benefits on lipid homeostasis. Beta blockers should be avoided.

Respiratory. Asthma or COAD or bronchitis or emphysema: beta blockers should be avoided.

Other. Impotence: diuretics should be avoided as they may cause impotence as a side effect.

6. The Hackney Hypertension Guide (1994) quotes Professor Swales opinion that for most patients diuretics and beta blockers and good first line treatments, although use of newer agents as initial therapy is increasing. The Guide makes the following suggestions:-

Cardiac. Cardiac Failure: beta blockers should be avoided; Peripheral vascular disease: beta blockers should be avoided.

Renal. Renal Artery Stenosis: ace inhibitors should be avoided as they may precipitate a fall in renal function in patients with renal artery stenosis.

Diabetes. Diabetes Mellitus: diuretics should be avoided as they may reduce glucose tolerance. beta blockers should be avoided as they decrease glucose tolerance and may mask hypoglycaemic episodes.

Dyslipidaemia. Diuretics should be avoided as they may increase the total lipid to high density lipoprotein ratio. Beta blockers should be avoided as they increase the total cholesterol to high density lipoprotein ratio.

Respiratory. Asthma or COAD or Bronchitis or Emphysema: beta blockers should be avoided.

Other. Gout: diuretics should be avoided; Ethnicity: calcium antagonists have been shown in clinical trials to be effective in the treatment of afro-caribbean blacks and are therefore recommended (Materson, 1993). Beta blockers and ace inhibitors are less effective as monotherapy in afro-caribbeans; Age: elderly are less tolerant of calcium antagonists and ace inhibitors, lower doses may be required.

7. The 1992 guidelines from The Royal College of General Practitioners report that diuretics and beta blockers are of proven value in reducing morbidity in large studies and are thus recommended as the drugs of choice. Calcium antagonists and ace inhibitors are second line drugs, although they are frequently indicated as the first choice where beta blockers and diuretics are contraindicated. Specific indications include:-

Cardiac. Angina or Ischaemic Heart Disease: beta blockers are recommended. Calcium antagonists are recommended; Bradycardia or Heart Block or Sick Sinus Syndrome: beta blockers should be avoided; Cardiac Failure: diuretics and ace inhibitors are recommended. Beta blockers should be avoided; Peripheral vascular disease: ace inhibitors are recommended but should be used with caution due to an association between peripheral vascular disease and renal artery stenosis. Beta blockers should be avoided.

Renal. Renal Artery Stenosis: ace inhibitors should be used with caution in patients with renal disease, and should probably not be started by a general practitioner; Renal Disease: ace inhibitors should be used with caution in patients with renal disease, and should probably not be started by a general practitioner.

Diabetes. Diabetes Mellitus: ace inhibitors and alpha blockers are recommended as they may have a beneficial effect on glucose tolerance. Ace inhibitors are increasingly being recommended as a first line treatment in diabetic hypertensive patients. Calcium

antagonists are also recommended as they do not effect glucose tolerance. Diuretics and beta blockers should be avoided as they may have adverse effects on glucose tolerance.

Dyslipidaemia. ace inhibitors and alpha blockers are recommended as they may have a beneficial effect on lipid profiles. Calcium antagonists are also recommended as they do not effect lipid profiles. Diuretics and beta blockers should be avoided as they may have adverse effects on lipid profiles.

Respiratory. Asthma or COAD or bronchitis or emphysema: calcium antagonists are recommended. Beta blockers should be avoided.

Other. Gout: diuretics should be avoided; Impotence: diuretics and beta blockers should be avoided as they may cause impotence as a side effect; Ethnicity: diuretics are recommended for afro-Caribbean blacks; Age: diuretics recommended for elderly persons.

8. The British National Formulary in its notes on appropriate prescribing, recommends diuretics as first line therapy, beta blockers secondly, and then either calcium antagonists or ace inhibitors. Other drugs such as vasodilators, alpha blockers and centrally acting drugs should be reserved for patients whose blood pressure is not controlled by, or have contraindications to, the drugs previously mentioned. However, specific indications for an antihypertensive agent include:-

Cardiac. Angina or Ischaemic Heart Disease: beta blockers are recommended, and can improve exercise tolerance and relieve symptoms. Calcium antagonists are recommended; Bradycardia or Heart Block or Sick Sinus Syndrome: beta blockers and calcium antagonists should be avoided; Cardiac Failure: ace inhibitors are recommended. Centrally acting drugs can be used safely. Beta blockers should be avoided. Calcium antagonists should be avoided as they may depress cardiac function and cause clinically significant deterioration; Peripheral vascular disease: calcium antagonists are recommended. Ace inhibitors are recommended but should be used with caution as patients may have clinically silent renovascular disease. Beta blockers should be avoided; Previous MI: beta blockers are recommended, they may cause a reduction in

the recurrence rate of subsequent MI's; Left Ventricular Dysfunction: calcium antagonists should be avoided.

Renal. Renal Artery Stenosis: ace inhibitors should be avoided in patients with renal artery stenosis as they may cause impairment of renal function; Renal Disease: diuretics should be avoided. Ace inhibitors should be avoided in paients with renal failure as they may impair renal function.

Diabetes. Diabetes Mellitus: beta blockers should be avoided as they interfere with metabolic and autonomic responses to hypoglycaemia and can lead to deterioration of glucose tolerance. Diuretics should be avoided. The vasodilator, 'diazoxide' should be avoided as it is diabetogenic.

Dyslipidaemia. Diuretics should be avoided as they may increase plasma cholesterol concentration.

Respiratory. Asthma or COAD or Bronchitis or Emphysema: centrally acting drugs can be used safely. Beta blockers should be avoided.

Other. Gout: diuretics should be avoided; Migraine: beta blockers are recommended for the prophylaxis of migraine; Impotence: diuretics should be avoided as they may cause impotence as a side effect; Age: elderly may be less tolerant of ace inhibitors.

Table 4.1 is a summary of advice for the drug treatment of essential hypertension based on compiled data from the eight sources previously described. The figures after the recommendations refer to the references in which they appear, and relate to the order in which the references have been described.

Concurrent problem	Recommended drugs	Contraindicated drugs
Angina pectoris ischaemic heart disease	beta blockers [1,2,4,5,7,8] diuretics [4] ace inhibitors [4] calcium antagonists [1,2,4,7,8] alpha blockers [4]	direct vasodilators [1]
Bradycardia heart block sick sinus syndrome	none specific	beta blockers [1,2,7,8] calcium antagonists [1,2,8]
Cardiac failure	diuretics [1,2,4,7] ace inhibitors [1,2,4,5,7,8] alpha blockers [2,4] central [2,8]	beta blockers [1,2,3,4,5,6,7,8] calcium antagonists [1,2,4,5,8]
Left ventricular hypertrophy	none specific	vasodilators [1]
Peripheral vascular disease	diuretic[4] calcium antagonist[2,4,8] ace inhibitors [2,4,7,8] centrally acting [2] alpha blockers [2,4]	beta blockers[1,2,4,5,6,7,8]
Previous MI	beta blockers [1,2,3,5,8] ace inhibitors [5] calcium antagonists [5]	direct vasodilators [1]
Left ventricular dysfunction	ace inhibitor [3]	calcium antagonist [5,8]
Atherosclerotic arterial disease	calcium antagonists [5]	none specific

Renal arterial disease renal artery stenosis	diuretic[4] beta blocker[4] calciumantagonist[4] alpha blocker[4]	ace inhibitors [1,2,4,5,6,7,8]
Renal insufficiency Raised creatinine Renal failure	beta blocker[2] calcium-antagonist. [2] alpha blockers [2] centrally acting drugs[2]	ace inhibitors [1,2,7,8] thiazides [2,8]
Diabetes types 1 and 2 brittle diabetes reduced glucose tolerance	ace inhibitors [1,2,3,4,5,7] possibly calcium antagonists [2,4,7] alpha blockers [2,4,5,7] centrally acting [2]	beta blockers [1,2,4,5,6,7,8] thiazide diuretics [1,2,4,5,6,7,8] vasodilator [8]
Dyslipidaemia	alpha blockers[1,4,5,7] ace inhibitors [1,4,5,7] calcium antagonists [1,4,7]	beta blockers [1,4,5,6,7] diuretics [1,4,6,7,8]
Asthma COAD Partly reversible airflow obstruction bronchospasm	calcium antagonists [1,2,4,7] diuretic[1,2,4] ace inhibitor[1,2,4] alpha blocker[1,2,4] centrally acting [1,2,8]	beta blockers [1,2,4,5,6,7,8]
Depression	ace inhibitors [2] diuretic[2] calcium antagonist [2]	centrally acting [1,2] beta blockers [2]
Gout	beta blocker[4] ace inhibitor [4] calcium antagonist [4] alpha blocker [4]	diuretics [1,2,4,6,7,8]
Migraine	beta blockers [1,8]	none specific
Impotence	calcium antagonists [2] ace inhibitors [2]	thiazides [2,4,5,7,8] beta blockers [2,4,7] centrally acting [2]

Blacks	diuretics [1,2,7] calcium antagonists [1,6]	beta blockers and ace inhibitors as monotherapy [1,3,6]
Elderly persons	thiazide diuretics [1,2,3,7]	none specific
Younger persons	beta blockers [1,2,3]	none specific
initial treatment	beta blockers [1,3,4,5,6,7] diuretics [1,3,4,5,6,7]	none specific

Table 4.1 Summary of Drug Treatment Advice

4.4.5.3 Knowledge Base for Cardiovascular Risk Module

Hypertension is one of a number of risk factors in the development of cardiovascular disease. It is widely accepted that the assessment of patients cardiovascular risk is an important component of the decision to initiate treatment to lower blood pressure, and many methods and tools have been developed to assist medical practitioners in recent years.

The knowledge base for the cardiovascular risk module uses a cardiovascular risk equation developed by the American Heart Association, which was published by the Journal Circulation in 1991. The aim of the developers was to elucidate the multi-factorial nature of coronary heart disease; to facilitate discussion between clinicians and their patients; and to encourage use of cardiovascular risk as the framework for intervention. However the authors do not attempt to offer guidance on how cardiovascular risk should be interpreted and how it should influence patient management.

The relationships between cardiovascular risk factors were derived using a parametric regression model based on data from a large prospective observational study, the Framingham Heart Study. Risk factors used in the equation include Age (years); Sex (male / female); systolic blood pressure (mmHg). The predicted risk can be calculated

with either systolic or diastolic blood pressure, however the American Heart Association recommends use of systolic blood pressure because it is more accurately determined; has a wider range of values; and is a stronger predictor of risk, particularly in the elderly; Total cholesterol (mg/dl); High Density Lipoprotein Cholesterol (mg/dl); smoking (either non smoker, or smoker or quit during last year); diabetes (either not diabetic, or diabetic defined by treatment with insulin or oral agents or a fasting glucose greater or equal to 140 mg/dl); left ventricular hypertrophy (LVH) as shown on E.C.G. (either not present, or signs of LVH on ECG.). The justification for using these measures are that they are objective; strongly and independently related to coronary heart disease; can be measured through simple office procedures and laboratory tests. The authors acknowledge that there are other important risk factors which have not been included in these equations, such as heredity and obesity. Explanation for the omission of these variables is that heredity is difficult to quantify or obtain accurately, and the effect of obesity in shorter term studies tends to be mediated by other risk factors. The derived relations are presented in Table 4.2.

1. Compute an interim number, 'a', that is based on risk factor measurements:-

$$a = (11.1122) - (0.9119 \times \ln(\textit{systolic blood pressure})) - (0.2767 \times (\textit{smoking}))$$
$$-(0.7181 \times \ln(\textit{total cholesterol} \div \textit{HDL cholesterol})) - (0.5865 \times (\textit{lvh}))$$

2. Computer a second interim value m, which is different for men and women:-

for men calculate:-

$$m = (a) - (1.4792 \times \ln(\textit{age})) - (0.1759 \times (\textit{diabetes}))$$

for women calculate:-

$$m = (a) - (5.8549) + (1.8515 \times (\ln(\textit{age} \div 74))^2) - (0.3758 \times (\textit{diabetes}))$$

3. Next, for both sexes, compute:-

$$u = 4.4181 + m$$

4. Then compute:-

$$\sigma = \exp(-0.3155) - (0.2784 \times m)$$

5. Finally, choose the number of years over which you want to predict the patients cardiovascular risk, (t),:-

$$\mu = (\ln(t) - u) \div \sigma$$

6. The predicted probability over time t, is :-

$$p = 1 - (\exp(-(\exp^{\mu})))$$

Table 4.2 Cardiovascular Risk Algorithm

4.4.5.4 Knowledge Base for the Interactions Module

The aim of this module is to ensure that the users choice of antihypertensive drug treatment does not interact with any of the patients concurrent medication. Interations between drugs can occur for two reasons. Firstly if two or more drugs have either similar or different pharmacological effects or side effects, they will be perpetuated or reduced. These interactions are usually predictable from a knowledge of the mechanisms of actions of the drugs concerned, and will occur in most patients. Secondly if one drug alters the absorption, distribution, metabolism or excretion of another, the amount of drug available to produce its pharmacological effect will be altered. These interactions are not easily predicted. When prescribing it is important to be aware of all possible drug interactions to avoid detrimental effects to the patient. This presents a challenge to the clinician, especially when a patient is on multiple drug therapy. Thus the interactions module in the E.D.S. system reflects the need to ensure safety in medical prescribing. The knowledge base is taken from the British National Formulary (BNF) which provides a comprehensive list of all drugs available to U.K. prescribers, and their interactions. This source of information is widely used and respected by medical practitioners. The BNF classifies interactions into two groups, those that are potentially hazardous and should be avoided, and those where the interaction does not usually have serious consequences. Interactions for each of the seven classes of antihypertensive drugs are listed below. The symbol * refers to an interaction which should be avoided.

Beta Blockers Interact With :	**Effect**
alcohol	enhanced hypotensive effect
*anaesthetics	enhanced hypotensive effect
analgesic	NSAIDs antagonise hypotensive effect
*anti-arrhythmics	increased risk of myocardial depression and bradycardia; with amiodarone, increased risk of bradycardia and AV block; increased risk of lignocaine toxicity with propranolol.

antibacterial	rifampicin accelerates metabolism of bisoprolol and propranolol (reduced plasma concentrations).
antidepressant	fluvoxamine increases plasma concentration of propranolol
antidiabetics	enhanced hypoglycaemic effect and masking of warning signs such as tremor.
* vasodilator antihypertensive	enhanced hypotensive effect
* centrally acting antihypertensive	enhanced hypotensive effect; increased risk of withdrawal hypertension with clonidine
*alpha blocker	enhanced hypotensive effect; increased risk of first dose hypotensive effect with post-synaptic alpha blockers such as prazosin and terazosin.
*ace inhibitor	enhanced hypotensive effect
antimalarial	increased risk of bradycardia with mefloquine
antipsychotic	plasma concentration of chlorpromazine increased by propanolol
anxiolytics, hypnotics.	enhanced hypotensive effect
*diltiazem (calcium antagonist)	increased risk of bradycardia and AV block
*nifedipine (calcium antagonist)	severe hypotension and cardiac failure occasionally
*verapamil (calcium antagonist)	asystole, severe hypotension and cardiac failure
cardiac glycosides	increased AV block and bradycardia
cholinergics	propanolol antagonises effect of neostigmine and pyridostigmine
corticosteriods	antagonism of hypotensive effect
diuretics	enhanced hypotensive effect; risk of ventricular arrhythmias, associated with sotalol, increased by hypokalaemia.
ergotamine	increased peripheral vasoconstriction

muscle relaxants	propranolol enhances effect
sex hormones	oestrogens and combined oral contraceptives antagonise hypotensive effect
*sympathominetics	severe hypertension with adrenaline and noradrenaline (especially with non-selective beta blockers); severe hypertension also possible with sympathominetics in anorectics and cough and cold remedies.
*theophylline	beta blockers should be avoided on pharmacological grounds (bronchospasm).
thyroxine	metabolism of propranolol accelerated (reduced effect)
ulcer healing drugs	Hypotensive effect antagonised by carbenoxolone; plasma concentrations of labetalol and propranolol increased by cimetidine
xamoterol	antagonism of effect of xamoterol and reduction in beta blockade.

Table 4.3 Interactions Between Beta Blockers and Other Agents

Diuretics Interact With:	**Effect**
analgesic	diuretics increase risk of nephrotoxicity of NSAIDs; NSAIDs, notably with indomethacin, antagonise diuretic effect; Indomethacin and possible other NSAIDs increase risk of hyperkalaemia with potassium sparing diuretics; diuretic effect of spironolactone antagonised by aspirin; aspirin reduces excretion of acetazolamide (risk of toxicity).
anion-exchange resins	cholestyramine and colestipol reduce absorption of thiazides (give at least 2 hours apart).
*anti-arrhythmics	toxicity of amiodarone, disopyramide, flecainide, quinidine increased if hypokalaemia occurs; action of lignocaine, mexiletine, tocainide antagonised by hypokalaemia; acetazolamide reduces excretion of quinidine (increased plasma concentration)

antibacterials	loop diuretics increase ototoxicity of aminoglycosides, polymyxins and vancomycin.
antidepressants	increased risk of postural hypotension with tricyclics.
antidiabetics	hypoglycaemic effect antagonised by loop and thiazide diuretics; chlorpropamide increases risk of hyponatraemia associated with thiazides in combination with potassium sparing diuretics.
*vasodilator antihypertensive	enhanced hypotensive effect; increased risk of hypokalaemia with indapamide;
*centrally acting antihypertensive	enhanced hypotensive effect; increased risk of hypokalaemia with indapamide;
*alpha blockers	enhanced hypotensive effect; increased risk of first dose hypotensive effect of post synaptic alpha blockers such as prazosin and terazosin; increased risk of hypokalaemia with indapamide;
*ace inhibitor	enhanced hypotensive effect; enhancement of effect of ACE inhibitors (risk of extreme hypotension, also risk of hyperkalaemia with potassium sparing diuretics); increased risk of hypokalaemia with indapamide;
antipsychotics	pimozide increases risk of ventricular arrhythmias if hypokalaemia occurs
beta blocker	sotalol increases risk of ventricular arrhythmias if hypokalaemia occurs
calcium salts	risk of hypercalcaemia with thiazides
*cardiac glycosides	increased toxicity if hypokalaemia occurs with acetazolamide, loop diuretics and thiazides; effect enhanced by spironolactone.
corticosteriods	increased risk of hypokalaemia, with acetazolamide, loop diuretics and thiazides; antagonism of diuretic effect.
*cyclosporin	increased risk of hyperkalaemia with potassium sparing diuretics
diuretic	increased risk of hypokalaemia if acetazolamide, loop

	diuretcs or thiazides given together; profound diuresis possible if metolazone given with frusemide
*lithium	lithium excretion reduced (risk of lithium toxicity) with loop diuretics and thiazides; lithium excretion increased by acetazolamide.
potassium salts	hyperkalaemia with potassium sparing diuretics.
sex hormones	oestrogens and combined oral contraceptives antagonise diuretic effect.
ulcer healing drug	increased risk of hypokalaemia if acetazolamide, loop diuretics or thiazides given with carbenoxolone; carbenoxolone antagonises diuretic effect; amiloride and spironolactone antagonise ulcer healing effect of carbenoxolone.

Table 4.4 Interactions Between Diuretics and Other Agents

Calcium Antagonists Interact with:	**Effect**
*anaesthetics	verapamil increases hypotensive effect / risk of AV delay
* anti-arrhythmic	Amiodarone-induced risk of bradycardia, AV block and myocardial depression increased by diltiazem and verapamil; with verapamil raised plasma concentration of quinidine (extreme hypotension may occur).
antibacterial	rifampicin increases metabolism of verapamil, and possibly isradipine and nifedipine
antidepressants	diltiazem and verapamil increase plasma concentration of imipramine and possibly other tricyclics.
antidiabetics	nifedipine may impair glucose tolerance
*anti-epileptic	Effect of carbamazapine enhanced by diltiazem and verapamil; diltiazem increases plasma concentration of phenytoin; effect of verapamil reduced by phenytoin; effect of felodipine, isradipine, nicardipine and nifedipine reduced by carbamazapine, phenobarbitone,

	phenytoin, primidone.
vasodilator	enhanced hypotensive effect
centrally acting drugs	enhanced hypotensive effect
alpha blockers	enhanced hypotensive effect
ace inhibitors	enhanced hypotensive effect
antimalarial	possible increased risk of bradycardia with some calcium channel blockers and mefloquine.
antipsychotics	enhanced hypotensive effect
*beta blockers	increased risk of bradycardia and AV block with diltiazem; severe hypotension and heart failure with nifedipine; asystole, severe hypotension and heart failure with verapamil
*cardiac glycosides	plasma concentrations of digoxin increased by diltiazem, nicardipine and verapamil; increased risk of AV block and bradycardia with verapamil.
cyclosporin	plasma-cyclosporin concentration increased by diltiazem, nicardipine, verapamil; possibly increases plasma concentration of nifedipine.
lithium	neurotoxicity may occur without increased plasma lithium concentrations with diltiazem and verapamil
muscle relaxants	Nifedipine and verapamil enhance effect of non-depolarising muscle relaxants such as tubocurarine; hypotension, myocardial depression and hyperkalaemia with verapamil and IV dantrolene.
*theophylline	diltiazem and verapamil enhance effect.
ulcer healing drug	cimetidine inhibits metabolism of calcium antagonists (increased plasma concentrations).

Table 4.5 Interactions Between Calcium Antagonists and Other Agents

Ace Inhibitors Interact With:	Effect
alcohol	enhanced hypotensive effect
*anaesthetics	enhanced hypotensive effect
analgesics	antagonism of hypotensive effect and increased risk of renal failure with NSAIDs; hyperkalaemia with indomethacin and possibly other NSAIDs.
antacids	absorption of fosinopril reduced
antibacterial	absorption of tetracyclines reduced by quinapril.
antidepressants	enhanced hypotensive effect
vasodilator antihypertensive	enhanced hypotensive effect
centrally acting antihypertensive	enhanced hypotensive effect
alpha blockers	enhanced hypotensive effect
antipsychotic	severe postural hypotension with chlorpromazine and possibly other phenothiazines
anxiolytics and hypnotics	enhanced hypotensive effect
beta blocker	enhanced hypotensive effect
cardiac glycosides	plasma concentrations of digoxin increased by captopril
diltiazem	enhanced hypotensive effect.
nifedipine	enhanced hypotensive effect.
verapamil	enhanced hypotensive effect.
corticosteriods	antagonism of hypotensive effect
cyclosporin	increased risk of hyperkalaemia
*diuretics	enhanced hypotensive effect (can be extreme). hyperkalaemia with potassium sparing diuretics.
dopaminergics	levodopa enhances hypotensive effect
*lithium	reduced excretion of lithium (increased plasma-lithium concentrations)
muscle relaxants	baclofen enhances hypotensive effect
nitrates	enhance hypotensive effect

*potassium salts	hyperkalaemia
sex hormones	oestrogens and combined oral contraceptives antagonise hypotensive effect
ulcer healing drug	carbenoxolone antagonises hypotensive effect
uricosurics	probenecid reduces excretion of captopril.

Table 4.6 Interactions Between Ace Inhibitors and Other Agents

Alpha Blockers Interact With:	**Effect**
alcohol	sedative effect of indoramin enhanced
anxiolytics and hypnotics	enhanced sedative effect
*beta blockers	increased risk of first dose hypotensive effect of post-synaptic alpha blockers such as prazosin and terazosin
*diuretics	increased risk of first dose hypotensive effect of post-synaptic alpha blockers such as prazosin and terazosin

Table 4.7 Interactions Between Alpha Blockers and Other Agents

Interactions for alpha blockers are the same as vasodilators, except for those listed in the table.

Centrally Acting Drugs Interact With:	**Effect**
alcohol	enhanced hypotensive effect
*anaesthetics	enhanced hypotensive effect
analgesic	NSAIDs antagonise antihypertensive effect
antidepressants	enhanced hypotensive effect
vasodilator antihypertensives	enhanced hypotensive effect
alpha blockers	enhanced hypotensive effect
ace inhibitors	enhanced hypotensive effect

antipsychotics	increased risk of extrapyramidal effects; enhanced hypotensive effect
beta blockers	enhanced hypotensive effect
diltiazem	enhanced hypotensive effect
nifedipine	enhanced hypotensive effect
verapamil	enhanced hypotensive effect
corticosteriods	antagonism of hypotensive effect
diuretics	enhanced hypotensive effect
dopaminergics	1)antagonism of antiparkinsonian effect 2) levodopa enhances hypotensive effect
lithium	neurotoxicity may occur without increased plasma lithium concentrations
nitrates	enhanced hypotensive effect
sex hormones	oestrogens and combined oral contraceptives antagonise hypotensive effect
ulcer healing drug	carbenoxolone antagonises hypotensive effect

Table 4.8 Interactions Between Centrally Acting Drugs and Other Agents

Vasodilators Interact With:	**Effect**
alcohol	enhanced hypotensive effect
*anaesthetics	enhanced hypotensive effect
analgesic	NSAIDs antagonise hypotensive effect
antidepressants	enhanced hypotensive effect
antidiabetic	diazoxide antagonises hypoglycaemic effect
centrally acting antihypertensive	enhanced hypotensive effect
alpha blockers	enhanced hypotensive effect
ace inhibitors	enhanced hypotensive effect
antipsychotics	enhanced hypotensive effect
anxiolytics and hypnotics	enhanced hypotensive effect

beta blockers	enhanced hypotensive effect
diltiazem	enhanced hypotensive effect
nifedipine	enhanced hypotensive effect
verapamil	enhanced hypotensive effect
corticosteriods	antagonism of hypotensive effect
diuretics	enhanced hypotensive effect
dopaminergic	levodopa enhances hypotensive effect
muscle relaxants	baclofen enhances hypotensive effect
nitrates	enhanced hypotensive effect
sex hormones	oestrogens and combined oral contraceptives antagonise hypotensive effect
ulcer healing drug	carbenoxolone antagonises hypotensive effect.

Table 4.9 Interactions Between Vasodilators and Other Agents

4.5 Summary

In this chapter an introduction to the cardiovascular system has been presented in order to provide the context for a discussion of the medical domain of hypertension. A definition of hypertension was presented and the key issues leading to uncertainty in its diagnosis and management were highlighted. The review focused on the problems which could be overcome by the development of a decision support system. The development of the knowledge base of the Embedded Decision Support system from clinical guidelines and other published documents was discussed. The review included a summary of those problems commonly experienced when developing knowledge bases of decision support systems; the background to the development of clinical guidelines; a review of those documents used in the development of the E.D.S. systems knowledge base and finally a detailed description of how information was extracted from the documents to form the foundation of the E.D.S. systems knowledge base.

This chapter provided the evidence of clinical need in the field of hypertension, which is essential for the successful implementation of decision support systems in the clinical environment. A solution to one of the major barriers to such implementation, that of developing a verifiable and referenced knowledge base, was also presented. In the following chapter the development issues of the prototype embedded decision support system will be presented.

5. Chapter Five : Implementation of an Embedded Decision Support System for the Management of Essential Hypertension

5.1 Introduction

In this chapter the implementation of the embedded decision support system is presented. The reasons for choosing LPA-Prolog as the development language are outlined. The components of decision support systems including knowledge representation, representation of uncertainty, manipulating knowledge and explanation generation are presented, and the different techniques used to implement them are reviewed. The methods adopted in the development of the E.D.S. system are outlined and examples of source code are presented. Full listings of the source code are available on the disc accompanying this thesis. The importance of interface design is discussed and the screen design and functionality of the E.D.S. system are described.

5.2 Development Language

The implementation of the conceptual model presented in chapter three, has to be done in the context of the current state of technology. In the past fifteen years microcomputer technology has progressed from the point where system developers were implementing their systems using hexidecimal code directly programmed into chip sets. The advent of the IBM personal computer and the decision by IBM to use an open computer architecture that could be cloned, coupled with a disk operating system (DOS), from a then small company called MICROSOFT, produced a universal computer system implementation environment. DOS progressed through several generations until Windows 95 was introduced in 1995, which has already been updated to Windows 97 (1997). The purpose of an increasingly sophisticated computer environment is that system developers can operate at higher levels of abstraction using higher level software tools which include many lower level features. In this context the embedded decision

support system has been developed on a 486 PC with a Windows 3.1 operating system. A review of some of the decision support design tools currently available was made and LPA Prolog was chosen as the preferred development tool. This choice was made because Prolog is a high level programming language, which although often compared with 3 GLs like Pascal and C, or 4GLs and programmable database systems, is officially described as a fifth generation computer language. This is because it is said to reflect human cognitive processes more closely than electronic circuit hardware. Prolog was developed in the early 1970s, from the work of Robert A. Kowalski then of Edinburgh University and Alain Colmerauer of the University of Aix-Marseille who developed the idea of using formal logic and theorem proving as the basis for a programming language. Kowalski's research provided the theoretical framework, while Colmerauer's work provided the language. Colmerauer and Roussel built the first Prolog interpreter and David Warren of the University of Edinburgh built the first Prolog compiler. Prolog was brought to prominence and made popular in the 1980s by the development of Borland's Turbo Prolog and the Japanese decision to base their fifth generation program around Prolog (Roth and Spencer, 1994). Since then the language has matured. It is now moving towards ISO standardisation and has commercial applications from companies including :

- ICL, who developed a business process modelling tool known as ProcessWise WorkBench. This tool has been used by the Bank of England, Northern Telecom and Barclays Bank to re-engineer their business processes.

- Boeing, who developed an expert system, known as CASEy (Connector Assembly Specifications Expert), to guide shopfloor personnel in the correct use of electrical process specification. The tool has reduced assembly time from 42 minutes to 5 minutes.

- Boeing Computer Services who developed an intelligent client server architecture.

- British Telecom, who developed an expert system known as ATMS (Advanced Traffic Management System), for real time control of traffic flows in the UK telephone network.

- Knowledgeware, who developed a case tool known as ADW (Application Development Workbench), which has been sold worldwide.

Features of LPA-Prolog which make it particularly suitable for the development language of the Embedded Decision Support system include:-

- Prolog has been closely associated with expert system development and as a tool for rapid prototyping, which enables end users to be involved early in the system development cycle.

- Integration of Prolog with a windows graphical user interface toolkit, which provides access to many of the GUI functions of windows including windows, menus, fonts, dialogs and graphics in a high level and declarative manner.

- Expressiveness : One of Prolog's key attributes is its code typically contains domain specific terms that users understand, rather than low-level programming constructs. This makes the code readable, understandable, manageable and easier to maintain.

- No global variables : Prolog has no global variables, nor any means of changing assignments, as with X=X+1 in other languages. Thus each statement can be considered independently which makes it easier to manage source code and to find programming errors.

- Type free : Data types and structures do not have to be declared in advance. This encourages a natural level of abstraction and means that it is a possible to reason about data in a symbolic manner, which facilitates high level generic programming.

- Automatic memory management : All working memory a program needs is allocated and de-allocated automatically. This means that development time can be devoted to designing solutions, rather than managing machine resources.

These features make LPA-Prolog a powerful general purpose programming language ideal for building windows based applications.

5.3 Components of Decision Support Systems

A medical decision support system which is intended to give patient specific diagnostic or treatment advice has three basic components. That is, a knowledge base, an inference mechanism and some input and output data which are displayed to the user on an interface (fig 5.1). *The emphasis in medical decision support is on assisting the user to make appropriate diagnostic or therapeutic decisions and not on replacing this role.* This contrasts with many industrial applications in which the decision support system changes the state of the system it controls on the basis of the decisions it makes. This is unacceptable in the medical profession because of legal implications and the direct threat to human life.

A computerised medical decision support system is a program that is capable of solving problems that require expert knowledge in a given application domain. This implies certain facts about the system; firstly it should contain the experts' knowledge in some form; Secondly the problem solving process should be able to reason with uncertainty as the input information is often unreliable and relations in the knowledge base are often approximate. For example, clinicians are not always sure whether a specific symptom is present in a particular patient, or that measurement data are absolutely correct, or the likelihood that known side effect 'A', will affect patient 'B'. Thirdly the system should be capable of explaining the decisions that are reached. This enhances the user's confidence in the system's advice and enables possible flaws in the systems' reasoning to be detected. Finally it is important that the system has a user friendly interface which allows the user to enter patient data and view the results of the generated advice. These issues are considered to be central to the implementation of decision support systems and will be described in more detail in this chapter.

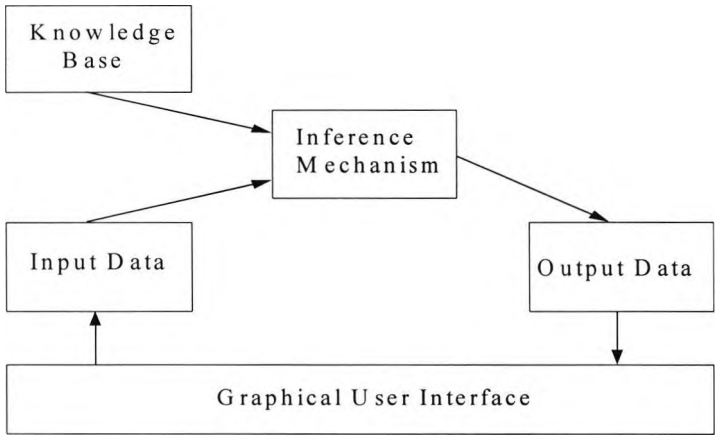

Figure 5.1 Components of Decision Support Systems

5.3.1 Knowledge Representation

A decision support system has a knowledge base specific to the domain application. It includes simple facts, rules that describe relations or phenomena, and possibly methods, heuristics and ideas for solving problems in the domain. The knowledge is represented in a formalism which is accessible to the computer program in order that it can be manipulated by the inference engine in response to the input data. Selection of a specific representation scheme partly determines the set of inferences which will be possible; the interaction mode between user and system; the balance between explicit and implicit knowledge and the range of automatic checking procedures available. Thus the final performance of the system is closely related to the knowledge representation strategy. Fieschi (1984), suggested three criteria should be met when considering knowledge representation in a decision support system:

- Extendible : The data structures should be flexible enough to allow extension of the knowledge base without requiring serious revisions of the program.

- Simple : Representation should be simple and understandable to a non-computer expert.

- Explicit : This is important in the search for errors and for the generation of explanations and justifications.

There are four common methods of representing knowledge; frames, databases, graphs and logic. These techniques will be briefly described in the following section. The most appropriate formalism should be selected based on a knowledge of the application domain and the intended use of the final system.

5.3.1.1 Frames

A frame is a data structure that represents a complete object, situation or stereotype with the concepts name and various properties arranged in slot-filler pairs (Minsky, 1975). Frames are usually linked together to form a frame tree or network. Different frames can inherit values in their slots from each other. The slot represents a property of the object (e.g. blood pressure), and the filler is either a value which occupies the slot (e.g. 90 mmHg), or a pointer to another frame.

5.3.1.2 Databases

A database is, in general, a large group of integrated data that can be retrieved and manipulated (Date, 1983). Data items are typically organised into fields, records and files. There are three database models, hierarchical, network and relational.

5.3.1.3 Logic

Logic is concerned with the truthfulness of a chain of statements. There are two common logic systems; Firstly propositional logic which consists of expressions that can either be true or false and that can be linked by the logical connectors AND, OR, IMPLIES, EQUIVALENT, NOT, to form compound expressions. Secondly predicate calculus which consists of objects and predicates (statements about those objects or relations between them), for example: drug(penicillin), causes(penicillin, rash). The

statements can be manipulated by a series of rules of the form, IF (condition) THEN (action).

5.3.1.4 Graphs

A graph is a structure consisting of nodes and arcs arranged with arbitrary connections, either directed or undirected, that can model the structure of, and interrelationships between, concepts (Deutsch et al. 1994). There are four types of graphs, semantic networks, causal probabilistic networks, decision trees and markov chains which will be briefly described below:-

- Semantic networks: In this type of graph nodes are concepts, objects, entities, processes or events and arcs are the relations (causal, temporal, associative) between them.

- Causal probabilistic networks: These are also known as bayesian belief network or influence diagrams. This is a graphical representation of the probabilistic relations among objects in a knowledge base. Nodes are concepts or objects (objects may have different states. e.g. a disease represented by a node may be present or absent. A blood pressure may be low, normal or high), and arcs are the probabilistic dependencies among these objects. Information flow or causality, propagates from parent to child nodes.

- Decision trees also known as decision analysis: Decision analysis is a method for representing and comparing the expected outcomes of different solutions to a given problem. Initially a decision tree is created. The decision problem is formulated, alternative actions and outcomes are made explicit, probabilities are assigned to each option (these are estimates based on previous patient data, statistics and expert opinions), and the likelihood, cost and benefits of each outcome which can be a subjective measurement dependent on patient preferences, or a value such as expected length of life or quality of life are defined. Then the expected value of each decision alternative is calculated and the decision alternative with the highest

expected value (the actions which optimise the outcome), is chosen. Sensitivity analyses can be used to test the conclusions of the analysis. The probabilities used in the decision analysis are considered to be the best estimate, however there may be a range of reasonable probabilities. Sensitivity analyses test if the preferred choice changes when the probability and outcome estimates change. If the conclusions do remain the same over a reasonable range of assumed values, the recommendation is considered to be acceptable. The conclusions of sensitivity analysis indicate the range of probabilities over which the conclusions apply. The disadvantages of this technique are that clinicians find it difficult to assign probabilities and utilities to different treatment options and outcomes.

- Markov Chain: If relations in a graph represent transitions over time, the graph is known as a Markov chain. Nodes represent the state of the system and arcs the state transitions over time. For example, consider the changing state of a patient from well to ill to dead. This is an example of a three state model. The possible transactions that can occur in patient state between time i and time i+1 are depicted together with the probabilities attached to each possible transition over one unit time.

5.3.1.5 Knowledge Representation in the E.D.S. system

The knowledge representation technique was chosen because the knowledge base presented in chapter 4, could be conveniently and easily coded in sets of logical statements which could then be manipulated by rules according to the decision making strategy specified by the model described in chapter 3, and implemented in computable form via Prolog. This will now be demonstrated with a series of examples.

<u>An example from the treatment module</u>

If patient has had a previous myocardial infarction (MI)
Then recommend beta blocker, calcium antagonist, ace inhibitor
And avoid vasodilator.

This is represented in Prolog code as:-

```
previousmi:-
wlbxsel((drug,2),0,MI),
MI==1
->      wbtnsel((drug,8),1),
        wbtnsel((drug,17),1),
        wbtnsel((drug,14),1),
        wbtnsel((drug,21),1)
!.
```

In Prolog code each statement in the drug treatment knowledge base is identified by the name of the disease or situation for which the drug treatment advice is related, for example:-

previousmi:-
bradycardia:-
sicksinussyndrome:-
migraine:-

Any program wishing to access information about drug treatment of hypertension in the presence of a specific situation calls that part of the knowledge base using the identifier.

previousmi:- This is the identifier

wlbxsel((drug,2),0,MI), This statement accesses information from the patient record concerning whether or not the patient has had a previous myocardial infarction. If the patient has had a previous MI, the variable *MI* is assigned to 1.

MI == 1 This is the 'IF' statement. If the patient has had an MI, then the statement is true, since the variable MI will have been assigned to 1 (1 = 1), and control continues to the 'THEN' part of the rule. If it is not true, the statement fails and the program returns to the point where the call to the knowledge base was made.

-> *wbtnsel((drug,8),1)*

wbtnsel((drug,14),1)

wbtnsel((drug,17),1)

wbtnsel((drug,21),1)

This is the 'THEN' part of the statement, which contains the drug treatment advice for patients with hypertension who have also suffered a previous MI. The drug treatment advice is written directly to the graphical user interface, which is a fixed display. Each drug for the treatment of hypertension has two numbers to indicate on the GUI whether it is recommended or should be avoided:-

8 beta blocker recommended
9 beta blocker should be avoided
11 diuretic recommended
12 diuretic should be avoided
14 calcium antagonist recommended
15 calcium antagonist should be avoided
17 ace inhibitor recommended
18 ace inhibitor should be avoided
20 vasodilator recommended
21 vasodilator should be avoided
23 alpha blocker recommended
24 alpha blocker should be avoided
26 centrally acting drug recommended
27 centrally acting drug should be avoided

In this case,
beta blockers are recommended, so on the GUI, statement 8 is highlighted indicating that beta blockers are recommended.

calcium antagonists are recommended, so on the GUI, statement 14 is highlighted indicating that calcium antagonists are recommended.

ace inhibitors are recommended, so on the GUI, statement 17 is highlighted indicating that ace inhibitors are recommended.

vasodilators should be avoided, so on the GUI, statement 21 is highlighted indicating that vasodilators should be avoided.

!. This statement identifies the end of the rule.

These statements are repeated for each condition used to make a treatment recommendation for example,

```
bradycardia:-
wlbxsel((drug,2),6,Bradycardia),
Bradycardia == 1
->      wbtnsel((drug,9),1),
        wbtnsel((drug,15),1),
!.

sicksinussyndrome
wlbxsel((drug,2),8,SSS),
SSS == 1
->      wbtnsel((drug,9),1),
        wbtnsel((drug,15,1)
!.

migraine:-
wlbxsel((drug,2),20,Migraine),
Migraine == 1
->wbtnsel((drug,8),1)
!.
```

An example from the management module

IF diastolic blood pressure is less than 90mmHg
THEN repeat blood pressure measurements at least three monthly for one year
ELSE test whether the diastolic blood pressure is between 90-105mmHg

This is represented in Prolog code as :-

```
dbp_less_90(Av_sbp, Av_dbp):-
Av_dbp <90
->wedtsel((fred,12),0,3000),
wedttxt((fred,12),`repeat blood pressure measurements at least three monthly for one year`)
;dbp_90_105(Av_sbp, Av_dbp),
!.
```

dbp_less_90(Av_sbp, Av_dbp):- This is the rule identifier. This rule contains management advice about patients who have a diastolic blood pressure (dbp) of less than 90 mmHg, hence the rule is called dbp_less_90. Two parameters are sent to the rule from the patient data base, the patients average systolic and diastolic blood pressures, which are held in the variables Av_sbp and Av-dbp.

Av_dbp<90 This is the IF statement. If the average diastolic blood pressure is less than 90mmHg, then the test succeeds and control continues to the THEN part of the rule. If the average diastolic blood pressure is greater than or equal to 90, then the test fails and control continues to the ELSE part of the rule.

->wedtsel((fred,12),0,3000),
wedttxt((fred,12),`repeat blood pressure measurements at least three monthly for one year`) This is the THEN part of the rule. Firstly the window which the advice is to be written to is specified, cleared of any previous advice and then the advice is specified.

;dbp_90_105(Av_sbp, Av_dbp), This is the ELSE part of the rule, which is a call to a new rule identified as dbp_90_105.

!. This statement identifies the end of the rule.

5.3.2 Representation of Uncertainty

Uncertainty is inherent in medical reasoning for a number of reasons. Firstly, due to the nature of clinical reasoning, which tries to link direct observations to generalised conclusions. For example, "the patient has a cough" could be linked to the clinical condition "bronchitis". This association has a probability of being correct. Secondly incomplete data. Not all patient specific information or test results will be available when decisions are made. Finally incorrect data from poor measurement techniques, test results or misunderstandings. To measure this uncertainty, numeric and symbolic formalisms have been developed, these include probability, the Dempster-Shafer theory, the theory of endorsement and fuzzy set membership (Deutsch et al. 1994). These techniques will be briefly described in the following section.

5.3.2.1 Probability

Probability measures the frequency with which an event occurs in a population, and it reflects the decision makers belief that the event will occur in a particular situation. There are two types of probabilities,

- Qualitative: 'Symptom S is frequently associated with disease D'

- Quantitative: 'The probability of the occurrence of symptom S in patients having disease D is P'

Probabilities are assigned to individual hypotheses. Problems with this method of representing uncertainty include; how to represent ignorance; and the requirement that the subjective beliefs assigned to an event and its negation must sum to one.

5.3.2.2 Dempster-Shafer Theory

The basis of this theory is that diagnoses are grouped together into subsets rather than individual hypotheses. The total set of hypotheses is defined as the "frame of discernment", and is denoted 'H'. The effect of a piece of evidence on a given proposition 'A', which is subset of 'H', is measured by making a basic probability assignment for 'A' in the range of 0 to 1. This is denoted m(A). Basic probability assignments are made throughout the subsets of 'H'. The total belief in the proposition A is defined by a belief function (belief(A)) which is the sum of the basic probability assignments for all propositions which are subsets of 'A'. However unlike probability theory, the Dempster-Shafer theory does not necessarily assign to the complement of 'A' the belief that remains unassigned to 'A'. Instead this belief can be assigned to 'H' itself.

5.3.2.3 Theory of Endorsement

This is a qualitative approach to the representation of uncertainty. It is based on dealing with the reasons for believing and disbelieving a hypothesis, rather than summarising this knowledge into a single number.

5.3.2.4 Fuzzy Sets

This is a method to deal with uncertainty within classical set theory. Each member of a set has a membership grade, in the range 0-1. This is described as the 'fuzzy set membership function'. For example a patient may belong to various diagnostic or symptomatic classes (or sets), to different extents, e.g. mild, moderate, severe.

5.3.2.5 Representing Uncertainty in the E.D.S. system

The E.D.S. system adopts solutions to two areas of uncertainty.

Firstly uncertainty in the input data. This is overcome by accepting all the input data as reflecting the true patient state, but in the explanation of the generated advice referring explicitly to which patient characteristic was linked to what advice. For example, the drug beta blocker was contraindicated because the patient has asthma. Thus the doctor is aware of what patient characteristics the system has used to generate its advice.

This is represented in Prolog code as:-

```
bb_asthma_cont:-
wlbxsel((drug,2),18,Asthma),
Asthma == 1
->wedttxt((reason,12),(`patient has asthma[1,2,4,5,6,7,8]`)
!.
```

bb_asthma_cont:- This is the identifier

wlbxsel((drug,2),18,Asthma), This statement accesses information from the patient record concerning whether or not the patient has a history of asthma. If the patient does have a history of asthma, the variable 'Asthma' is assigned to 1.

Asthma == 1 This is the IF statement. If the patient has a history of asthma, then the statement is true and control continues to the THEN part of the rule. If it is not true, the statement fails and the program returns to the point where the call to the knowledge base was made.

->wedttxt((reason,12),(`patient has asthma[1,2,4,5,6,7,8]`) This is the THEN part of the rule. Firstly the window to which the advice is to be written is selected. In this case it is the window on the user interface which displays information concerning why certain drugs have been contraindicated (reason,12). Then the advice is specified. In this case,

the text informs the user that beta blockers should be avoided because the patient has asthma, and this is supported by seven independent references, as indicated by [1,2,4,5,6,7,8], each number referring to a reference as described in section 4.4.4.

!. This statement identifies the end of the rule.

Secondly uncertainty in medical knowledge. This is overcome in two ways, firstly by reporting the source of the knowledge used to generate the advice, and secondly by explicitly reporting areas of uncertainty (for example, there is conflicting evidence about the use of calcium antagonists in patients with diabetes). The view is taken that it is not the function of the decision support system to guess at a solution where lack of evidence from clinical research leads to uncertainty, but to highlight these areas to enable the doctor to make informed decisions.

This is represented in Prolog code as :-

```
calcium_diabetes_rec:-
wlbxsel((drug,2),15,Diabetes),
Diabetes == 1
->wedttxt((reason,10),`patient has diabetes, evidence for use is contradictory [2,4,7]`)
!.
```

The format of the code is the same as in the previous example. However, the text is written to the window on the user interface which displays information concerning why certain drugs have been recommended (reasons,10). However the advice explicitly reports that the evidence is conflicting and this view is supported by references 2, 4 and 7.

The system also makes use of static displays on the user interface to report the source of knowledge used to generate advice, where this is appropriate. For example, the method used to calculate patients cardiovascular risk is taken from an American Heart Association statement, published in 1991. This is represented in Prolog code as:-

wcreate ((new,20), static,`( Information source: Anderson, 1991 ) ` , 10, 360, 350, 64, 16'5000000B),

This statement specifies the window, position and style in which the text is to be displayed.

5.3.3 Knowledge Manipulation

This is the process of using the information stored in the knowledge base with the patient specific input data to solve problems. Many inference techniques and algorithms have been developed; these include neural networks, criteria tables, search techniques, statistical methods, rule based systems and model based systems. These techniques will be briefly described in the following section.

5.3.3.1 Neural Networks

Medical knowledge is stored as a connection strength between input, hidden and output layers. The advantages of neural networks include experienced based learning, fault tolerance, noise rejection, graceful degradation and speed once trained. Disadvantages include training the network is time consuming, once the network has been trained the system cannot be modified without additional learning, and no explanation can be obtained for the conclusions the network reaches. An example of a system using a neural network for its inference procedure is Poli's system for the treatment of hypertension (Poli, 1991).

5.3.3.2 Criteria Tables

Criteria tables can be considered as kinds of rules. They include major and minor decision elements (e.g. patient signs and symptoms and characteristics), decision tuples (e.g. logical combinations of major and minor decision elements hat can trigger a conclusion. These can be general, for example two major decision elements and one

minor element. Or specific, for example major element #2 and either minor element #3 or minor element #7), requirements and exclusions. (Cheh and Kingsland, 1992).

5.3.3.3 Search Techniques

These can be defined as a search for goal state in a problem space. Examples of techniques include, depth first search, breadth first search, best first search, A* algorithm, hill climbing etc.

The problem can be formulated in the following way:

S = search space

So = starting space

G = goal

T = transformation function (method of getting from So to G).

The search technique should aim to be complete, consistent and find the optimal solution.

5.3.3.4 Statistical Methods

Three statistical methods will be briefly described:-

- Data Mining / Database Supported Classification System: This method relies on access to a large clinical database. Using statistical pattern recognition, patients who have known correct diagnoses (from surgery or post mortem) are identified and their clinical features, diagnoses, treatments and outcomes noted. These patients constitute a training set. Relationships are then extracted between sets of features and disease or treatment categories which are subsequently used to decide which diagnosis or treatment strategy is best suited to a new patient.

- Bayesian Statistics: The relationship between cause and effect (disease : symptoms), can be represented and manipulated in causal probabilistic networks. *A priori* probability reflects the belief about a specific condition before any other information is available. As evidence is collected hypothesis belief increases if evidence supports it,

and decreases if evidence opposes it. *A posteriori* probability reflects the belief about a condition in the light of the collected evidence. Belief is propagated through a system using Bayes' Theorem to compute all the *a posteriori* probabilities of the hypotheses, this is updated with each new piece of new evidence. The set of these probabilities provides comparative rankings for all possible hypotheses. Berger (1985) suggested that a diagnosis based solely on *a posteriori* probabilities is not satisfactory, because of the potential for harmful intervention based on the wrong diagnosis. Dangers that arise from misclassification can be expressed as values of a loss function. Loss functions have two arguments, L(D, d), where D is the patient's true disease state and d is the disease allocated by decision. The value L(Di, dk) measures the loss arising from diagnosing a patient with disease Di as suffering from disease dk, (it is a measure of whether misdiagnosis has drastic consequences or whether it doesn't really matter). The best diagnostic decision has the lowest expected loss, (zero loss represents the correct assignment). An example of a decision support system based on Bayesian statistics is De Dombal's system for the diagnosis of abdominal pain (De Dombal et al. 1972).

- Linear Discriminant Functions: This is a method to express associations between features and disease categories. Patient features are related to probabilities of them belonging to each specified disease category. A new patient is classified in the category for which their symptoms have the highest probability.

5.3.3.5 Rule based System

A production rule based system is a collection of 'condition implies action' type rules, plus an inference engine to generate conclusions. Knowledge manipulation is related to the reasoning process. The conditions usually test the current state of the facts. Actions may trigger other rules in the system. This iterative process leads to the conclusions (decisions) the system makes. The method for controlling the sequence of rule evocation is known as the 'control strategy' used by the inference engine. At any point several rules may be activated, these potential rules constituting the 'conflict set'. A strategy is needed to determine in which order they are activated. The control strategy is usually a

combination of forward and backward chaining. Rule based systems can provide explanations for their conclusions.

Backward chaining, also known as consequent driven logic. This is a technique based on deductive reasoning, which attempts to prove the truth of a statement by proving all its conditions. The inference process starts from the goal statement (fact to be proven) and proceeds towards conditions that confirm it. The result is that the hypothesis is either confirmed or rejected or has a certainty factor attached to it which represents the strength of belief in the hypothesis.

1. goal statement (fact). (i.e. tonsillitis)
2. find rules with that fact in their conclusion. (IF hot and sore throat THEN tonsillitis)
3. prove conditions of those rules. (patient(hot), patient(sore throat)).

Forward chaining, also known as antecedent driven or data driven reasoning. This technique is based on abductive reasoning, which generates hypotheses to explain data or events that have been observed. The inference process proceeds from conditions to conclusions. All rules whose conditions are true are triggered and represent the conflict set.

1. Observed data (patient (hot), patient (sore throat)).
2. Find rules with those facts in their conditions; these represent the conflict set (IF hot THEN ****, IF sore throat THEN ****, IF hot and sore throat THEN tonsillitis).
3. Try and reach one conclusion.

The classical example of a rule based system is MYCIN, a decision support tool for the diagnosis and treatment of bacterial infections (Shortliffe, 1976).

5.3.3.6 Model Based System

Causal models represent the behaviour of a dynamic system. Therefore it is possible to study how the system evolves over time to predict future states. This is achieved by taking the current state and generating all possible successive states, then filtering out those states that violate consistency criteria. Therefore only the set of transitions

consistent with the network are retained. Diagnosis is the path between the observed signs and symptoms and the cause. As patient data are obtained, the relevant part of the general medical knowledge base is activated. This constitutes a summary of the evidence / conclusions about the patient's illness as it gradually evolves over time. It is both a structured representation of facts and conclusions and a chain of inferences justifying why conclusions are thought to be the case. An example of a model based system is the Heart Failure Program developed at Massachusetts Institute of Technology (Long et al. 1984).

5.3.3.7 Knowledge Manipulation in the E.D.S. system

The E.D.S. system uses a forward chaining rule based system. Each decision support module has a set of rules which represent the method by which advice can be generated. The set of rules are based on the conceptual model of the doctors decision making process described in section 3.2.2. In general when the user requests some advice, a patient model is created by accessing patient data from the patient record. Patient specific advice is then generated by matching the patient model to the information held in the systems knowledge base, processing the data where appropriate and then presenting the results to the user.

An example from the treatment module

Two rules in the treatment module specify how advice is generated. They are:-

- *give_treatment_advice:-*
- *check_states:-*

The first rule contains the set of factors which influence the decision what drug to recommend. They include the patients concurrent diseases, age, ethnic origin and whether the drug advice is for an initial treatment. Each factor is considered in turn by a call to the knowledge base to access information about that factor. If the factor is relevant to the individual patient the advice is displayed on the user interface as

previously described in the section on knowledge representation, 5.3.1.5. This is represented in Prolog code as:-

```
give_treatment_recommendation:-
previousmi,
cardiacfailure,
lvh,
leftventriculardysfunction,
angina,
ischaemicheartdisease,
bradycardia,
heartblock,
sicksinussyndrome,
peripheralvasculardisease,
artheroscleroticdisease,
renalfailure,
renalinsufficiency,
raisedcreatinine,
renalarterialdisease,
diabetes,
reducedglucosetolerance,
dyslipidaemia,
asthma,
coad,
migraine,
depression,
gout,
impotence,
age,
ethnicity,
initial_treatment,
!.
```

The second rule, manages inconsistencies arising from a drug being both recommended and contraindicated due to the presence of two or more factors, for example, beta blockers are recommended for angina and contraindicated for asthma. This is achieved by taking the presence of a contraindication as the dominant characteristic, although all reasons for and against drug treatment advice are presented to the user in the explanation. This allows the user to make the final decision with all the available evidence.

This is represented in Prolog code as:-

```
check_states:-
check_betablockers,
check_diuretics,
check_calcium,
check_ace,
check_vaso,
check_alpha,
check_central,
!.
```

Each drug is checked in turn by a call to the appropriate function. for example:-

```
check_betablockers:-
wbtnsel((drug,9),State),
State == 1
->wbtnsel((drug,8),0)
!.
```

check_betablockers:- This is the identifier.

wbtnsel((drug,9),State), This statement accesses information from the user interface to determine whether or not beta blockers have been contraindicated, as indicated by the

highlighting of the beta blockers contraindicated sign on the GUI (defined as (drug,9)). If beta blockers have been contraindicated, the variable State is assigned to 1.

State == 1 This is the IF statement. If beta blockers have been contraindicated then the statement is true and control continues to the THEN part of the rule. If it is not true, the statement fails and the program returns to the point where the call to the knowledge base was made.

->wbtnsel((drug,8),0) This is the THEN statement, in which the beta blocker recommended sign on the GUI is deselected. This results in only the beta blocker contraindicated sign (defined by (drug,9)) being highlighted.

!. This statement identifies the end of the rule.

An example from the management module

The management module uses a different method of using a rule based system to generate advice. In the treatment module all the relevant rules are listed in the order in which they are to be accessed. In the management module a branching tree-like structure of rules is more appropriate. This is achieved by the THEN and ELSE parts of the rule specifying the next rule to be accessed. This means that it is possible to specify that more than one condition should be satisfied before an action is performed. For example:

IF patient has been monitored for less than 4 weeks
THEN rule one
ELSE rule two

This is represented in Prolog code as :-

check_weeks_monitored(Monitored, Av_sbp, Av_dbp):-
Monitored < 4
->rule_base_one(Av_sbp, Av_dbp)

; monitored_rule_2(Monitored, Av_sbp, Av_dbp),

!.

check_weeks_monitored(Monitored, Av_sbp, Av_dbp):- This is the rule identifier. Three parameters are sent from the patient data base, the number of weeks the patient has been monitored and their average systolic and diastolic blood pressures. These are held in the variables, Monitored, Av_sbp and Av_dbp.

Monitored < 4 This is the IF statement. IF the patient has been monitored for less than 4 weeks, then the test succeeds and control continues to the THEN part of the rule. If the patient has been monitored for 4 weeks or more, then the test fails and control continues to the ELSE part of the rule.

->rule_base_one(Av_sbp, Av_dbp) This is the THEN part of the rule. It is a call to another rule called rule_base_one. Two parameters are sent to that rule, the patients average systolic and diastolic blood pressure.

; monitored_rule_2(Monitored, Av_sbp, Av_dbp), This is the ELSE part of the rule. It is a call to another rule called monitored_rule_two. Three parameters are sent to that rule, the number of weeks the patient has been monitored, and their average systolic and diastolic blood pressure.

!. This statement identifies the end of the rule.

5.3.4 Explanation Generation

A decision support system must be able to explain or justify its advice. This requirement reflects a simple need to display tact when offering advice, and also acknowledges that the users are ultimately making the decision and are using the computer program as an adjunct, as they would use a textbook, journal or other informational aid (Shortliffe and Perreault, 1990). Methods of explanation generation include: pre-prepared explanatory text, relying on computer code / traces of program

execution or based on the program's knowledge and reasoning mechanism. These techniques will be briefly described.

5.3.4.1 Prepared Text

User's questions are anticipated and the answers are stored as 'canned text'. There are three disadvantages of this method. Firstly all possible questions must be anticipated, and answers constructed in advance. It results in a rigid system with loss of flexibility and in large programs that manipulate extensive knowledge bases it becomes an impossible task.

5.3.4.2 Trace of Program's Execution

This technique can be used in rule based systems. Rules represent the sub goals that reflect the knowledge used in the reasoning process. Therefore if past and current rules are stored the system can provide explanations for how and why questions.
example: IF a, b, c, THEN d.
why a.....because trying to prove d
why d.....because a, b, c are true.

5.3.4.3 Reasoning Method

This technique can be used in model based systems. As the program uses knowledge and makes decisions, the chain of events are stored and can be provided as an explanation. e.g. Digitalis Advisor Xplain (Swartout, 1983).

5.3.4.4 Explanation Generation in the E.D.S. system

The E.D.S. systems drug treatment module explanations are generated using a method of combining pre-prepared text with a series of rules to enable patient specific explanations

to be generated. Firstly a patient model is constructed. Then the system accesses a set of rules which determine what are all the possible reasons for and against prescribing specific drugs. Factors taken into account include, concurrent problems, age and ethnic origin. The system works through the rules (forward chaining) to determine which ones apply to the specific patient, thus constructing a patient specific explanation. The advice is presented to the user on the graphical user interface.

For example, suppose the user wants to know why the system has recommended a diuretic for a patient aged 70 with cardiac failure. Firstly the rule listing all the possible reasons for prescribing a diuretic is accessed. Each factor in the list represents a call to the knowledge base. This is represented in Prolog code as:-

```
diuretic_reason:-
d_cardiacfailure_rec,
d_angina_rec,
d_ischaemicheartdisease_rec,
d_peripheralvasculardisease_rec,
d_renalarterialdisease_rec,
d_asthma_rec,
d_coad_rec,
d_depression_rec,
d_initialtreatment_rec,
d_blacks_rec,
d_elderly_rec,
d_renalinsufficiency_cont,
d_raisedcreatinine_cont,
d_renalfailure_cont,
d_diabetes_cont,
d_reducedglucosetolerance_cont,
d_dyslipidemia_cont,
d_gout_cont,
d_impotence_cont,
!.
```

Each factor is considered in turn, however only the advice from those factors which apply to the specific patient is displayed on the user interface. Using the example above,

```
diuretic_cardiacfailure_rec:-
wllbxsel((reason,4),1,Cardiacfailure),
Cardiacfailure == 1
wedttxt((reason,10),`
patient has cardiac failure [1,2,4,7]
nl,
!.

Age >= 70
-> wedttxt((reason,10),`
patient is elderly [1,2,3,7]
nl,
!.
```

The format of this code has been described in the section on representing uncertainty, 5.3.2.5.

5.3.5 Testing the E.D.S. System Code

After the code had been debugged it was tested to ensure that the knowledge base had been coded correctly and the inference engine was manipulating the knowledge base appropriately. This was achieved by defining a large number of hypothetical patient scenarios which covered the full range of possible input combinations for each of the decision support modules. The systems output was then compared to the predicted output from the written version of the knowledge base. Examples of hypothetical patient scenarios include:

- male, black, 75, smokes 30 per day, total cholesterol 300mg/dl, hdl cholesterol 50mg/dl, blood pressure 190/100mmHg, concurrent problems: ischaemic heart

disease, sick sinus syndrome, artherosclerotic arterial disease, reduced glucose tolerance.

- female, white, 60, non smoker, total cholesterol 250mg/dl, hdl cholesterol 45mg/dl, blood pressure 150/90mmHg, concurrent problems: bronchospasm, raised creatinine, depression.

- male, asian, 40, smokes 10 per day, total cholesterol 200 mg/dl, hdl cholesterol 70mg/dl, blood pressure 170/110mmHg, concurrent problems: peripheral vascular disease, diabetes, gout, left ventricular dysfunction.

5.4 Human Computer Interface

Poor human computer interfaces is often cited as the reason for system failure at the implementation stage. The review of human computer interaction has been presented in chapter three, and in this section some general design principles are outlined. This provides the background for the presentation of the interface design features which have been developed for the E.D.S. system.

5.4.1 Principles of Design

There are a huge number of objects in modern society. Irving Biederman, a psychologist who studied visual perception, estimated that the adult human could easily discriminate between 30,000 different objects, each serving some function for manufacturability, usage or appearance. Each object requires its own method of operation, each has to be learned, each does its own specialised task, and each has been designed separately. The question can be asked, how do people cope? This can be answered in several ways (Norman, 1995).

- In the way the mind works - the psychology of human thought and cognition

- From the information available from the appearance of objects

- From the ability of the designer to make the operation clear, to project a good image of the operation and to take advantage of other things people might be expected to know.

Well designed objects are easy to interpret and understand. They contain visible clues to their operation, and do not rely on users memorising instruction manuals. Poorly designed objects can be difficult and frustrating to use. They provide no clues, or false clues inhibiting the normal process of interpretation and understanding. The aim of a good design is to develop an object or device which is easy and attractive to use, in which the interface is effectively transparent allowing the functionality of the system to be dominant. Issues which influence this process will be considered in the following sections (Norman, 1995).

5.4.1.1 Visibility

The designer must make it obvious how to use the object by indicating which parts operate and how the user is to interact with them to achieve the desired outcome. For example, in the case of designing a glass door, a vertical plate could be placed on the side to be pushed. This is a natural sign which can be easily interpreted without the user being conscious of the instructions. Another example, demonstrating the importance of visibility can be provided by the telephone system. An office telephone system was developed to have a hold function, so users could push a button and hang up the phone without losing the call. A flashing light indicated the hold function was in use. When the system was upgraded, the hold button was replaced by users dialling an arbitrary sequence of digits. This lack of visibility made the system more difficult to use. Secondly the visible outcome of the operation, the flashing light, was lost in the new system, so users were never sure whether the desired result had been obtained. This lack of feedback is considered again in section 5.4.1.5.

5.4.1.2 Affordances

The term affordance refers to the perceived or actual properties of an object and reflects common uses, for example, glass is transparent, is for seeing through and can be easily broken; chairs offer support and can be sat on; rubbish bins are for disposing of unwanted objects; knobs are for turning; slots are for inserting things into; balls are for bouncing. Affordances provide strong clues about how things operate and when used effectively, users know exactly how to operate novel devices just by looking, no picture, label or instructions are required.

5.4.1.3 Mapping

This refers to the relationship between two things, in this case between what the user wants to do and what appears to be possible. For example, Norman (1995) demonstrates this principle by describing a slide projector which has a single button to control whether the slides are fed forward or backwards through the projector. The problem here is there is one button to control two functions. There are no visible clues to aid the user work out how to use the projector. The projector actually works by the length of time the user depresses the button, a short press and the slides move forward, a long press and the slides move backwards. This example demonstrates the problems users face when there is no clear relationship between an objects operating controls and its functions. In general controls with more than one function are harder to remember and use. When the number of controls equals the number of functions, each control can be specialised and labelled. The possible functions are visible because each corresponds with a control. If the user forgets a system or devices functions, the controls can also act as reminders.

Mapping also refers to the way in which a control works to achieve the desired outcome. Norman (1995) demonstrates this concept by describing the mapping relationships involved in steering a car. To turn the car to the right, the steering wheel is turned clockwise. Although the mapping is arbitrary, the wheel and clockwise direction are natural choices, the control (e.g. the steering wheel) is visible, the action is closely

related to the desired outcome and immediate feedback is provided. Thus the mapping is easily learned and remembered.

By taking advantage of physical analogies and cultural standards, designers can develop objects which are immediately understood, because they appear to be logical and are familiar to the user. In effect they exploit natural mappings, examples of which include; to move an object up, move the control up; a rising level represents more, a diminishing one, less.

5.4.1.4 Conceptual Model

This is the user's perception of how an object or device operates, which enables them to predict the effect of their actions. Without such a model, users operate by rote, performing operations according to specific instructions without understanding. This results in users being unable to adapt to novel situations or cope when things go wrong. For simple devices, conceptual models simply map controls to outcomes. More complex systems need more sophisticated models. The designer expects the users model to be identical to the design model (see fig 5.2). However there is usually no direct communication between user and designer, all interaction takes place through the system image. It is therefore crucial that the system image makes the design model clear and consistent in order for the user to develop the correct mental model and thus be able to use the system effectively.

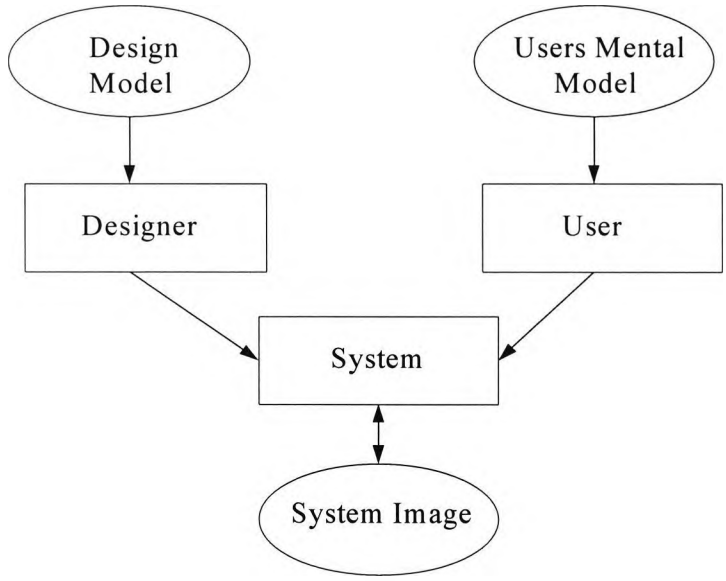

Figure 5.2 Relation Between Design Model and Users Mental Model

5.4.1.5 Causality and Feedback

Something that happens just after an action appears to have been caused by that action. When an action has no apparent result it is logical to conclude the action was ineffective, which naturally leads to the action being repeated. For example, early word processors did not always show the results of their operations on the visual display unit. The lack of visible effect would often lead users to assume their commands had not been executed, and thus the actions would be repeated, to their later regret. Thus it is important that designs indicate when inputs have been received. This can be achieved by feedback, a process of sending information to the user about what action has been performed and what results have been achieved. An example of feedback is the flashing light on a telephone to indicate the hold function is in operation.

5.4.1.6 Complexity

Another problem which has arisen from modern day designs is complexity. Advances in technology enable more and more functions to be included in a design, which in turn require more and more controls to operate. This often results in consumers memorising one or two fixed settings to approximate what is desired, thus the whole purpose of the design is lost. This is particularly well demonstrated by modern washing machines and video recorders. Essentially simple things end up with complex interfaces which in turn restrict the use of the device.

5.4.2 Computer Interface Design

Computer interface design is a specific instance of general design. When users interact with a computer system they are primarily interacting with information, accessing, manipulating or creating. The computer and peripheral devices are the means through which the user achieves their objectives. Thus the way in which the interface is designed has a huge effect on the users perception of the systems usability. In the following section four components of computer interface design will be considered, screen design, communication styles, input devices and output devices.

5.4.2.1 Screen Design

The format and content of information displayed on the screen is important in determining the success of a user's interaction with a system. If the information displayed is confusing or does not provide users with what they need, their performance will degrade. Issues to consider when designing a screen include (Tullis, 1988) :-

Amount of Information. The aim is to present the user with minimum amount of information needed to complete the current task. This can be achieved by using concise wording; using familiar data formats; using tabular formats with column headings; avoiding unnecessary detail; making appropriate use of abbreviations.

Grouping of Information. Grouping similar items in a display together improves readability and can highlight relationships between different groups of data. This can be achieved by colour coding; using graphic borders around different groups of information; highlighting using brightness.

Highlighting of Information. It is often necessary to focus the user's attention on a specific piece of information, this can be achieved by using techniques such as flashing; underlining; making the information bolder and brighter; using a colour that stands out from the rest of the screen.

Standardisation of Screen Displays. One of the aims of screen design is to enable users to locate relevant information quickly and easily, this can be achieved by using a consistent format for all the screens in the application; displaying important information in a prominent place; avoiding displaying redundant information unless it facilitates the user's ability to process the current information; grouping reports and reference information together and displaying them on the more peripheral areas of the screen.

Presentation of Text. It is important to ensure that any text is legible, in that it doesn't flicker and is easily readable at a glance; distinguishable from the background; comprehensible, using words and phrases that are familiar to the user; uncluttered, making use of tables and charts where appropriate; logical and meaningfully structured to help users find relevant information. Other points to consider include; conventional upper and lower case text can be read about 13% faster than text that is all upper case; upper case characters are most effective for items that need to attract attention; right-justified test, where the words have variable spacing, is more difficult to read than evenly spaced text with a ragged right margin; optimal spacing between lines is equal to or slightly greater than the height of the characters themselves.

Graphics. Graphical representations have an important role in information display, particularly when users are required to make visual judgements, detect trends, or when data is multidimensional or constantly changing. Examples include scatter plots; line graphs or curves; area, band, strata or surface charts; bar graphs, column charts or histograms; pie charts; simulated meters; star, circular or pattern charts.

Icons. Icons are small graphic images that are used to represent different parts of a system. For example in an office system, icons may represent files, folders, printers etc. The advantages of icons compared with command names is that in many cases they are easier to learn and remember because they provide visual information about the underlying object or task and they act as powerful mnemonic clues. When designing icons it is important to take into account:

- The context in which the icon is used. This is because context influences the comprehensibility of the icons. For example, one reason why the meaning of the icons designed for office systems are easily recognisable is that they represent objects within the specific context of the office environment (e.g. files and printers). This reduces the possibility of misinterpretation.

- The task domain for which they are used. Some tasks are more suited to graphic representation than others; in general the more abstract the task, the more difficult it is to represent in iconic form.

- The graphic form that is used to depict the object. Icons can be concrete representations, abstract symbols or a combination of the two.

- The extent to which one icon can be discriminated from other icons displayed, this is an important consideration, especially when a large number of icons are being used.

Colour. Colour can be used with good effect to provide effective and pleasing screens. Colour is particularly effective for segmenting a display into separate regions, for search and detection tasks and to enhance the legibility of a colour symbol against its background. However, colour should be used conservatively as too many colours clutter up the screen and increase search times. Certain colour combinations, such as red on blue should also be avoided and the prevalence of colour-blindness should also be considered. Other issues to consider when making use of colour include:

- For graphics that are designed to resemble the real world, such as flight simulators or virtual realities, it is desirable to use colours that resemble their everyday counterparts, e.g. blue for sky and green for grass

- For systems that use schematic representations, it is preferable to use existing conventions, e.g. red for danger, green for go.

- For more abstract representations, such as text or flowcharts, colour should be used more as a form of additional coding, to highlight or draw attention etc.

5.4.2.2 Communication Styles

Another issue to consider is the method by which the user exchanges instructions and information with the computer system. Different styles are not mutually exclusive and it is likely that systems will use various combinations, five commonly used techniques will now be considered in more detail.

Command Languages. This method of communication requires the user to know the command language and the sequence of commands required to complete a specific task. Command languages require instructions to be expressed using a precise syntax, and are intolerant of even the slightest syntax error. This is clearly unacceptable for novice users, however for the expert it is often the quickest form of communication.

Menus. A menu consists of a set of options; the user is required to select one of the options which results in an event. Unlike command languages the user does not have to remember the name of a command, merely to recognise it from a list of options. However for a menu to be successful, the names of the options have to be self-explanatory; the order of the menu items e.g. alphabetically, by category or by frequency, has to be logical to the user; and the method by which items are selected e.g. use of a pointing device or typing has to be considered.

Question and Answer Dialogues. In this method, the system prompts the user with a question to which they respond yes or no, or select an answer from a list. This method is suitable for novice users, but can be frustrating for experienced users, especially if there is a long sequence of questions to achieve a goal.

Form Filling. In this method the screen is designed to resemble a paper based form, and the user is required to enter the data in a similar manner. This method of communication is particularly suited to data processing applications.

Natural Language Dialogue. The use of ordinary language as a means of communicating with a computer, particularly when combined by speech recognition as the input mechanism, is considered to be highly desirable because of its flexibility, ease of use and naturalness. However the problems of vagueness, ambiguity and ungrammatical language have not yet been overcome by the research community, thus currently there are no true natural language systems. Those that have been developed are restricted to well defined domains using a limited vocabulary, which in effect resembles a command language.

5.4.2.3 Input / Output Devices

In Appendix 3, a summary of common input / output devices is presented. Each device has a set of characteristics that makes it more or less suitable for a particular task. Selecting an appropriate input / output device is influenced by the user, their physiological and psychological characteristics, training and expertise; the task to be performed; and the environment in which the system is to be used; and the technical and logistical constraints imposed on the system designer, e.g. cost, existing devices etc.

5.4.3 Screen Design and Functionality of the E.D.S. System

In this section the general design features that have been incorporated into the screen design of the embedded decision support system will be presented, followed by descriptions of each of the interfaces and their functions.

Modularity. The system is modular, so each module (e.g. drug treatment, health advice) is a self contained unit. Users can access the modules in any order and are thus not constrained to follow a style of working imposed by the system designer. This style of programming is often refered to as event driven. For example, once a decision support module has been accessed, the user has to return to the simulated patient record if they wish to access a different decision support module. Each module contains no more than three screens, for example the drug treatment module has three screens, a drug advice screen, a reasons screen and a references screen. From the drug advice screen the user can either return to the patient record or access the reasons screen. From the reasons screen, the user can either return to the drug advice screen or access the references screen. From the references screen the user can only return to the reasons screen.

Data summaries. Each of the modules provide the user with summaries of the patient data relevant to the module. For example, in the screen offering drug treatment advice, the patients ethnic origin, age and concurrent problems are displayed.

Familiar words and phrases. The modules present their advice using words and phrases that reflect the health care professionals working vocabulary.

Concise. Where written advice is used, it is as concise as possible, and where appropriate advice is presented as a list of key points.

Lower case. The modules use lower case letters to present advice, accept where a piece of information needs to be highlighted to attract the users attention, in which case upper case letters are used.

Consistency. Consistency is considered to be an important component of design and it is observed through the E.D.S. system. For example, in the

- the order in which the items in lists are presented.

- the positions of components in the screen display, e.g. buttons representing a function which is used throughout the system (e.g. close) are in the same physical position on the GUI.

- use of buttons as the method by which users request advice

- use of the same labels to represent similar functions. e.g. use of the label 'close', to exit the current screen is used throughout the system.

Input / Output. The input devices used are the QWERTY keyboard and the mouse. The output devices used are the VDU and the printer. These are currently the most common input / output devices used by general practitioners.

Communication styles. The user interacts with the system using a system of menus, buttons and form filling.

5.4.3.1 Simulated Patient Record

When the system is switched on, a simulated patient record is displayed to the user (fig 5.3). This is a GUI which is designed to resemble a paper based form, with various categories, e.g. name, address, age, in which the user can enter specific details. In a working system this would be replaced by the general practitioners clinical information system. The top of the GUI is a menu bar which has various options to allow the user to exit; select a patient record from the database, or enter new patient details; access a decision support system. The first action the user is required to complete is to access a patient data file or enter some new patient details. This is achieved by either selecting the name of the patient, or selecting the new patient option, from a menu. Once this is complete, the user may then select a decision support system from the menu bar. In the hypertension decision support system six modules are currently available, drug treatment; health advice, management advice; cardiovascular risk; critique; drug interactions. The health advice module contains a sub-menu of seven health topics related to hypertension; weight, cholesterol, alcohol, salt, smoking, exercise, hormone

therapy. The screen design and functionality of each of these modules will now be described in more detail.

5.4.3.2 Treatment Advice Module

This module consists of three screens; drug advice screen (fig 5.4); reasons screen (fig 5.5); references screen (fig 5.6).

Drug advice screen.

This screen presents the user with a summary of data from the patient record, including the patients ethnic origin, age and concurrent problems. The ethnic origin is presented as a drop down list, with the patients ethnic origin being displayed in the selection box which is visible at all times. The order of the items in the list is black, white, asian, other. This order is consistent throughout the system. The list of concurrent problems is a fixed length, so all concurrent problems are visible to the user at all times. Those problems which refer to the patient are highlighted. The items in the list are grouped together in major disease classes: cardiac, renal, diabetes, dyslipidemia, respiratory and other. The list includes, previousMI, cardiac failure, lvh, left ventricular dysfunction, angina, ischaemic heart disease, bradycardia, heart block, sick sinus syndrome, peripheral vascular disease, artherosclerotic disease, renal failure, renal insufficiency, raised creatinine, renal arterial disease, diabetes (1&2), reduced glucose tolerance, dyslipidaemia, asthma / bronchospasm, COAD, migraine, depression, gout, impotence. This order is consistent throughout the system.

The drug treatment advice is generated automatically when the user accesses the screen and is presented as a 3 column table. The first column is a list of the seven classes of antihypertensive drug; beta blockers; diuretics; calcium antagonists; ace inhibitors; vasodilators; alpha blockers; centrally acting. The second column contains a checkbox associated with the word 'recommended'. The third column contains a checkbox associated with the word 'avoid'. The state of a checkbox indicates whether the drug is recommended or should be avoided.

Three buttons are displayed their labels and functions are as follows:

'close', the system returns to the simulated patient record.

'recommend', the system generates a new set of drug treatment advice based on the patient data displayed on the GUI. This option enables the user to simulate different patient states by changing the patient data displayed on this screen, and observe the effect on treatment advice. Data stored in the patient record are not effected by changes to data on this screen.

'reasons', the system accesses a screen which allows the user to request reasons for the systems treatment advice.

Reasons Screen

This screen presents the user with seven checkboxes associated with the names of the seven classes of antihypertensive drugs. These are presented as two horizontal rows, beta blocker, diuretic, calcium antagonist and ace inhibitor in the first row, and vasodilator, alpha blocker and centrally acting in the second row. Despite the changes in layout, from a vertical list in the drug advice screen, to a horizontal list in this screen, the order of the items remains constant. All the checkboxes and their labels are visible at all times.

The screen also contains two large boxes for displaying text based advice. They are labelled 'recommended because...', and 'use with caution because...'.

To obtain reasons, the user is required to select which antihypertensive medication they want to know the reasons for and against prescribing by clicking the mouse on the appropriate checkbox, and then selecting the 'give reasons' button.

Three buttons are displayed, their labels and functions are as follows :-

'close', the system returns to the drug advice screen.

'give reasons', the system generates two lists. One list, in the box labelled 'recommended because', contains the reasons and their supporting references for recommending that drug, and a second list, in the box labelled 'use with caution because', contains the reasons and their supporting references, for avoiding that drug. If for a specific patient there are reasons for and against prescribing a specific drug, both lists are displayed to the user. The user is able to select each of the antihypertensive drugs in turn, and request reasons for and against their prescription.

'references', the system accesses a screen which contains the list of references supporting the advice in the systems knowledge base.

References screen

This screen presents a set of references used by the system to support its drug treatment advice.

One button is displayed, its label and function is as follows:-

'close', the system returns to the reasons screen.

5.4.3.3 Health Advice

Health advice is an umbrella term for a set of seven separate modules providing information for health care professionals and patient education material. The modules are accessed from the health advice submenu and include; weight, cholesterol, alcohol, salt, smoking, exercise, and hormone therapy (fig 5.7).

Weight

This module has 2 screens, weight advice screen and a patient education screen.

Weight advice screen

This screen presents the user with a summary of data from the patient record, including the patients height and weight.

The patient's Body Mass Index (BMI) is automatically calculated and a written interpretation and appropriate advice is displayed when the user accesses the screen.

Four buttons are displayed, their labels and functions are as follows:-

'close', system returns to the simulated patient record

'calculate BMI', the system generates a new BMI, based on the patient data displayed on the GUI. This enables the user to simulate different patient weights and observe the effect on BMI. Data in the patient record are not effected by changes to data on this screen.

'advice', the system interprets the patients BMI, and offers appropriate advice.

'patient education', the system accesses a screen displaying patient education material.

Patient education screen

This screen presents the user with patient education material, for example, advice concerning diet and exercise.

Two buttons are displayed, their labels and functions are as follows:-

'close', the system returns to the weight advice screen.

'print', the system prints out the patient education material to enable the patient to take relevant information home.

Cholesterol

This module contains one screen, the cholesterol advice screen.

Cholesterol advice screen

This screen presents the user with information concerning the relevance of cholesterol to the management of the hypertensive patient, and the references ranges for normal cholesterol levels. It also contains patient education material.

Two buttons are displayed, their labels and functions are as follows:-

'close', the system returns to the simulated patient record.

'print', the system prints out the patient education material to enable the patient to take relevant information home.

Alcohol

This module contains one screen, the alcohol advice screen.

Alcohol advice screen

This screen presents the user with information concerning the relevance of controlling alcohol intake in the management of the hypertensive patient. The recommended limits on alcohol consumption and patient education material is also available.

Two buttons are displayed, their labels and functions are as follows:-

'close', the system returns to the simulated patient record.

'print', the system prints out the patient education material to enable the patient to take relevant information home.

Salt

This module contains one screen, the salt advice screen.

Salt advice screen

This screen presents the user with information concerning the relevance of restricting dietary salt in the management of the hypertensive patient, and presents the recommendations for acceptable salt intake. It also contains patient education material.

Two buttons are displayed, their labels and functions are as follows:-
'close', the system returns to the simulated patient record.

'print', the system prints out the patient education material to enable the patient to take relevant information home.

Smoking

This module contains one screen, the smoking advice screen.

Smoking advice screen

This screen presents the user with information concerning the relevance of smoking to the management of the hypertensive patient. It also contains patient education material.

Two buttons are displayed, their labels and functions are as follows:-

'close', the system returns to the simulated patient record.

'print', the system prints out the patient education material to enable the patient to take relevant information home.

Exercise

This module contains one screen, the exercise advice screen.

Exercise advice screen

This screen presents the user with information concerning the relevance of exercise to the management of the hypertensive patient. It also contains patient education material, including local information about sports centres and clubs.

Two buttons are displayed, their labels and functions are as follows:-

'close', the system returns to the simulated patient record.

'print', the system prints out the patient education material to enable the patient to take relevant information home.

Hormone therapy

This module contains one screen, the hormone advice screen.

Hormone advice screen

This screen presents the user with a summary of the patients current hormone therapy.

The advice concerning the specific hormone therapy and its relevance to the management of hypertension is displayed along with patient education material.

Three buttons are displayed, their labels and functions are as follows:-

'close', the system returns to the simulated patient record.

'advice', the system displays advice based on the patients current hormone therapy as displayed on the GUI. This option enables the user to simulate different patient states and learn about their relevance to antihypertensive treatment. Data in the patient record is not effected by changes to data on this screen.

'print', the system prints out the patient education material to enable the patient to take relevant information home.

5.4.3.4 Initial Management Module

This module contains one screen, the initial management advice screen (fig 5.8).

Initial management advice screen

This screen presents a summary of data from the patient record, including the patients age, average blood pressure and the number of weeks their blood pressure has been monitored.

In a fully operational system the number of weeks the patients blood pressure has been monitored would be automatically calculated from the systems time clock and the patients average blood pressure would be calculated from data stored in the patient record, however in the prototype system, these facilities have not been fully implemented and the user is required to enter this data manually.

The screen also contains a large box for displaying text based advice, the box is labelled 'Advice'.

The source of the knowledge used to calculate the management advice is displayed to the user, in this case, WHO guidelines 1993.

Two buttons are displayed, their labels and functions are as follows:-

'close', the system returns to the simulated patient record.

'management advice', the system generates management advice based on the patient data displayed on the GUI. This enables the user to simulate different patient states and observe the effect on management advice. Data in the patient record are not effected by changes to data on this screen.

5.4.3.5 Cardiovascular Risk Module

This module contains one screen, the cardiovascular risk screen (fig 5.9).

Cardiovascular risk screen

This screen presents a summary of data from the patient record, including the patients age, sex, smoking history, total cholesterol, HDL cholesterol, blood pressure and concurrent problems. The smoking history is presented as a drop down list, with the patients smoking habit being displayed in the selection box which is visible at all times. The order of the items in the list is: non smoker, less than 10 per day, 10-20 per day, more than 20 per day. The list of concurrent problems is displayed in a scrolling list due to lack of space, however 20 of the 24 items are visible at all times. Those concurrent problems which are relevant to the patient are highlighted. The order of the items in the list is consistent with the drug treatment screen and is relatively in the same physical location.

The patient's ten year cardiovascular risk is automatically calculated and displayed when the user accesses the screen.

The source of the knowledge used to calculate the cardiovascular risk is displayed to the user, in this case Anderson (1991).

Two buttons are displayed, their labels and functions are as follows:-

'close', the system returns to the simulated patient record.

'calculate cv-risk', the system calculates a new cardiovascular risk based on the patient data displayed on the GUI. This enables the user to simulate different patient states and observe the effect on the patients ten year cardiovascular risk. Data in the patient record are not effected by changes to data on this screen.

5.4.3.6 Critique Module

This module has two screens, prescription critique screen (fig 5.10) and a references screen (fig 5.6).

Prescription critique screen

This screen presents a summary of data from the patient record, including the patients ethnic origin, age and concurrent problems, the layout and content is consistent with the drug treatment screen.

There is a drop down list labelled prescription, which contains the seven classes of antihypertensive drugs. The order of the drugs in the list is consistent with the order of the drugs in the drug treatment screen, e.g. beta blockers, diuretics, calcium antagonists, ace inhibitors, vasodilators, alpha blockers, centrally acting. From this list the user is required to select the medication they wish to have appraised. The drug they have selected appears in the selection box and is visible at all times.

The screen also contains two large boxes for displaying text based advice. They are labelled ' recommended because...', and 'use with caution because...'. These labels are consistent with the reasons screen.

Three buttons are displayed, their labels and functions are as follows:-

'close', the system returns to the drug advice screen.

'critique', the system determines which drug has been selected from the list of antihypertensive drugs, and what are the patients characteristics displayed on the GUI, before generating a list of reasons for and against prescribing the selected drug for the patient. The reasons and the references which support them, are then displayed on the GUI. This enables users to simulate different patient states, and choose different antihypertensive medications and observe the reasons for and against the prescription. Data in the patient record are not effected by changes on this screen.

'references', the system accesses a screen which contains the list of references supporting the advice in the systems knowledge base.

References screen

This screen presents a set of references used by the system to support its prescription critique advice. One button is displayed, its label and function is as follows:-

'close', the system returns to the prescription critique screen.

5.4.3.7 Interactions Module

This module has one screen, the interactions screen (fig 5.11).

Interactions screen

This screen presents the user with a summary of the patients concurrent medication. This is displayed as scrolling list which contains 39 drugs. 24 drugs are visible to the user at all times. The drugs are presented in alphabetical order. The drugs which refer to the patient are highlighted. The list contains the following drugs. Alcohol, anaesthetics, analgesic, anion-exchange resin, antacids, anti-arrhythmics, antibacterial, antidepressant, antidiabetics, antiepileptic, antihypertensive-vasodilator, antihypertensive-centrally acting, alpha blockers, ace inhibitors, antimalarial, antipsychotic, anxiolytics and hypnotics, beta blockers, calcium antagonist - diltiazem,

calcium antagonist - nifedipine, calcium antagonist - verapamil, calcium salts, cardiac glycosides, cholestyramine, cholinergics, corticosteriods, cyclosporin, diuretics, dopaminergic, ergotamine, lithium, muscle relaxant, nitrates, potassium salts, sex hormones, sympathominetics, theophylline, thyroxine, ulcer healing drugs, uricosurics, xamoterol.

There is a drop down list labelled prescription, which contains the seven classes of antihypertensive drugs. The order of the items in this list is consistent with the drug treatment screen, e.g. beta blockers, diuretics, calcium antagonists, ace inhibitors, vasodilators, alpha blockers, centrally acting. From this list the user is required to select which drug they want to check for interactions. The drug they have selected appears in the selection box and is visible at all times. The screen also contains two large boxes for displaying text based advice. They are labelled 'AVOID' and 'CAUTION'.

The source of the knowledge used to generate the drug interactions is displayed to the user, in this case the British National Formulary (1996).

Two buttons are displayed, their labels and functions are as follows:-

'close', the system returns to the simulated patient record.

'interaction', the system determines from the GUI, which antihypertensive drug has been selected and what are the patients concurrent medications, and generates 2 lists of drug interactions. One list for those interactions which should definitely by avoided, and one list for those interactions for which caution should be used. This enables the user to simulate different concurrent medications and antihypertensive drugs and observe the effect on possible interactions. Data in the patient record are not effected by changes to data on this screen.

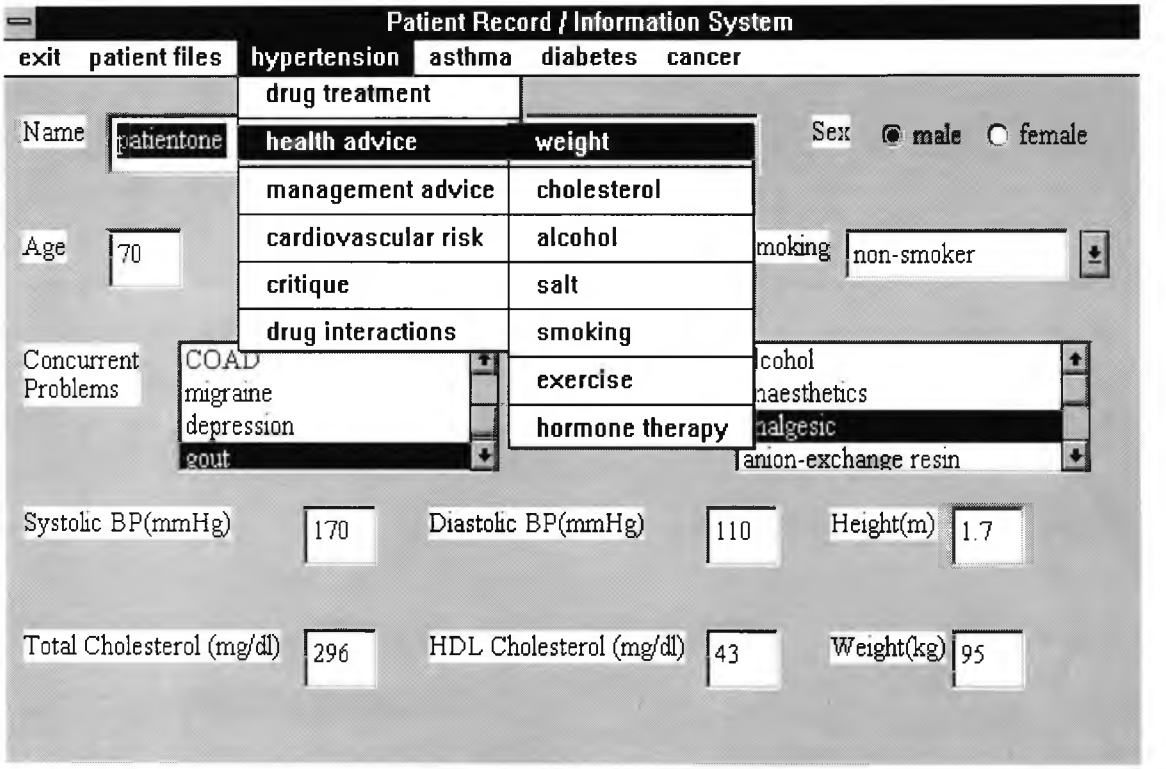

Figure 5.3 Simulated Patient Record

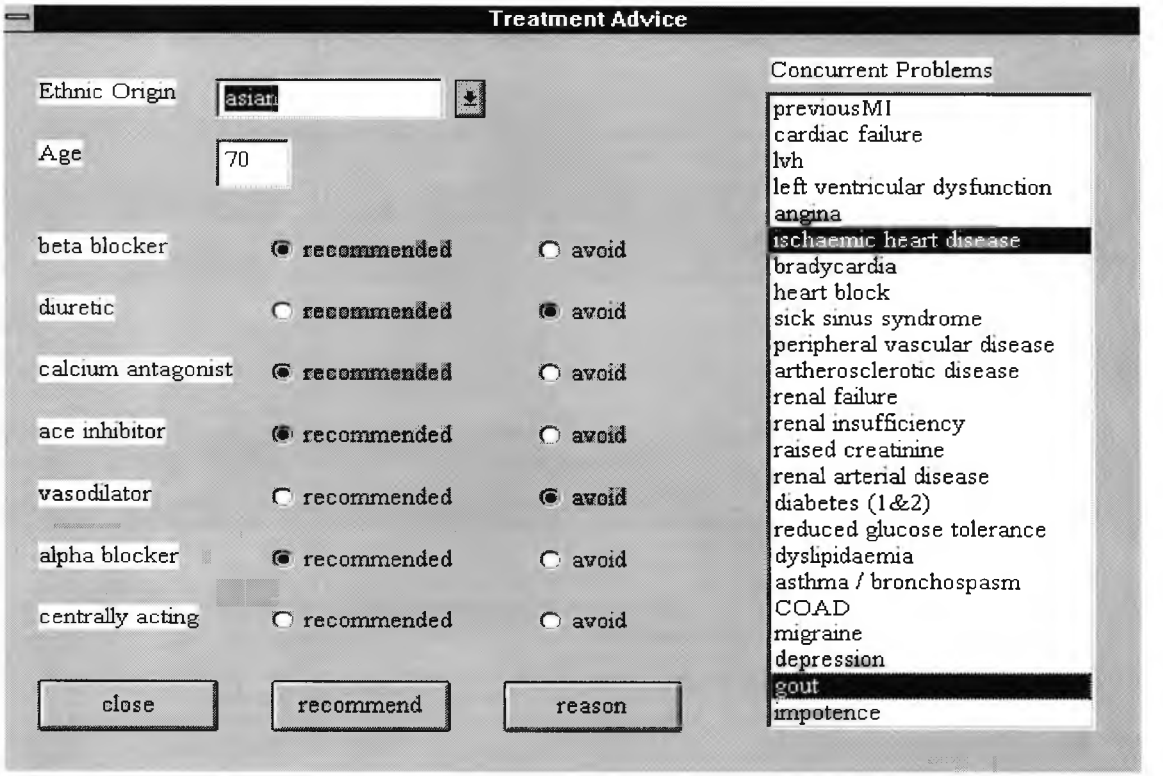

Figure 5.4 Drug Treatment Screen

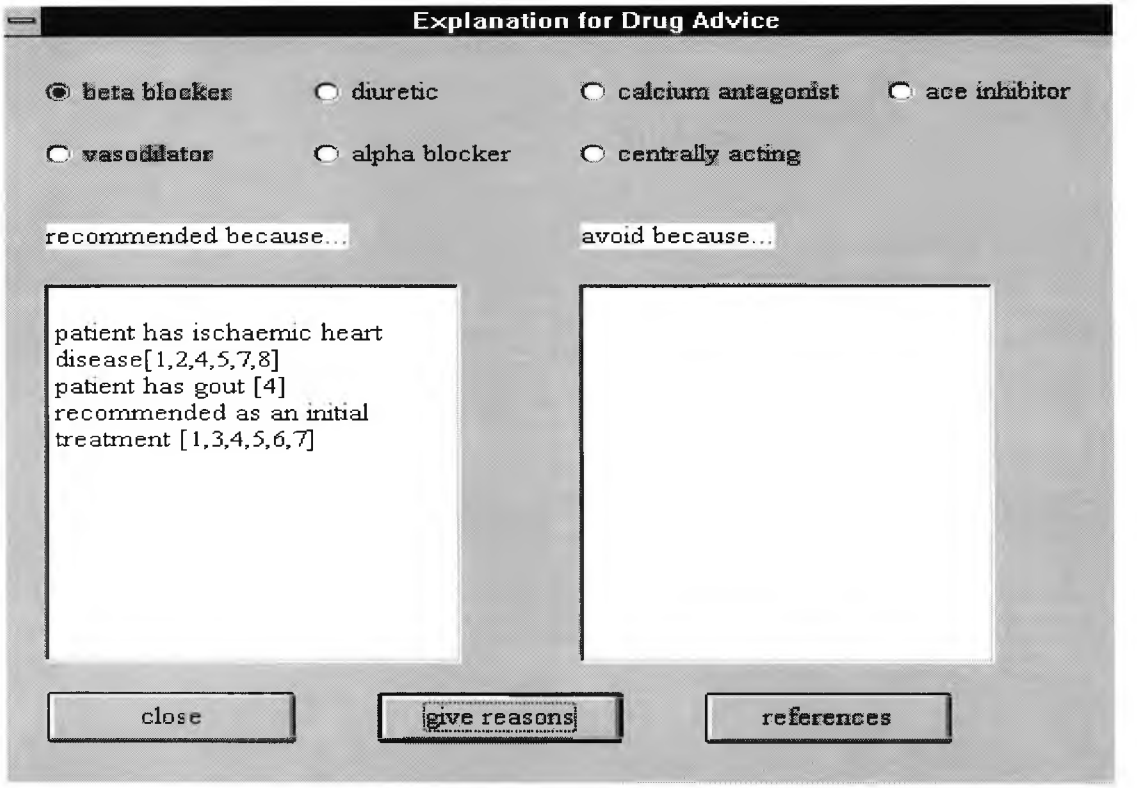

Figure 5.5 Reasons Screen

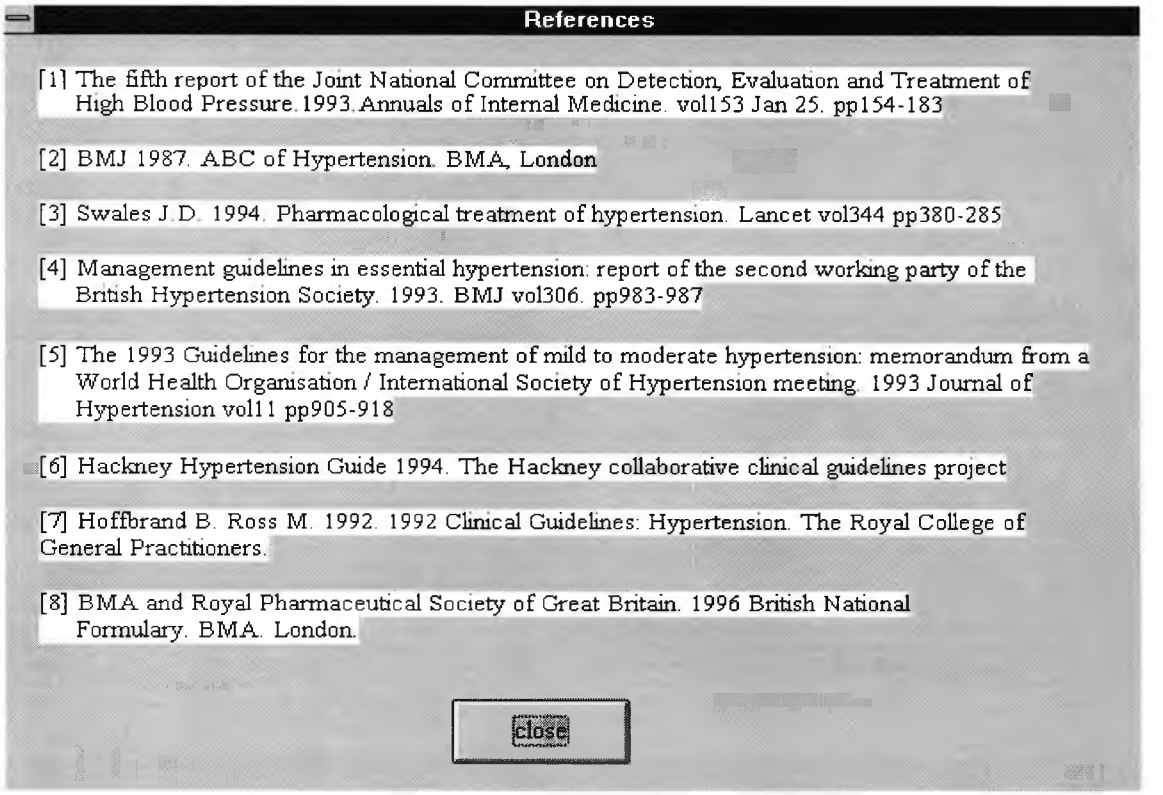

Figure 5.6 References Screen

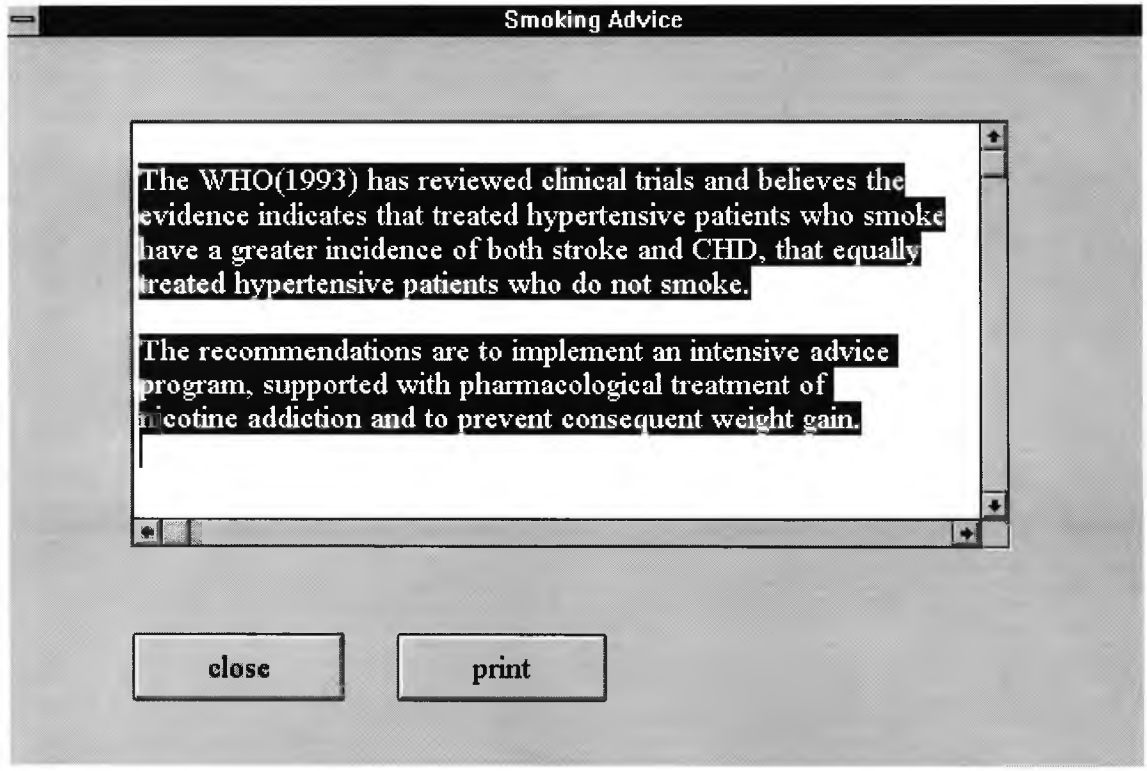

Figure 5.7 Health Advice - Smoking Screen

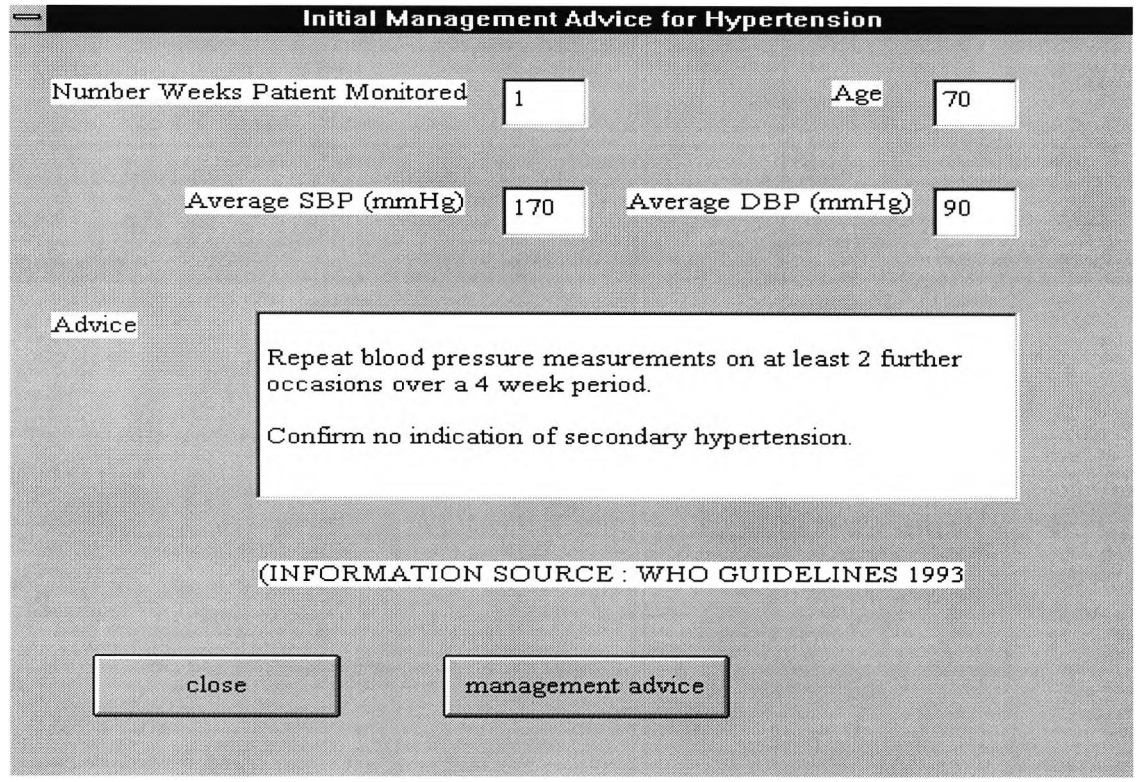

Figure 5.8 Management Screen

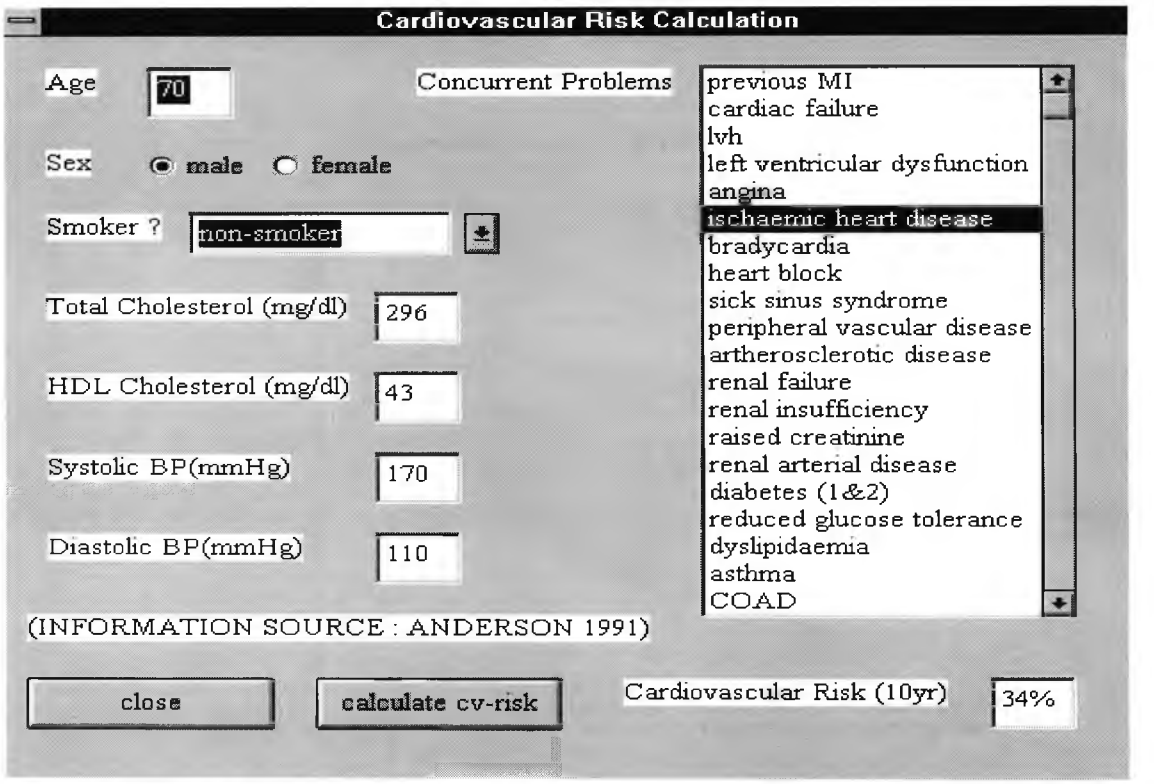

Figure 5.9 Cardiovascular Risk Screen

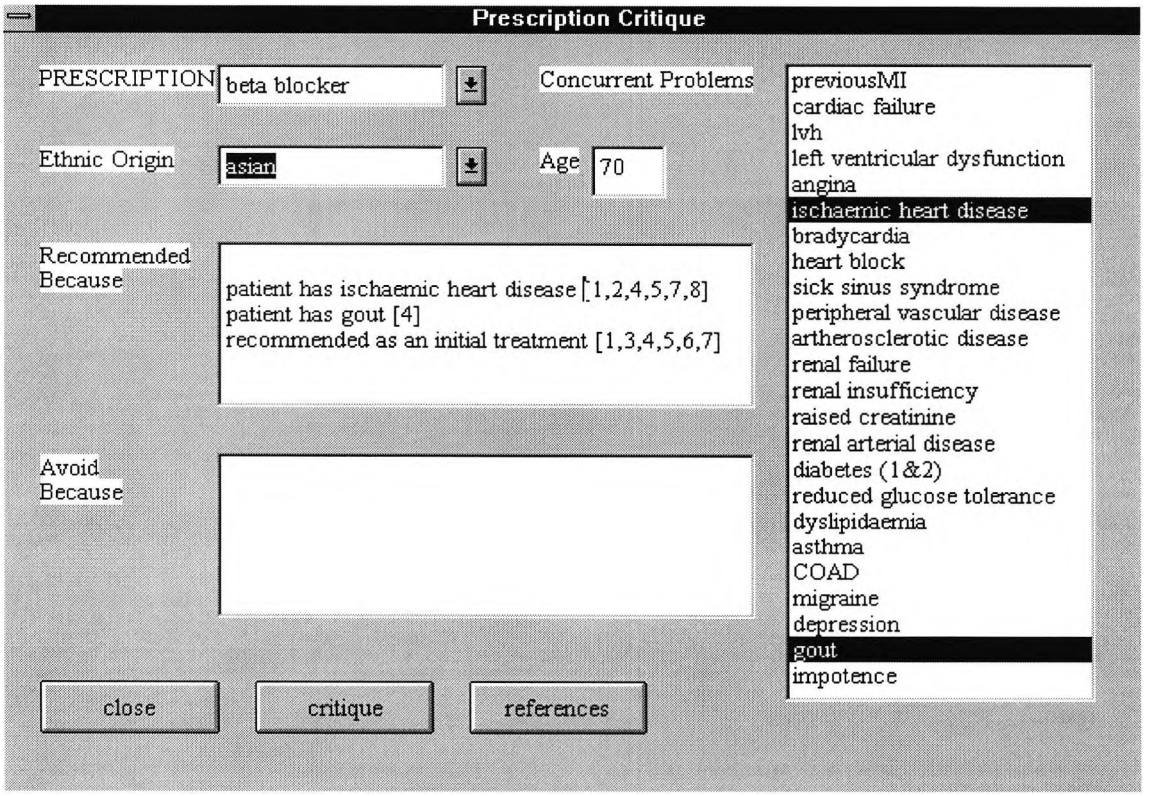

Figure 5.10 Prescription Critique Screen

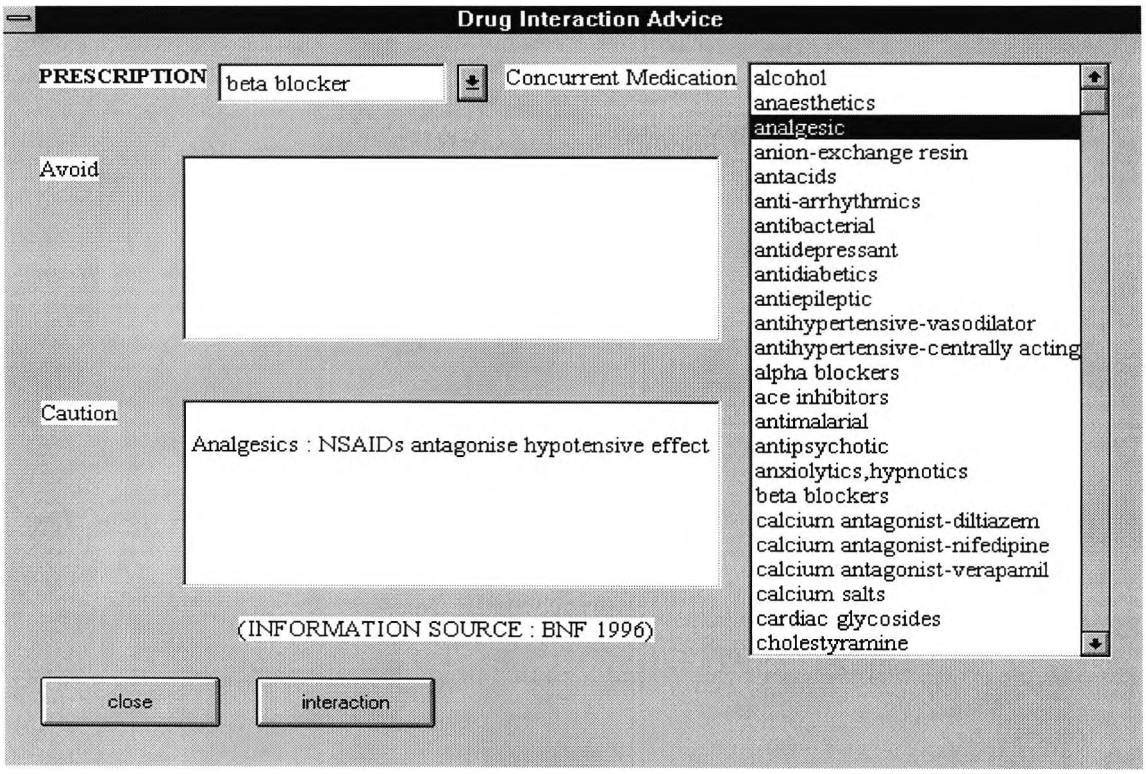

Figure 5.11 Interactions Screen

5.5 Summary

In this chapter the implementation of the embedded decision support system was presented. The reasons for choosing LPA-Prolog as the development language were outlined. The components of decision support systems including knowledge representation, representation of uncertainty, manipulating knowledge and explanation generation were presented, and the different techniques used to implement them were reviewed. The methods adopted in the development of the E.D.S. system were outlined and examples of source code were presented. The importance of interface design was discussed and the screen design and functionality of the E.D.S. system were described.

This chapter reported the development of a prototype decision support system that was built from the conceptual model described in chapter three and used the knowledge base described in chapter four. The next chapter reports the evaluation of the prototype system which provides evidence of the effectiveness of the procedures and processes used to develop the system.

6. Chapter Six : System Evaluation

6.1 Introduction

In chapter three the process and principles of evaluating new medical decision systems were discussed and the basis of the evaluation procedure was presented. In this chapter the aims and objectives of the evaluation of the prototype embedded decision support system will be identified and the evaluation criteria, measures and methodologies will be defined. This will provide the means for assessing whether the advice generated by the system is safe and appropriate; whether the format in which the advice is presented is acceptable to potential users and whether potential users will consider using the system in routine clinical practice. The results of the evaluation will be presented and the chapter ends with a summary of the key findings.

6.2 Aims and Objectives of the Evaluation

The aim of the evaluation is to demonstrate that the E.D.S. system is reliable, effective and easy to use.

The objectives of the evaluation are to:-

- Demonstrate that the different modules in the decision support system can generate consistent and reproducable advice for a range of different patient profiles.

- Demonstrate that the knowledge bases which support the different modules are sufficiently comprehensive to provide advice for a range of patient profiles.

- Demonstrate that the different modules in the decision support system generate advice which is considered medically safe and appropriate.

- Demonstrate that the format in which the advice is presented is acceptable to potential users and that will consider using the system in routine clinical practice.

To achieve these aims and objectives the evaluation was carried out in two parts. Firstly an evaluation of the safety and appropriateness of the advice was carried out, and secondly an evaluation of the usability of the system was conducted. The criteria and measures that were chosen to provide evidence are presented in the next section.

6.3 Evaluation Criteria and Measures

The specific criteria and measures, which are summarised in table 6.1, were chosen to reflect a view that medical decision support systems will not succeed unless they are wanted, usable in the clinical environment, and draw conclusions that seem reasonable to the user. This may seem obvious, but many systems have failed because they were too cumbersome to use, asked too many questions in an unintuitive order, took up more time than was available and produced answers which were clearly wrong but for which they had no explanation (Wyatt and Spiegelhalter, 1990; Wyatt, 1992). For a decision support system to be successful it must be acceptable to clinicians and hence its 'usability' is an important aspect for study and evaluation. This latter point is supported by Shortliffe and Perreault (1990) who comments that developers of medical computer systems have paid insufficient attention to the quality of the interface between users and computers.

Component of evaluation	**Criteria**	**Measures**
Safety	Reliable Sufficient Scope Safe Appropriate	1. The system produces consistent and reproducable results 2. The system produces advice for a wide range of different input data. 3. The system produces advice which is considered to be safe and appropriate when reviewed by medical experts.

Usability	Accessible Acceptable Effective	Accessible 1. The decision support system is convenient to access. Acceptable 1. Advice is generated quickly enough. 2. Advice is presented in a format which is easy to read. 3. Advice is presented using appropriate language. 4. Names of menu options self-explanatory. 5. Names of buttons / labels representing different functions are self-explanatory 6. When lists are used, items are in an appropriate order. 7. When lists are used, sufficient range of options available for current task. 8. Sufficient data summaries to enable user to understand current task. Effective 1. Decision support facilities are relevant to the doctors needs. 2. Medically sensible advice. 3. Advice supported by reasons. 4. Advice supported by references. 5. Users confidence in accuracy of advice. 6. User envisages incorporating decision support facilities into clinical practice.

Table 6.1 Evaluation Criteria and Measures

6.4 Methods of Safety Evaluation

This part of the evaluation was to provide evidence that the advice the system generated was reliable, safe and appropriate, and that the knowledge bases were of sufficient scope to deal with a wide range of different cases. This was achieved by obtaining a set of 23 cases which described a range of patient profiles and for which appropriate treatment and management options were specified. The details of the cases can be found in Appendix 1. Case providers included :-

- four general practitioners.
- Zeneca Pharmaceuticals medical information group
- The Hypertension Insight group, who are a specialist panel of medical experts interested in the field of hypertension.

Three of the E.D.S. systems modules have undergone a safety evaluation using the criteria, reliability, scope, safety and appropriateness.

- 22 cases were available to assess the treatment module.
- 16 cases were available to assess the cardiovascular risk module.
- 5 cases were available to assess the management module.

The case studies were entered into the prototype system and the advice the system generated was recorded. The system's advice was compared to the advice specified by the case provider. Finally the case studies and the systems advice, but not the advice specified by the provider, were reviewed by independent medical experts to obtain further opinion on whether the advice the system generates was considered to be safe and medically appropriate. The results are presented in section 6.5.1.

6.5 Method of Usability Evaluation

This part of the evaluation was to provide evidence that the system was easy to access, easy to use and effective. This was achieved by designing a structured interview (see Appendix 2) to assess users reactions to the prototype system. The system was installed on a laptop computer and demonstrated to four different general practitioners, with different levels of computing experience, from those working in fully computerised environments through to those who was just setting up computing facilities. In this way, although it was a small scale study, a range of user attitudes and experiences of computer technology were covered. The system was demonstrated to the practitioners in their normal working environment and they were given the opportunity to use the system themselves. During the interview the practitioners responses to the questions were noted. The demonstrations and interviews provided evidence on the systems design features, ease of use and acceptability. The results are presented in section 6.5.2.

6.6 Results of Safety Evaluation

6.6.1 Treatment Module

Twenty two cases were available to test the drug treatment module. The profiles of the 22 patients are shown in table 6.2, and cover a wide range of different patient states. The drug treatment advice generated by the system is shown in table 6.3. The drug treatment advice generated by the system was then compared to the advice from the case provider, see table 6.4. In the 7 cases where the case provider has specified contraindicated drugs, the system also specifies the drugs to be contraindicated. This is a 100% match. In 21 of the 22 cases there is agreement in a least one recommended drug between case provider and system. This is a 95% match. In 17 of the 22 cases, all the drugs which the case provider state as recommended also appear in the systems list of recommended drugs. This is a 77% total match. In 4 cases, at least one of the drugs which the case provider state as recommended also appear in the systems list of recommended drugs. This is a 18% partial match. In one case, none of the drugs in the case provider list appears in the

systems list of recommended drugs. This is a 1% failure. In the cases where the system failed to match the opinion of the case provider, this was due to recommending ace inhibitors and calcium antagonists and in one case an alpha blocker as a suitable first line therapy. The system currently does not recommend these agents unless specifically indicated. This is based on evidence from the literature which suggests that while calcium antagonists, ace inhibitors and alpha blockers are effective at reducing blood pressure, they have not been used in long term controlled trials to demonstrate their efficacy in reducing morbidity and mortality. Therefore it is suggested that these drugs should be used where specifically indicated (e.g. use of ace inhibitors when the patient suffers from diabetes, as there is evidence to suggest that this drug protect renal function), or when diuretics and beta blockers have proved unacceptable or ineffective (Hoffbrand and Ross, 1992; Guidelines Sub-Committe of the WHO/ISH Mild Hypertension Liason Committee, 1993; Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure, 1993; Sever et al. 1993; Swales, 1994).

The drug treatment advice generated by the system was reviewed by two medical experts. In each of the 22 cases reviewed, the advice was considered to be safe, acceptable and useful. However the following comments were made.

- The system includes the group of drugs vasodilators and centrally acting drugs. In one doctor's opinion, these drugs would not be used as first line treatments or monotherapy for the treatment of hypertension, but as an adjuvant treatment in resistant hypertension under specialist guidance. Therefore the relevance of including these two groups of drugs in a decision support system for use by general practitioners is questioned.

- The level of blood pressure on which the decision to initiate drug treatment is made, influences one doctor's choice of antihypertensive medication. For example, in one doctor's experience thiazide diuretics are a good first choice in mild hypertension, however they are likely to be less effective as monotherapy if the initial blood pressure is very high.

- One doctor considered beta blockers should be used with caution in the elderly.

- One doctor considered that ace inhibitors and calcium antagonists can be used without caution in the elderly.

- One doctor considered that beta blockers and diuretics are not absolutely but relatively contraindicated in the presence of diabetes. The system suggests that both these groups of drugs should be avoided if the patient has diabetes.

- One doctor considered that ace inhibitors and calcium antagonists are appropriate first line treatments in uncomplicated hypertension.

- One doctor considered that ace inhibitors are the drug of choice if the patient suffers from either left ventricular hypertrophy or hypertrophic cardiomyopathy.

Category	**Ranges**	**Number of Cases**
sex	male	16
	female	6
ethnic origin	Afro-Caribbean	1
	Asian	2
	White	19
age	less than 40	1
	40-44	2
	45-49	1
	50-54	4
	55-59	5
	60-64	1
	65-69	1
	70-74	1
	75-79	4
	80 or greater	2
no. of concurrent problems	0	3

	1	8
	2	5
	3	4
	4	0
	5	2
concurrent problems	dyslipidaemia	10
	diabetes	5
	peripheral vascular disease	3
	gout	2
	cardiac failure	2
	artherosclerotic arterial disease	2
	impotence	2
	atrial fibrillation	2
	left ventricular hypertrophy	2
	angina	2
	raised creatinine	2
	carpal tunnel syndrome	1
	cerebro vascular accident	1
	depression	1
	bronchospasm	1
	COAD	1

Table 6.2 Profile of the 22 Patients Used to Test the Drug Treatment Module

Case Identifier	Recommended Drugs and Reasons from the System	Contraindicated Drugs and Reasons from the System
1	beta blocker, because gout [4] and initial treatment [1,3,4,5,6,7]. calcium antagonist, because gout [4] but caution as elderly are less tolerant [6]. ace inhibitor because gout [4] but caution as elderly are less tolerant [6,8]. alpha blocker because gout [4].	diuretic because gout [1,2,4,6,7,8].
2	ace inhibitor because diabetes [1,2,3,4,5,7] and peripheral vascular disease, but care due to an association with renal artery stenosis [2,4,7,8]. calcium antagonist because diabetes (but evidence is contradictory) [2,4,7] and peripheral vascular disease [2,4,8]. alpha blocker because diabetes [2,4,5,7] and peripheral vascular disease [2,4]. centrally acting because	beta blocker because diabetes [1,2,4,5,6,7,8] and peripheral vascular disease [1,2,4,5,6,7,8]. diuretic because diabetes [1,2,4,5,6,7,8]. vasodilator because diazoxide is diabetogenic and should be avoided in patients with diabetes [8].

	diabetes [2] and peripheral vascular disease [2].	
3	ace inhibitor because diabetes [1,2,3,4,5,7]. calcium antagonist because diabetes, but evidence contradictory [2,4,7]. alpha blocker because diabetes [2,4,5,7]. centrally acting because diabetes [2].	beta blocker because diabetes [1,2,4,5,6,7,8]. diuretic because diabetes [1,2,4,5,6,7,8]. vasodilator, because diazoxide is diabetogenic and should be avoided in patients with diabetes [8].
4	beta blocker because younger patient [1,2,3] and initial treatment [1,3,4,5,6,7]. diuretic because initial treatment [1,3,4,5,6,7]. calcium antagonist because atherosclerotic arterial disease [5].	none
5	beta blocker because younger patient [1,2,3] and initial treatment [1,3,4,5,6,7]. diuretic because initial treatment [1,3,4,5,6,7].	none

6	calcium antagonist, because impotence [2], but use with caution as elderly are less tolerant [6]. ace inhibitor because impotence [2], but use with caution as elderly are less tolerant [6,8].	beta blocker because impotence [2,4,7]. diuretic because impotence [2,4,5,7,8]. centrally acting because impotence [2].
7	beta blocker because younger patient [1,2,3] and initial treatment [1,3,4,5,6,7]. diuretic because initial treatment [1,3,4,5,6,7].	none.
8	beta blocker because younger patient [1,2,3] and initial treatment [1,3,4,5,6,7]. diuretic because initial treatment [1,3,4,5,6,7].	none.
9	beta blocker because younger patient [1,2,3]; initial treatment [1,3,4,5,6,7]. diuretic because initial treatment [1,3,4,5,6,7].	none.
10	beta blocker because younger patient [1,2,3] and initial treatment [1,3,4,5,6,7].	none.

	diuretic because initial treatment [1,3,4,5,6,7].	
11	beta blocker because younger patient [1,2,3] and initial treatment [1,3,4,5,6,7]. diuretic because initial treatment [1,3,4,5,6,7].	none.
12	diuretic because cardiac failure [1,2,4,7] and elderly patient [1,2,3,7] and initial treatment [1,3,4,5,6,7]. ace inhibitor because cardiac failure [1,2,4,5,7,8], but caution as elderly are less tolerant [6,8]. alpha blocker because cardiac failure [2,4]. centrally acting because cardiac failure [2,8].	beta blocker because cardiac failure [1,2,3,4,5,6,7,8]. calcium antagonist because cardiac failure [1,2,4,5,8] and elderly are less tolerant [6]. vasodilator because left ventricular hypertrophy [1].
13	calcium antagonist because black patient [1,6] and impotence [2] and dyslipidaemia [1,4,7] and depression [2]. alpha blocker because dyslipidaemia [1,4,5,7].	beta blocker because depression [2] and dyslipidaemia [1,4,5,6,7] and impotence [2,4,7] and less effective as monotherapy in blacks [1,3,6]. diuretic because dyslipidaemia [1,4,6,7,8] and impotence [2,4,5,7,8].

		ace inhibitor because less effective as monotherapy in blacks [1,3,6]. centrally acting because depression [1,2] and impotence [2].
14	ace inhibitor because bronchospasm [2,4] and gout [4]. calcium antagonist because bronchospasm [1,2,4,7] and gout [4]. alpha blocker because bronchospasm [2,4] and gout [4]. centrally acting because bronchospasm [1,2,8].	beta blocker because bronchospasm [1,2,4,5,6,7,8]. diuretic because gout [1,2,4,6,7,8].
15	ace inhibitor because diabetes [1,2,3,4,5,7]. calcium antagonist because diabetes, but evidence is contradictory [2,4,7]. alpha blocker because diabetes [2,4,5,7]. centrally acting because diabetes [2].	beta blocker because diabetes [1,2,4,5,6,7,8]. diuretic because diabetes [1,2,4,5,6,7,8]. vasodilator because the vasodilator, diazoxide, is diabetogenic and should be avoided in patients with diabetes [8].

16	diuretic because COAD [1,2,4] and elderly [1,2,3,7] and initial treatment [1,3,4,5,6,7]. ace inhibitor because COAD [1,2,4], but caution as elderly are less tolerant [6,8]. calcium antagonist because COAD [1,2,4,7], but caution as elderly are less tolerant [6]. alpha blocker because COAD [1,2,4]. centrally acting because COAD [1,2,8].	beta blocker because COAD [1,2,4,5,6,7,8].
18	beta blocker because angina [1,2,4,5,7,8] and younger patient [1,2,3] and initial treatment [1,3,4,5,6,7] calcium antagonist because angina [1,2,4,7,8]. diuretic because angina [4] and initial treatment [1,3,4,5,6,7] ace inhibitor because angina [4]. alpha blocker because angina [4].	vasodilator because angina [1].

19	calcium antagonist because angina [1,2,4,7,8] and raised creatinine [2] and diabetes, but evidence contradictory [2,4,7] and peripheral vascular disease [2,4,8] and dyslipidaemia [1,4,7] but caution as elderly less tolerant [6]. alpha blocker because angina [4] and raised creatinine [2] and diabetes [2,4,5,7] and peripheral vascular disease [2,4] and dyslipidaemia [1,4,5,7]. centrally acting because raised creatinine [2] and diabetes [2] and peripheral vascular disease [2].	beta blocker because peripheral vascular disease [1,2,4,5,6,7,8] and diabetes [1,2,4,5,6,7,8] and dyslipidaemia [1,4,5,6,7]. diuretic because raised creatinine [2,8] and diabetes [1,2,4,5,6,7,8] and dyslipidaemia [1,4,6,7,8]. ace inhibitor because raised creatinine [1,2,7,8] and peripheral vascular disease due to association with renal artery stenosis [2,4,7,8] and caution as elderly are less tolerant [6,8]. vasodilator because angina [1] and the vasodilator, diazoxide is diabetogenic and should be avoided in patients with diabetes [8].
20	beta blocker because younger patient [1,2,3] and initial treatment [1,3,4,5,6,7]. diuretic because initial treatment [1,3,4,5,6,7].	vasodilator because left ventricular hypertrophy [1].
21	calcium antagonist because diabetes [2,4,7] and raised creatinine [2] and dyslipidaemia [1,4,7] and peripheral vascular disease [2,4,8] and atherosclerotic arterial	ace inhibitor because raised creatinine [1,2,7,8] and peripheral vascular disease due to an association with renal artery stenosis [2,4,7,8]. beta blocker because diabetes

	disease [5]. alpha blocker because diabetes [2,4,5,7] and raised creatinine [2] and dyslipidaemia [1,4,5,7] and peripheral vascular disease [2,4]. centrally acting because diabetes [2] and raised creatinine [2] and peripheral vascular disease [2].	[1,2,4,5,6,7,8] and dyslipidaemia [1,4,5,6,7] and peripheral vascular disease [1,2,4,5,6,7,8]. diuretic because diabetes [1,2,4,5,6,7,8] and dyslipidaemia [1,4,6,7,8] and raised creatinine [2,8]. vasodilator because diazoxide is diabetogenic and should be avoided in patients with diabetes [8].
22	calcium antagonist because diabetes (evidence contradictory) [2,4,7] and atherosclerotic arterial disease [5] but caution as elderly less tolerant [6]. ace inhibitor because diabetes [1,2,3,4,5,7] but caution as elderly less tolerant [6,8]. alpha blocker because diabetes [2,4,5,7]. centrally acting because diabetes [2].	beta blocker because diabetes [1,2,4,5,6,7,8]. diuretic because diabetes [1,2,4,5,6,7,8]. vasodilator because diazoxide is diabetogenic and should be avoided in patients with diabetes [8].
23	ace inhibitor because cardiac failure [1,2,4,5,7,8] and caution as elderly are less tolerant [6,8].	beta blocker because cardiac failure [1,2,3,4,5,6,7,8].

	diuretic because cardiac failure [1,2,4,7] and elderly patient [1,2,3,7] and initial treatment [1,3,4,5,6,7]. alpha blocker because cardiac failure [2,4]. centrally acting because cardiac failure [2,8].	calcium antagonist because cardiac failure [1,2,4,5,8] and caution as elderly are less tolerant [6].

Table 6.3 Results From the Drug Treatment Module

Case Identifier	Recommended Drugs from the Case Provider	Recommended Drugs from the System	Contra-indicated Drugs from the Case Provider	Contra-indicated Drugs from the System
1	**beta blocker**	**beta blocker** c-antagonist ace inhibitor alpha blocker	**diuretic**	**diuretic**
2	**ace inhibitor**	**ace inhibitor** c-antagonist alpha blocker centrally acting	**beta blocker**	**beta blocker** diuretic vasodilator
3	**ace inhibitor**	**ace inhibitor** c-antagonist alpha blocker centrally acting	none	beta blocker diuretic vasodilator

4	**beta blocker** ace inhibitor	**beta blocker** diuretic c-antagonist	none	none
5	**diuretic**	**diuretic** beta blocker	none	none
6	**c-antagonist** **ace inhibitor**	**c-antagonist** **ace inhibitor**	none	beta blocker diuretic centrally acting
7	**beta blocker** ace inhibitor	**beta blocker** diuretic	none	none
8	**beta blocker** **diuretic**	**beta blocker** **diuretic**	none	none
9	**beta blocker** **diuretic**	**beta blocker** **diuretic**	none	none
10	**diuretic** c-antagonist ace inhibitor	**diuretic** beta blocker	none	none
11	c-antagonist ace inhibitor alpha blocker	beta blocker diuretic	none	none
12	**diuretic** **ace inhibitor**	**diuretic** **ace inhibitor** alpha blocker centrally acting	none	beta blocker c-antagonist vasodilator

13	**c-antagonist** **alpha blocker**	**c-antagonist** **alpha blocker**	**diuretic**	**diuretic** beta blocker ace inhibitor centrally acting
14	**ace inhibitor** **c-antagonist** **alpha blocker**	**ace inhibitor** **c-antagonist** **alpha blocker** centrally acting	**beta blocker** **diuretic**	**beta blocker** **diuretic**
15	**ace inhibitor** **c-antagonist** **alpha blocker**	**ace inhibitor** **c-antagonist** **alpha blocker** centrally acting	none	beta blocker diuretic vasodilator
16	**diuretic** **ace inhibitor** **c-antagonist**	**diuretic** **ace inhibitor** **c-antagonist** alpha blocker centrally acting	**beta blocker**	**beta blocker**
18	**beta blocker** **c-antagonist**	**beta blocker** **c-antagonist** diuretic ace inhibitor alpha blocker	none	vasodilator
19	**c-antagonist**	**c-antagonist** alpha blocker centrally acting	**beta blocker**	**beta blocker** diuretic ace inhibitor vasodilator
20	**beta blocker** **diuretic**	**beta blocker** **diuretic**	none	vasodilator

	ace inhibitor c-antagonist			
21	**c-antagonist**	**c-antagonist** vasodilator alpha blocker centrally acting	**ace inhibitor**	**ace inhibitor** beta blocker diuretic vasodilator
22	**c-antagonist**	**c-antagonist** ace inhibitor alpha blocker centrally acting	none	beta blocker diuretic vasodilator
23	**ace inhibitor** **diuretic**	**ace inhibitor** **diuretic** alpha blocker centrally acting	none	beta blocker c-antagonist

Table 6.4 Comparison of Drug Treatment Advice Between System and Expert

(note : agreement between the treatment advice specified by the system and that of the medical expert is highlighted in bold type; c-antagonist is an abbreviation of calcium antagonist)

6.6.2 Cardiovascular Risk Module

16 cases were defined and an appropriate cardiovascular risk assessment was made by the case provider. In none of the 16 cases was the HDL cholesterol level available, and so this was set at 45 mg/dl or 1.125 mmol/l which was within the normal range as specified by the American Heart Association from which the cardiovascular risk equation was taken. The profiles of the 16 patients are shown in table 6.5, and cover a wide range of different patient states. The cardiovascular risk generated by the E.D.S. system was compared to the advice from the case provider. To overcome inter-expert variability when assessing cardiovascular risk, each of the 16 cases (but not the original

experts opinions or the systems calculation of cardiovascular risk) were then reviewed by an independent medical expert, who gave a cardiovascular risk assessment for each case. See table 6.6. In all 16 cases there was a close match between the 2 experts. In 15 out of the 16 cases there was a close match between both experts and the E.D.S. system. In 15 out of the 16 cases analysed, there was a reasonable match between system and both the medical experts who specified the case and the independent medical expert. In case number 6, where a close match was not made, discussion with medical experts led to the conclusions that this was due to the fact that the patient was elderly and the medical experts placed less weight on this as a risk factor in the development of cardiovascular disease, than the system. The case profiles and the systems cardiovascular risk assessment was then reviewed by an independent medical expert. In each of the cases the systems risk assessment was considered to be safe, appropriate and useful.

Category	**Ranges**	**Number of Cases**
sex	male	12
	female	4
age	less than 40	2
	40-44	2
	45-49	0
	50-54	3
	55-59	3
	60-64	1
	65-69	1
	70-74	1
	75-79	2
	80 or greater	1
smoking	non smoker	11
	ex smoker	2
	smoker	3
no. of concurrent problems	0	5
	1	6

	2	2
	3	0
	4	1
	5	2
concurrent problems	dyslipidaemia	2
	diabetes	5
	peripheral vascular disease	2
	gout	1
	artherosclerotic arterial disease	3
	impotence	1
	atrial fibrillation	2
	left ventricular hypertrophy	2
	angina	2
	raised creatinine	2
	cerebro vascular accident	1
	transient ischaemic attack	1
Total Cholesterol (mmol/l)	4.0 - 4.4	1
	4.5 - 4.9	1
	5.0 - 5.4	2
	5.5 - 5.9	2
	6.0 - 6.4	3
	6.5 - 6.9	0
	7.0 - 7.4	3
	7.5 - 7.9	2
	8.0 - 8.4	1
	8.5 - 8.9	0
	9.0 or greater	1
Systolic blood pressure (mmHg)	150 - 154	2
	155 - 159	0

	160 - 164	6
	165 - 169	1
	170 - 174	1
	175 - 179	1
	180 - 184	2
	185 - 189	0
	190 or greater	3

Table 6.5 Profile of the 16 Patients Used to Test the Cardiovascular Risk Module

Case Identifier	Cardiovascular Risk Assessment from System (%)	Cardiovascular Risk Assessment from Case Provider	Cardiovascular Risk Assessment from Independent Medical Expert
17	3	low	low
10	4	medium	medium
7	6	medium	medium
9	7	medium	medium
3	10	medium	medium-high
20	15	medium	medium
5	17	medium-low	medium
4	21	medium-high	high
8	21	high	medium-high
22	32	high	high
18	32	high	high
2	32	high	high
1	34	high	high
6	35	medium	medium
19	47	high	high
21	52	high	high

Table 6.6 Comparison of System, Case Provider and Independent Experts Cardiovascular Risk Assessment

6.6.3 Management Module

Five cases were defined and an appropriate management decisions at zero weeks, when a raised blood pressure is first noted; four, sixteen and thirty weeks were specified by the case provider. The advice generated by the E.D.S. system is shown in table 6.7. The advice the system generated was then compared to the advice from the case provider, see table 6.8. In three of the five cases there was a close match between the stages of management specified by the system and that specified by the expert. Two of the cases were outside the range of the E.D.S. system, because the blood pressure was too high to be within WHO guidelines for the initial management of essential hypertension, in these cases the system provided a message to the user, reporting the fact that the case was outside the range of the expert system, and specialist advice should be sort. A greater number of cases would be required to fully assess this module. This module was not subjected to independent review due to the small number of cases.

Case Identifier	**week 0**	**week 4**	**week 16**	**week 30**
1	refer to specialist , outside range of expert system.	refer to specialist , outside range of expert system.	institute drug treatment.	institute drug treatment.
2	repeat blood pressure on at least 2 further occasions over a 4 week period. confirm no evidence of secondary hypertension.	non drug treatment. monitor over 3 months.	institute drug treatment.	end of initial management, drug treatment already started.

3	repeat blood pressure on at least 2 further occasions over a 4 week period. confirm no evidence of secondary hypertension.	non drug treatment. monitor over 3 months.	reinforce non drug treatment and consider drug treatment based on cardiovascular risk.	consider drug treatment based on cardiovascular risk.
4	refer to specialist outside range of expert system.	refer to specialist outside range of expert system.	refer to specialist outside range of expert system.	institute drug treatment.
5	repeat blood pressure measurement in 3-5 years.	institute non drug treatment, monitor blood pressure over a 3 month period.	reinforce non drug treatment. consider drug treatment based on cardiovascular risk.	institute drug treatment.

Table 6.7 Results From the Management Module

Case Identifier	Source of Advice	week 0	week 4	week 16	week 30
1	system	refer to specialist , outside range of expert system.	refer to specialist , outside range of expert system.	institute drug treatment.	institute drug treatment.
1	medical expert	review and check lipids and renal function.	review and ECG.	review.	start drug treatment.
2	system	repeat blood pressure on at least 2 further occasions over 4 week period. Confirm no evidence of secondary hypertension.	non drug treatment. monitor over 3 months.	institute drug treatment.	end of initial manage-ment, drug treatment already started.
2	medical expert	review.	non drug treatment advised.	review.	start drug treatment.
3	system	repeat blood pressure on at least 2 further occasions over	non drug treatment. monitor over 3 months.	reinforce non drug treatment and consider drug treatment	consider drug treatment based on

		a 4 week period. confirm no evidence of secondary hypertension.		based on cardiovascular risk.	cardio-vascular risk.
3	medical expert	review and cholesterol and urea and electrolytes.	review and non drug management.	fundus screening; chiropody; ECG; diabetic check; refer dietician.	start drug treatment.
4	system	refer to specialist outside range of expert system.	refer to specialist outside range of expert system.	refer to specialist outside range of expert system.	institute drug treatment.
4	medical expert	review 1-2 weeks.	non drug treatment and general advice.	prepare patient for the need for long term treatment.	start drug treatment.
5	system	repeat blood pressure measurement in 3-5 years.	institute non drug treatment, monitor blood pressure over	reinforce non drug treatment. consider drug treatment based on	institute drug treatment.

			a 3 month period.	cardiovascular risk.	
5	medical expert	nil.	review.	review.	start drug treatment.

Table 6.8 Comparison of Systems and Medical Experts Management Advice

6.7 Results of the Usability Evaluation

The results of the structured interview and the users responses are presented in terms of their contribution to each of the following categories, accessibility, acceptability and effectiveness. Overall the doctors who took part in the evaluation considered the system to be easy to use; the advice that the system generated was considered to be useful and the way in which the advice was presented was considered to be acceptable. All the doctors would envisage using the system if it was incorporated into their existing clinical information system.

6.7.1 Criterion One : Accessible

6.7.1.1 The decision support system is convenient to access

All the doctors liked the idea of accessing a decision support system from a menu bar in their existing clinical information system. They particularly liked the idea of having an additional feature in their normal working environment rather than a new environment. Other comments included; decision support would be convenient and readily available; their would be minimum fuss and hassle to find the information and advice required. One doctor commented that a normal consultation was 7-10 minutes, any decision support used during this time would have to be very quick and easy to access, and as the computer was already switched on and being used to access the patient record, decision support accessed via a menu in this environment would be convenient.

6.7.2 Criterion Two : Acceptable

6.7.2.1 Advice is Generated Quickly Enough

All the doctors considered the advice was generated quickly enough to be useful in routine clinical practice.

6.7.2.2 Advice is Presented in an Easy to Read Format

Overall all the doctors considered the advice was presented in a clear and easy to read format. A specific example from the drug treatment module illustrates this:- all the doctors considered it was obvious which drugs had been recommended and contraindicated. One doctor particularly liked the idea of two lists, to enable representation of the idea that while a drug may not be explicitly contraindicated, it may not be specifically recommended either. This feature was considered to be of considerable benefit in that it drew the users attention to potential problems.

6.7.2.3 Advice is Presented using Appropriate Language

Overall all the doctors considered the advice was clear and understandable, and was presented using appropriate language. All medical terminology was considered to have been used correctly. This is an important feature as language is crucial component of effective communication.

6.7.2.4 Names of Menu Options Self-Explanatory

The doctors were asked to look at the entry point to the hypertension decision support system - the hypertension menu - which consists of a list of six items, each representing a decision support facility. The doctors were asked to describe the functions of each module, before they were demonstrated. This was to assess whether the names of the

functions were self-explanatory and to demonstrate the value of effective language. The results are shown in table 6.9.

Names of Menu Options Describing Decision Support Modules	**Number of Doctors (total = 4) Who Correctly Described the Functions of the Decision Support Modules from their Labels**
Drug Treatment	4
Health Advice	3
Management Advice	2
Cardiovascular Risk	4
Critique	3
Drug Interactions	4

Table 6.9 Doctors Opinions on Whether Menu Options Were Self Explanatory

Each module was demonstrated and the doctors were then asked to make suggestions for what they considered to be more appropriate labels to describe the functions of the decision support facilities. The results are presented in table 10. These results demonstrate that doctors use of language is not wholly consistent and that there is a continuing need for the profession to use consistent language.

Current Label Describing Decision Support Module	**Suggestions for Alternative Labels**
Drug Treatment	none
Health Advice	Patient Education Lifestyle Advice
Management Advice	Decision to Treat ? When to Start ? When to Treat ? Treat ? Initiation

Cardiovascular Risk	none
Critique	Drug Appraisal Cautions / Contraindications Drug Contraindications
Drug Interactions	Concurrent Medication

Table 6.10 Doctors Suggestions for Names of Menu Options

6.7.2.5 Labels Representing Different Functions are Self-Explanatory

Overall the doctors considered it was obvious how to use the system which was facilitated by the self-explanatory nature of the screen design. This response is a mark of significant achievement, as it demonstrates that the design has correctly identified the doctors working practice and shows how decision support systems can be blended into that practice. Specific comments to improve the explicit nature of the screens are listed below, but all reflect the doctors sensitivity to the use of language.

- One doctor would change the word 'recommended' on the drug treatment screen to 'suitable' or 'consider'.

- Two doctors suggested changing the name of the button 'calculate' on the cardiovascular risk screen to 'recalculate' to more accurately reflect the function of this button.

- One doctor suggested changing the units that cholesterol and HDL cholesterol were recorded in on the cardiovascular risk screen from mg/dl to mmol/l as doctors were more familiar with the latter units.

- One doctor suggested changing the label 'cardiovascular risk (10 year)' on the cardiovascular risk screen to 'Chances of having a heart attack or a stroke in the next 10 years', as this would make what the cardiovascular risk represented more explicit.

6.7.2.6 Appropriate Order to Items in Lists

The system uses 3 main lists, the list of decision support facilities in the main hypertension decision support system menu; the list of possible drug treatments for hypertension in the drug treatment module; and the list of concurrent problems in the drug treatment module and in the critique module.

All the doctors considered the order of the items in the main hypertension decision support system menu was important, and all expressed a preference for a chronological order, in terms of decisions they would make when managing a patient with essential hypertension.

Two doctors suggested the same chronological order:

cardiovascular risk
health advice
management advice
drug treatment
critique
drug interactions.

One doctor suggested an appropriate chronological order to be:

management advice
drug treatment
interactions
critique
cardiovascular risk
health advice

The health advice option, currently contains a submenu, and all three doctors preferred to have the items in the health advice list as a submenu and would not want it to be incorporated into the main list. Two doctors considered that the order of the items in the

health advice list was acceptable and would not be changed. One doctor expressed a preference for putting the items in order of importance and suggested :-

smoking
alcohol
cholesterol
exercise
weight
hormone therapy
salt.

All three doctors did not consider the order of the drugs displayed in the drug treatment module to be important, and all considered the current order of drugs to be acceptable. Two of the doctors considered that the order of the drugs conveyed priority, first drug in the list has the greatest priority, the last drug has the least priority. One doctor assumed the list of drugs to be in a random order. When asked whether the doctors would change the order of the drugs in the display, one doctor would not change the order; Two doctors suggested putting the drugs in the order of most commonly prescribed, the most commonly prescribed drug at the top of the list, and the least commonly prescribed at the bottom. However, two different orders were suggested:

suggested order one : diuretic
beta blocker
calcium antagonist
ace inhibitor
alpha blocker
vasodilator
centrally acting

suggested order two : diuretic
calcium antagonist
ace inhibitor
beta blocker
alpha blocker
vasodilator
centrally acting

All the doctors considered that the order of the items in the list of concurrent problems in the drug treatment and critique modules, was important to enable them to quickly locate and select the patients concurrent problems. The doctors considered the current order to be acceptable, however two doctors suggested a different order. One doctor suggested the list of concurrent problems should be placed in alphabetical order. One doctor suggested the list of concurrent problems should be grouped into major disease groups with sub-headings, for example, cardiovascular; renal; endocrine; respiratory. It was suggested that the disease groupings should follow those in the BNF, as doctors were familiar with this format. These comments demonstrate the lack of a consistent methodology in doctors use of procedures and language, and indicates that there is a need for consensus of opinion to determine a recommended format.

6.7.2.7 ***Sufficient Range of Options in Lists***

There are two instances in the system when it is important that a list represents a comprehensive set of options, firstly in the list of possible drug treatments for hypertension, and secondly in the list of concurrent problems.

possible drug treatments : All the doctors considered the list of possible drug treatments for essential hypertension to be complete, which confirmed that the knowledge base covered the full range of treatment options and demonstrated that medical advice can be quantified and presented through a decision support system.

concurrent problems : Two of the doctors considered the list of concurrent problems relevant to the management of the patient with essential hypertension to be comprehensive. One doctor suggested the addition of Transient Ischaemic Attack (TIA), and Cerebro Vascular Accident (CVA).

6.7.2.8 Concise But Sufficient Data For User to Understand Current Task

Each of the decision support facilities contains a summary of patient data relevant to that module. The doctors were asked whether the summaries of data were useful and whether there were sufficient data for them to understand the current task. All the doctors considered the summaries of patient data to be helpful; one doctor considered the summary to be 'vital'; all the doctors considered the summary of patient data in each of the decision support modules to be relevant and sufficient. However in two of the modules suggestions for additional useful data items were made. These included:

In the drug treatment module each doctor suggested one additional item of patient data. There was no consensus on the items, which included: patient's sex; patient's blood pressure, today's blood pressure and the trend; concurrent medication.

In the management module, one doctor commented that it would be useful to know the patient's cardiovascular risk. Another doctor suggested that it would be useful to see all the patients' blood pressure measurements, not just the average. This was for two reasons. Firstly, one spurious blood pressure measurement and the average blood pressure does not reflect the trend, (the doctor indicated that in his opinion the trend was more important than the individual measurements). Secondly, if the general trend is a dropping blood pressure, because the patient is making lifestyle changes, the doctor may want to wait until the patients blood pressure plateau's before initiating drug treatment. This information would not be available from an average measurement.

In the cardiovascular risk module, one doctor suggested it would be useful to know the ration of Total Cholesterol : HDL Cholesterol as well as the individual values, as this

ration was considered to be more reflective of risk of cardiovascular disease than the individual measurements.

6.7.3 Criterion Three : Effectiveness

6.7.3.1 Decision support facilities are relevant to doctor's needs

Overall, all the doctors considered that the decision support facilities were relevant to the treatment and management of a patient with essential hypertension. Specific comments concerning individual modules included:

Drug treatment module : All the doctors considered this was a very useful module and one to which they would often refer. They particularly liked the option to change the patient data on the screen and generate another treatment recommendation. Two doctors wanted more guidance as to what to prescribe. They wanted to know the drug of choice for a specific patient and for the drugs to be listed in order of priority, best choice, worst choice.

Health advice module : All the doctors considered health advice to be an essential part of the treatment of essential hypertension, and considered this to be a very useful module, and one that they would use a great deal. All the doctors had a positive response to the print option which would enable patients to take home copies of the advice. Two of the doctors wanted the option to tailor the advice contained in these modules to suit their own specific needs. For example, one practice had a specific diet programme they wanted to be able to incorporate; a different practice had a specific exercise programme. All three doctors considered that the discrete modules were acceptable and not excessively time consuming. However one doctor requested the opportunity to be able to quickly select module's to be printed, without having to enter each module. It was suggested that this would be particularly useful once the doctor was familiar with the advice in the modules, or for printing out several patient education leaflets on a range of health advice topics. One doctor highlighted a practical problem with the printer, which would reduce the module's usefulness. It was indicated that each

doctor had one printer in their office, which was loaded with prescription forms. The doctors would not have the time to insert ordinary paper. It was considered to be too expensive to buy two printers per office. However, a different doctor had overcome this problem by installing one laser printer in reception, to which all the doctor's office computers were connected. All patient education material was printed out in reception, and the patient collected the paper copies from reception on their way out. This reflects the need for doctors to appreciate the range of computer options and facilities currently available.

Management advice module : All the doctors considered this to be a useful module which they would use in routine clinical practice. One doctor stated it would be particularly helpful in patients with borderline hypertension when initiating drug treatment is not an obvious decision. One doctor stated it would provide useful guidance through appropriate pre-drug management of the hypertensive patient.

Cardiovascular risk module : All the doctors considered this to be a very useful module, and one they would use. All the doctors indicated that the patient's cardiovascular risk was an important aspect of the decision to initiate treatment, and was part of the cost benefit analysis (the cost of treating a patient in terms of the financial implication and the possible detrimental side-effects to the patient, versus the benefit of lowering the patient's blood pressure in terms of reducing their risk of cardiovascular disease). One doctor commented that this module would be very useful in cases when the doctor was not sure of the patient's cardiovascular risk, however in most cases, this doctor felt confident in assessing the patients risk without the need for a tool. The comment was made that this was a 'fascinating gadget.....but more of an epidemiological rather than a clinical tool'. This opinion contrasted with the opinion of a different doctor who commented that over recent years much work had been done on assessing cardiovascular risk, and it was no longer satisfactory for doctors to estimate patient's cardiovascular risk. The use of a computer based tool was supported. All the doctors liked the idea of being able to change the patient data and recalculate the cardiovascular risk. They all indicated it would be a very useful tool in patient education to encourage lifestyle modification, for example by showing patients the change in their cardiovascular risk if their blood pressure or cholesterol was reduced. One doctor

commented that it would be useful to be able to specify the number of years for which the cardiovascular risk was calculated. Currently the module is fixed to calculate the patient's cardiovascular risk over 10 years, however the doctor suggested it would be useful to know the risk over 1,2 or 5 years.

Critique module : One of the doctors liked the idea of a critique module and would envisage using it. Two of the doctors stated they would not use this module because once they had decided to prescribe a specific drug for a patient they would not be interested in the system's opinion of their choice. Two doctors would encourage medical students and qualified doctors specialising in general practice to use this module as an educational tool. One doctor also envisaged this module being used by practice nurses to check the doctors prescribed medication.

Drug interaction module : One doctor indicated that this module would be used routinely. Two of the doctors would not use this module, due to the electronic BNF already being installed on their desk-top computer. Despite the fact that the interactions module of the hypertension decision support system gives patient specific advice on drug interactions, and the eBNF does not, the two doctors would still find it easier and would feel more confident in using the search features in the eBNF to check for drug interactions. This highlights a key psychological issue of confidence in tools which are tried and tested.

Suggestions for additional decision support facilities included :

- Diagnostic advice. A module to include what tests and procedures (e.g. cholesterol level or ECG) should be performed and when, to exclude secondary causes of hypertension.

- A series of prompts and reminders for information not present or up to date in the patient record. e.g. cholesterol or weight. The doctor should have the option of customising the system if he does not want the prompts to appear.

- A graphical summary of patient's blood pressure over time to enable the doctor to see trends quickly and easily.

- A teaching module aimed at the doctor, which contains a protocol or guideline to provide a structured approach to lead a novice through the appropriate stages of diagnosis, treatment and management of a patient with hypertension.

The fact that the doctors suggested these additional modules, which although not developed in the version of the prototype that was evaluated, are part of the system architecture design. Evidence such as this supports the accuracy of the original assessment of the doctors decision making needs.

6.7.3.2 Medically Sensible Advice

Throughout the demonstration, in which all the doctors agreed that the patient data used were realistic, all the doctors agreed with all the advice and explanations the system generated. This provides evidence in support of the structure of the knowledge base, the information it contains and the decision making strategy.

6.7.3.3 Advice Supported by Reasons

All the doctors considered that it was essential that a system could offer reasons for the advice it generated. However, overall confidence in the advice was not changed as the doctors had a fixed level of confidence in computer generated advice.

6.7.3.4 Advice Supported by References

All three doctors liked the use of references to support the advice the system generated and considered this to be a very positive feature throughout the system. One doctor said confidence with the advice was increased due to knowing where the advice came from and by whom it was supported. One doctor commented that the inclusion of local as

well as national and international guidelines in the systems knowledge base was a good idea because many general practitioners were actively involved in the development of local practice guidelines. It was suggested that by incorporating this work it would not only enable the systems advice to reflects the needs of local doctors and their patients but could lead to increased interest in the use of decision support systems due to a sense of 'ownership'.

6.7.3.5 Users Confidence in Accuracy of Advice

During the demonstration all the doctors had confidence that the advice and explanations were correct, which could be attributed to the fact that they agreed with them. However when the broader question was posed, 'How confident are you in the accuracy of the advice a system such as this can generate?', there was a mixed reaction.

One doctor was very confident in the accuracy of the advice. Although it was appreciated that other doctors may not be so enthusiastic, it was believed that more doctors would gain confidence through training and routine use, and once the benefits of such types of decision support were realised through use, decision support would be more widely used. This reflects a common problem that conservative professions are reluctant to adopt new ideas.

One doctor suggested that if it was possible to check the advice the system was generating from a respected source, and the advice matched, then they would be more confident in the advice the system subsequently produced. However, if they came across one significant difference between the system and the 'respected source', they would rapidly lose confidence. This was revealed during the demonstration of the drug interactions module. Two of the doctors compared the advice the system generated with the information in the book, the BNF. The advice from the two sources correlated directly and both doctors subsequently expressed more confidence in the systems drug interactions module.

One doctor was unsure about the level of confidence in the advice the system generated. It was believed that the advice was as good as its knowledge base, and therefore potentially very accurate. However, the doctor would feel more confident if the system had an official seal of approval from either the Royal College of Physicians (RCP) or the Royal College of General Practitioners (RCGP) endorsing its use.

6.7.3.6 User Envisages Incorporating Decision Support Facilities into Clinical Practice

All the doctors would envisage using the system if it was incorporated into their existing clinical information system. Table 6.11 shows which modules the doctors would use routinely.

Decision Support Module	**Number of Doctors (total = 4) Using the Module Routinely**
drug treatment	4
health advice	4
management advice	4
cardiovascular risk	4
critique	1
drug interactions	1

Table 6.11 Number of Doctors Using Each Decision Support Module Routinely

6.7.3.7 Issues Raised in General Discussion

The importance of ease of use was emphasised by all three doctors. It was commented that learning how to use a new piece of software, has to be done in the doctors limited spare time, and so becoming an expert-user may take a considerable length of time, hence the need for easy to use software. It was indicated that most doctors would not have the time or inclination to read a large and complex user-manual. All instructions on how to use the system must be explicit from its design and screen layout. It was

commented that the decision support system would be used as a source of advice to refer to in cases where the doctor was unsure of appropriate treatment or management, this may be on average once a day, or more likely, even less frequently. Thus, because the doctor is not using the tool every minute of every day, it is likely that he or she will quickly forget how the system works. Thus it is essential that the system is easy to use. If it takes more than a moment to find the required advice, the doctor will quickly loose interest in using the system, regardless of how good or useful the advice.

The issue of reluctance to use new technology was raised. It was commented that many doctors still feel reluctant to use computer technology and so it was emphasised that any new system must look and feel familiar.

Another comment concerned the patient record. The issue of completeness of patient data was raised, and it was suggested that patient data required by the decision support system to generate advice may not always be available. If the information in the patient record does not accurately reflect the true patient state, then the relevance of the advice generated by the decision support system will be reduced / impaired.

The option to save any patient data that may have been added / changed during use of the decision support system, to the patient record would be appreciated. The comment was made 'any opportunity to enter patient data into the record should not be missed'.

It was suggested there should be an exit button on each screen in the decision support system to enable a quick route back to the clinical information system. The following scenario was described as an example. The doctor is using the decision support system between seeing patients during morning surgery, he is looking at the reasons screen in the treatment module. A nurse walks in and asks for a repeat prescription for a patient, the doctor wants to return quickly and easily to the clinical information system, without having to think how to close down the decision support system. This supports the need to model the doctors normal working practice, to understand how they work, to enable decision support systems to be embedded into the clinical environment and reflect the users needs.

The issue of how to update the knowledge base as new research / guidelines were published was raised.

6.8 Key Findings

6.8.1 Safety

The results of the safety test demonstrate that the system produces consistent and reproducable results. A total of 23 cases, covering patients of differing ages, sexes, ethnic origins and with various combinations of concurrent disease, cholesterol levels and smoking histories were used to test the system. It was shown that the system could produce advice for all the cases. This evidence demonstrates that the knowledge bases are of sufficient scope, depth and breadth. The systems advice was shown to compare favourably with the opinions of medical experts.

In the treatment module where drugs were contraindicated there was 100% agreement (7/7 cases) between medical expert opinions and the systems advice. Where drugs were recommended there was 95% agreement (21/22 cases) between medical expert opinion and the systems advice. The case where the system failed to match the opinion of the case provider was due to the medical expert recommending calcium antagonists, ace inhibitors and alpha blockers as suitable first line therapies. The system, which bases its advice on evidence from the literature, does not recommend these drugs unless specifically indicated by the presence of additional factors (e.g. concurrent diseases or ethnic origin). This is because these drugs have not been used in long term controlled trials to demonstrate their efficacy in reducing morbidity and mortality from cardiovascular disease.

In the cardiovascular risk module there was 94% agreement (15/16 cases) between medical expert opinion and the systems cardiovascular risk assessment. In the case where a close match was not made, discussion with medical experts led to the conclusion that this was due to the fact that the patient was elderly and the medical

experts placed less weight on this as a risk factor in the development of cardiovascular disease than the system.

In the management module there was 60% agreement (3/5 cases) between the stages of management specified by medical experts and those specified by the system. The two cases where the system did not match expert opinion was because the patients blood pressures were too high to be included in the WHO guidelines for the initial management of essential hypertension, on which the knowledge base for the module is based. In these cases the system provided a message to the user, reporting that the patient was outside the range of the expert system and specialist advice should be sort.

When the system was demonstrated to the doctors in the usability evaluation, they agreed with all the advice and explanations the system generated. This provides evidence in support of both the quality of the information in the systems knowledge base and the decision making strategy.

The results of the safety test provide evidence that the aims and objectives of the safety evaluation have been met. It has been demonstrated that the system is reliable, produces advice which is safe and appropriate and generates advice for a wide range of different input data.

6.8.2 Usability

The results of the usability test demonstrate that the system is accessible, acceptable and effective.

All the doctors liked the idea of accessing the decision support modules from their existing clinical information system. This method was considered to be a quick, easy and effective method of accessing information and advice about specific patients.

All the doctors considered the way in which the advice was presented was clear, concise and easy to understand. All medical terminology was used correctly and displays of

medical data (e.g. concurrent diseases and concurrent medication) facilitated quick and easy access to relevant information. The doctors considered the method of use was self explanatory. These responses demonstrate that the system design has correctly identified the doctors working practice and has shown how decision support can be integrated within it.

The doctors considered the advice to be safe and appropriate. They particularly liked the use of references to support the advice and this feature gave added confidence in the accuracy and relevance of the advice. All the doctors considered the list of possible drug treatments for hypertension to be complete. This confirmed that the knowledge base covered the full range of drug treatment options and demonstrates that medical advice can be quantified and presented through a decision support system.

Overall all the doctors would envisage using the system if it was incorporated into their existing clinical information system.

The results of the usability test provide evidence that the aims and objectives of the usability evaluation have been met. It has been demonstrated that the system is accessible, acceptable and effective.

6.9 Summary

In this chapter the results of the evaluation of the embedded decision support system have been reported. The aims and objectives of the evaluation were presented and the evaluation criteria and measures used in the evaluation were defined. The methods used to assess the systems safety and usability were described and the results presented. The chapter ended with a summary of the key findings.

In chapter seven, a discussion of the key findings of the thesis will be presented.

7. Chapter Seven : Discussion

7.1 Introduction

In this chapter the contributions the thesis has made to the field of medical decision support are discussed. These include, the development of a therapeutic model, the design of a flexible computer architecture, the design of a user centered graphical user interface and an analysis of the medical domain of essential hypertension. These contributions have been made through the integration of ideas from technology and medicine. This reflects the interdisciplinary nature of the field of medical decision support, which forms an interface between technology and medicine. This requires an understanding of both domains to ensure that effective computer based solutions are developed to meet genuine medical needs.

7.2 Key Issues

A fundamental problem that underpins all medically related research is that the processes and procedures are not underpinned by an exact medical science that enables the medical practitioner to proceed on any course of treatment with rigorous scientific certainty. Medical diagnosis and treatment are based on the concept of 'findings', in which the health care practitioner collects data, some objective, such as temperature, some subjective, such as pain, and some data that are collected by invasive (e.g. colonoscopy) and non invasive (e.g. blood pressure) techniques. The basis of treatment therefore contains an element of personalised opinion, which is exercised by the practitioner and any judgment is, in part, based on case law. It is in this context that decision support tools provide medical practitioners with much needed personal support that satisfies a range of particular needs which are dependent on the specific skills and previous experience of the user. It is in this context that the principal focus of the decision support system has to be, to provide advice and support to the medical practitioner, because the ethics of the medical profession are founded on the principle

that the treatment of a patient is based on the personal diagnosis of the medical practitioner who carries the responsibility for the proposed treatment. It is therefore within the context of medical ethics, that the decision support system for essential hypertension provides a range of facilities to the medical practitioner which are discussed and reviewed in this chapter.

In chapter two it was reported that many medical decision support systems have been developed over the past 30 years, many of which claimed to match doctors' decision making abilities. However, few systems are in routine clinical use. The factors restricting the routine use of decision support systems in clinical practice were discussed and included the fact that traditional knowledge elicitation techniques, which have been used to build the knowledge bases of decision support systems, are not generally accepted by medical practitioners. From the analysis of user need the following key issues were identified, which have been shown to contribute to improving general practitioners' acceptance of decision support systems.

Firstly decision support systems need to be underpinned by a recognisable therapeutic model that relates to the medical environment. Therefore a model of the therapeutic process has been developed based on the observation of the interactions between medical practitioner and patient. The model is based on the recognition and formalisation of the steps in the medical consultation process.

Secondly all models have to be implemented and this has been achieved by synthesising a flexible, event driven architecture. The architecture takes into account the user's operational and decision making needs but recognises that the medical practitioner must make the final judgment.

Thirdly usability is an essential feature for decision support system acceptance. Consequently a user interface has been created which sustains and supports a smooth continuum between medical practitioner and patient. The interface takes account of visibility, affordances, mapping and feedback, and these features are now recognised in the field of human computer interaction as essential features for computer based applications.

Forthly medical practitioners need to know the origins of the advice for which they are responsible. Consequently a verified and referenced knowledge base that clearly identifies the source of recommendations has been incorporated into the decision support system. It has already been reported that many previous decision support systems have been based on knowledge elicitation techniques from alleged experts. In general this approach has not found favour with medical practitioners who are nervous about decisions being based on knowledge derived from unconfirmed recommendations.

A decision support tool which provides medical practitioners with these facilities provides the basis for new modes of working within the health care environment. This is through the concept of 'treatment simulation' which is in its infancy in medical practice, for the reasons discussed above, i.e., diagnosis is based on observations and findings and not rigorous science. However, the decision support system provides medical practitioners with a range of 'what if' scenarios, in that the effects of various changes in treatment can be explored within the specific context of the expertise of the accredited knowledge base. This approach to the application of decision support is relatively unproven in medical practice, but represents a style of computer based applications that are in routine use in areas that are based on rigorous scientific principles. Particular aspects of the features of the decision support system will be discussed in further detail in the next sections.

7.3 Therapeutic Model

It was suggested in chapter two that previous decision support systems did not meet genuine medical needs. Consequently this research has been based on an analysis of user needs.

In chapter three, a model of the management of a patient with essential hypertension was presented. This model was based on the observation of the interactions between medical practitioner and patient, and the recognition and formalisation of the steps in that process. The model was used to identify those aspects of medical practice where

decision support was genuinely required. These issues have been presented at an International Symposium for Health Information Management Research (Wilson et al., 1996a).

In the evaluation, presented in chapter six, the doctors indicated that the decision support facilities in the E.D.S. system were relevant to their needs when treating and managing a patient with essential hypertension. This evidence supports the accuracy of the model in defining user needs and sustains the argument that a visible model must underpin specific applications.

In the prototype system specific modules were developed in detail for evaluation purposes. During the evaluation the doctors were asked to suggest additional modules which could be useful, and they confirmed that the facilities identified by the therapeutic model for essential hypertension covered all the issues in the treatment process. Operational evidence such as this confirms the accuracy of the assessment of the doctor's decision making needs.

7.4 Flexible Architecture

Implementing a model provides designers with many alternatives which determine the effectiveness of the resulting tool. The basic features that have been incorporated into the E.D.S. system architecture are based on an event driven, structured design that is functionally simple and extendible. In this context the architecture was composed of self contained modules that represented specific aspects of the therapeutic model. This provided users with natural information flows. An important aspect of the modular design is that users can access the decision support facilities in any order and are thus not constrained to follow a style of working imposed by the system designer. It is a key requirement that the architecture enables the medical practitioner to feel that the decision support system blends into their personal style of practice, and does not appear to constrain that style. It is in that context that the architecture is described as flexible in that it has a pliability to enable the medical practitioner to use the decision support system within the context of essential hypertension in a way that the medical

practitioner requires. These are simple concepts but are of considerable importance in the implementation of the therapeutic model. These issues have been presented at the Sixth International Conference on Systems Science in Health Care (Wilson et al., 1996b).

The evaluators of the decision support system found that the prototype provided them with a tool that was easy and convenient to use because it blended into their decision making style. This, of itself, is worthy of note because all medical practitioners have very personalised working styles, and the concept of flexibility is a key requirement in order that modern tools can accommodate a range of such working styles. Thus the flexible architecture was shown to map users operational and decision making needs while allowing the medical practitioner to make the final judgment. This was achieved by identifying those aspects of decision making where support was genuinely required, and by providing a range of facilities to support each stage of the clinical process. The synthesis of an architecture that models the practitioner - patient relationship requires a conceptual understanding of that relationship and of the operational environment in which it takes place.

7.5 User Interface

The implementation of the user interface is an important component which influences the utilisation of modern computer systems. In this context, a user interface has been developed which sustained and supported a smooth continuum between medical practitioner and patient. This was achieved by addressing the following key issues: convenience and ease of use; operational characteristics.

7.5.1 Convenience and Ease of Use

It has been a recognised failure that previous decision support systems were not convenient to use and thus failed to be integrated into routine clinical practice. This, in part, is not a criticism of previous work, but a recognition that the integration of computer technology requires more sophistication than early computers had the

processing power to provide. We are now fortunate that modern processing speeds can sustain systems that are more appropriate to user needs. In this context it was in chapter three that the need for system designers to develop an understanding of the environment in which general practitioners work was emphasised. In the design of the E.D.S. system it was therefore considered to be a central issue that decision support systems not only met users requirements, but also fitted smoothly into their everyday routines. While these issues have been at the forefront of the implementation process, it is important to recognise that the principles and features that have been incorporated in the interface can be further refined as technology improves. The prototype was developed in a machine that had an Intel 486 processor and used Windows 3.1 as the development environment. It is clear that with increased processing power and with the opportunity to incorporate additional features, such as data bases on CD ROM etc., then more powerful configurations can be developed. However, the key issue is that the principles of usability, that have been supported by evaluation, have demonstrated that an interface that is 'fit for purpose' can be achieved. The particular aspects that the evaluators drew attention to included:

- minimum fuss and hassle to find the required information and advice, which emphasises that the decision support system was an easy to use tool. This is an essential feature because patients require personalised attention, such that the computer must not become an impediment or barrier to efficient practitioner - patient interaction.

- additional feature in an existing environment rather than a new environment.

- decision support was convenient to access and readily available.

It was also confirmed that the prototype decision support system that was demonstrated generated advice quickly enough to be a realistic tool for use in routine clinical practice.

7.5.2 Operational Design Characteristics

It has been noted that for a variety of reasons, including the operational constraints of the technology and the psychological barriers between users and machine interfaces, previous decision support systems were often not easy to use. This has been a barrier to their successful implementation in medical practice. In view of this, ease of use was considered to be of major importance in the design and development of the E.D.S. system. Principles of interface design were considered in the specification of the conceptual framework that was presented in chapter three and in the implementation that was presented in chapter five. Emphasis has been placed on developing an attractive, easy to use interface, which required minimal learning. The operational features that have been employed to achieve this objective will be discussed further in this section.

The ability to design is one of the natural and fundamental characteristics which delineates Man from the general animal kingdom. What is a good design is of itself an abstract concept without a unique and unequivocal answer. We can illustrate this by an analogy with a cup. It is a vessel to "drink from", and from the beginning of recorded time various vessels to "drink from" have been created. There is no unique solution to the problem, but by common endeavour it is possible to find the same artifact in every house throughout the world, often very different in detail, but all essentially the same. The design of a modern decision support system interface has to be set in the same philosophical context. It is possible to identify desirable features that have now emerged from common endeavor, but which will have personalised features and constraints that are imposed by the implementation technology. In order to synthesise the interface the following principles have been considered.

- visibility
- affordance
- mapping
- feedback

In addition a modern implementation requires to be performed at a level of abstraction that enables the interface design to be incorporated into the decision support system. In this context, LPA Prolog provided that development tool and through the features of LPA Prolog the particular features of the interface were created. However it has to be recognised that design, as noted above, is a personalised activity and the features of the prototype demonstrator were the authors choice.

In the evaluation, the doctors considered that the advice was presented in a clear and easy to read format. The names of buttons, menu items and labels were generally considered to be self-explanatory. This is important as it reduces learning time and the demands on memorising functions. The order of the items in the various lists were generally considered to be acceptable. This is important to enable users to quickly locate and select relevant items. The doctors considered the method of use was self explanatory. This demonstrates that the design has correctly identified the doctors working practice and has shown how decision support can be integrated within it.

Interface design is still, and may always be, based on an inexact science, but the current prototype provided a demonstrator that incorporated a range of features that sustained the primary objectives and proved acceptable to those users who participated in the evaluation.

7.6 Medical Domain

On the basis of the work reported in this thesis, it is apparent that poor communication between system developers and medical experts is a factor which has inhibited the accurate formalisation of user needs, restricted development of knowledge bases and contributed to poorly designed user interfaces. In this context the authors contribution was to bridge, in part, that gap, because the author is a health care professional with a viable conceptual understanding of computer principles and technology. In chapter four an introduction to both the cardiovascular system and the medical condition of hypertension was presented. This provided an overview of the application domain and emphasised that the knowledge base of the decision support system must contain

appropriate medical terminology and represent a clear understanding of the application domain. Appropriate terminology is an important feature in the design of a medical decision support system because it is the cornerstone of effective communication.

In the evaluation the doctors considered the advice was clear and understandable and was presented using appropriate language. All medical terminology was considered to have been used correctly. This is important as language is a key component of effective communication. It was generally considered that there was sufficient data for users to put the current task and advice in context. This is important as it demonstrates an understanding of the key components in clinical decision making related to hypertension.

The evaluators noted that the knowledge base in the E.D.S. system was based on verified and referenced material, that clearly identified the source of the recommendations. It is an essential feature of the design that medical principles are sourced from identified agents in order that recommendations can be consistently referenced and updated. It has been noted that previous decision support systems had the potential to generate poor quality advice because the information in their knowledge bases was derived, in part, from traditional methods of knowledge elicitation. This issue is compounded by the combination of inter and intra expert variability and the personal nature of medical experts opinions, which leads to reluctance to publish knowledge bases in the public domain.

In the E.D.S. system's knowledge base this is overcome by the use of clinical guidelines and other published research papers, which represent quantified and public domain information. Details of the information used to develop this knowledge base was presented in chapter four. In the E.D.S. system the source of the information is made explicit to the user at the point of use. This enables the user to personally validate the knowledge base. This technique also facilitates the distribution of medical knowledge, an area of concern for the medical profession, as highlighted in chapter two. However, medical knowledge is consistently expanding and a key feature which is sustained by the modular architecture is that the knowledge bases are easily extendible and modifiable according to the demands of medical knowledge.

Evaluation of the systems knowledge base by generating advice for a range of patient scenarios and comparing the systems advice to that of medical experts, provides evidence that the current knowledge bases are of sufficient depth and breadth to be of use in clinical practice. The systems advice was shown to compare favourably with the opinions of medical experts. This provides evidence in support of both the quality of the information in the systems knowledge base and in the decision making strategy. In the evaluation the doctors indicated that the list of possible drug treatments for essential hypertension was complete. This provides evidence that the knowledge base covered the full range of drug treatment options and demonstrated that medical advice can be quantified and presented through a decision support system. In the evaluation the doctors considered it was essential that the system could provide explanations for its advice and they particularly like the use of references to support the advice and explanations. This gave them greater confidence in the accuracy of the advice the system generated. The general conclusion from the evaluation is that a broad based field trial is a logical development of the prototype demonstrator.

7.7 Summary

In this chapter the key issues that the thesis has explored were presented. These included: the need for a decision support systems to be underpinned by a therapeutic model that relates to the medical environment; the need for a computer architecture to take into account the users operational needs; the need for a user interface to sustain and support a smooth continuum between medical practitioner and patient; and finally the need for medical practitioners to know the origins of the advice for which they are responsible. These issues reflect the interdisciplinary nature of the field of medical decision support which forms an interface between technology and medicine. In the next chapter the conclusions to the thesis will be presented.

8. Chapter Eight : Conclusions

In this chapter the conclusions to the thesis will be presented. The extent to which the objectives have been met will be outlined. The contributions to knowledge will be discussed and the opportunities for future work will be presented.

8.1 Meeting the Objectives

In chapter one the principal objectives of the thesis were defined as a reliable, effective and easy to use decision support tool for the management of essential hypertension. The following summary indicates the achievements of the project while demonstrating that the objectives have been met.

Objective one was to analyse the issues preventing the widespread use of decision support in primary care and to develop a user centered application environment. These issues were presented and discussed in chapter two.

Objective two was to analyse the decision making needs of the clinician in the diagnosis, treatment and management of a patient with essential hypertension. In chapter three, a new model of the management of a patient with essential hypertension was presented. This model was used as the basis for the development of a new decision support system. The approach enabled decision support to reflect health care professionals decision making needs, to compliment the natural interaction between practitioner and patient and be sympathetic to the demands imposed by the working environment.

Objective three was to make recommendations for the design of a decision support system and objective four was to develop a prototype to demonstrate some of the recommendations. In chapters three and four recommendations for the design of a new decision support system were presented and in chapter five the prototype system was described. Key features included:

The structure of the system architecture modelled the consultation process and therefore provided the health care professional with a software tool which was effectively embedded into normal working practice. The success of this approach was demonstrated in the evaluations of the prototype E.D.S. system, which were reported in chapter six and discussed in chapter seven.

Usability was considered to be a key issue to ensure effective implementation in the clinical environment. The effectiveness of the prototype E.D.S. systems design in ensuring ease of use was supported with evidence from the evaluations, which were reported in chapter six and discussed in chapter seven.

The source of the information in the systems knowledge base was considered to be a key issue that influences health care professional's acceptance of decision support in clinical practice. In chapter four, a detailed analysis of the information used in the system knowledge base was presented. This was encapsulated into a rule base and through implementation in the language Prolog, it was demonstrated how clinical guidelines and other medical research data could be used to generate patient specific advice in a decision support system. An important feature of the E.D.S. system is that it presents the origins of the source material on which the recommended advice is based. The evaluations, which were reported in chapter six and discussed in chapter seven, provided evidence that a knowledge base which is verifiable by the user is a key feature of a decision support system.

This new and original approach to the design and development of a decision support system has led to a mode of use that is naturally integrated within the health care professional's normal working environment.

Objective five was to evaluate the prototype system. In chapter six the evaluations of the prototype system were reported. The evaluations provided evidence that:

- the system is reliable in that it produces consistent and reproducable results

- the system is effective in that the knowledge bases are comprehensive enough to cope with a wide range of different cases and the advice generated is medically safe and appropriate.

- the system is easy to use and the format in which the advice is presented is acceptable to the user.

8.2 Contributions to Knowledge

The initial hypothesis was that by developing a user centered approach to analysis and design, a decision support system could be developed that would satisfy the needs of users, who would then demonstrate the effectiveness of this approach by their willingness to incorporate the system into routine clinical practice.

In testing the hypothesis, contributions to knowledge in the field of medical decision support have been made in the following areas:-

- Constructing a conceptual model of the de facto environment that pervades in general practice and using this model to synthesise a flexible, event driven architecture which maps onto operational needs.

- Creating a representation of the general practitioner's mode of working that has been developed into a user centred interface.

- Analysing the structure of referenced medical knowledge in the area of essential hypertension and demonstrating that a referenced knowledge base can be implemented in a computable format.

8.2.1 Therapeutic Model and Flexible Architecture

The new model of the therapeutic process and the system architecture were presented in chapter three. In the evaluation the doctors indicated that the range of decision support facilities provided by the E.D.S. system were relevant to their needs, fitted smoothly into their everyday routines and were convenient to access. The GPs demonstrated a willingness to incorporate the system into their routine practice. This provides evidence which supports the fact that the model correctly defined user needs and identified the key components in clinical decision making related to hypertension. It also confirms that the system architecture effectively modelled the consultation process and that it would enable decision support to be embedded within normal working practice.

8.2.2 User Centred Interface

Usability has been recognised as a major factor that has inhibited the implementation of decision support systems into routine clinical practice. Not withstanding the fact that usability is an abstract concept that falls into the category, 'I know what I want when I see it', design guidelines have been formulated and provide a set of principles on which the interface has been implemented. This approach presents a quantifiable contribution in that it has been used to produce an evaluated outcome. In the evaluation the doctors indicated that the decision support system was easy and convenient to use. The doctors demonstrated a willingness to incorporate the system into their routine practice. This evidence supports the emphasis the design has placed on user needs and the success in developing an attractive easy to use interface which requires minimal learning. It also provides further evidence to support the success of modelling the consultation process and developing a system which can be integrated transparently within it.

8.2.3 Knowledge Base and Explanation Facility

There is a long tradition of using 'computing' machines to perform numerical calculations, the abacus is one such example, which predates the electronic digital computer by several centuries, but knowledge processing is not algorithmic and requires

different insights and perceptions. It is in this context that the potential for using clinical guidelines and other medical research papers as the foundation of the systems knowledge base was discussed in chapter four. A particularly important feature of the system is that it presents the origins of the source material on which the recommended advice is based to the user at the point of use. This enables the user to personally verify the systems knowledge base.

A further feature of the decision support system was that an advice explanation facility was implemented so that reasons could be presented for consideration. These features create the opportunity for new insights both into the treatment and the application of the decision support system.

In the evaluation the doctors indicated the advice the system generated was both useful and relevant. This provides evidence in support of both the quality of the information in the systems knowledge base and in the decision making strategy. The doctors indicated how the use of references to support the advice gave them greater confidence in the accuracy of the advice the system generated. This is a key issue which influences clinicians acceptance of decision support into routine practice as computerising personal expertise is rarely acceptable to practitioners because of its association with personal opinion.

8.3 Opportunities for Future Work

8.3.1 User Interface

It was noted in the discussion chapter that new technological features are becoming available and there is a need to continue to exploit the advances in multimedia facilities to provide further improvements in the visual presentation of data. It is already clear that with the continued improvements in microcomputer technology there will be opportunities to include new techniques based on, for example, voice inputs and outputs. However the rapidly developing techniques that support 'virtual reality' and the increasingly sophisticated interfaces that are being created for World Wide Web

applications are stimulating new interface techniques. Tools based on these new technologies will need thorough investigations to determine their most effective role in the clinical environment.

8.3.2 Clinical Trial

The current prototype system that has been based on an abstract conceptual model has demonstrated the success of the design in overcoming general practitioners reluctance to incorporate decision support into routine clinical practice. There is now an opportunity to explore whether further levels of abstraction can be used to develop the system further in preparation for a clinical trial. This would include integrating all the modules specified in the design within a clinical information system. A clinical trial would provide evidence of how and when the system is used in the normal clinical environment. There is also the need and opportunity to determine which members of the health care team use the system and in what context. Based on the evidence gained from the evaluation of the prototype decision support system, it is clear that a commercially robust decision support system would need an extensive field trial and that the preparation of such a clinical trial would be a major research undertaking that would require extensive time and expertise, but it is that commitment that is required to move the conceptually based work reported in this thesis into general practice.

8.3.3 Preventative Medicine

The success of the specialised hypertension knowledge base highlights the need for a major research initiative that relates to the significant volume of medical records that are kept in various forms in the general practitioners surgery. For decision support to move to the next stage and be able to predict illness and therefore enable the general practitioner to offer new forms of preventative medicine, the inference mechanisms need to be applied to the patients complete medical record. This issue represents a major area of work that requires a fundamental analysis of the problem, but technology, such as document scanners, is now in place to warrant research into this problem.

8.3.4 Descriptive Terminology

It was noted in chapter three that currently there is no consistent means of representing the interactions between medical practitioners and patients that is analagous to the engineer representing an electronic circuit using universally recognised symbols, e.g. capacitors and resistors. This has led to many models of the therapeutic process being developed, all of which use different descriptive notations. There is clearly a need for the development of a consistent terminology to represent the medical environment and the interactions between patients and practitioners. This would enable designers to use a common language and would facilitate the exploration of new designs based on universally accepted terminology.

8.3.5 Design Principles

The work reported in this thesis has shown that by developing a model of the therapeutic process, users decision making and operational needs can be defined. These definitions can then be used as the basis for the design of a decision support system. Evaluation studies have shown the success of applying these principles to the development of a prototype decision support system for the management of essential hypertension. Opportunities now exist to demonstrate whether these principles can be successfully applied to other medical domains in order to explore the extent to which these principles are universally applicable.

8.3.6 Event Driven Architecture

The architecture of the current prototype system has been based on an event driven, structured design. A key feature of the architecture is that it is composed of self contained modules which can be accessed in any order, thus the designer does not impose their own style of working on the user. Evaluation studies have shown the success of the design in over coming general practitioners reluctance to incorporate decision support into routine clinical practice. Opportunities now exist to explore

whether these design principles can be successfully applied to other medical domains in order to demonstrate whether this approach has broad applicability.

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10. Appendix 1

Profile for 23 case histories, including advice from case provider.

Case Identifier	1
Sex	male
Ethnic Origin	asian
Age	70
Smoking History	non-smoker
Total Cholesterol (mmol/l and mg/dl)	7.5 mmol/l or 300 mg/dl
HDL Cholesterol (mmol/l and mg/dl)	1.125 mmol/l or 45 mg/dl
Blood pressure (systolic/diastolic mmHg)	170/110 mmHg
Concurrent Problems	gout
Concurrent Medication	allopurinol indomethacin paracetamol
Recommended Drug Treatment	Beta blocker
Contraindicated Drug Treatment	Diuretic because patient has gout
Cardiovascular Risk Assessment	high
Management Advice: on first visit	BP 162/108 mmHg. Review and check lipids and renal function
Management Advice: at week 4	BP 168/108 mmHg. Review and ECG
Management Advice: at week 16	BP 160/104 mmHg. Review.
Management Advice: at week 30	BP 170/110 mmHg. start drug treatment.

Case Identifier	2
Sex	male
Ethnic Origin	white
Age	58
Smoking History	20 per day
Cholesterol (mmol/l and mg/dl)	6mmol/l or 240 mg/dl
HDL Cholesterol (mmol/l and mg/dl)	1.125 mmol/l or 45 mg/dl
Blood pressure (systolic/diastolic mmHg)	160/96 mmHg
Concurrent Problems	Diabetes mellitus, with persistant microscopic albuminuria Peripheral vascular disease
Concurrent Medication	Insulin
Recommended Drug Treatment	Ace inhibitor, because proteinuria is a positive indication for use of ace inhibitors.
Contraindicated Drug Treatment	Beta blocker
Cardiovascular Risk Assessment	high
Management Advice: on first visit	BP 140/92. Review.
Management Advice: at week 4	BP 148/90. Non drug treatment advised
Management Advice: at week 16	BP 160/96. Review.
Management Advice: at week 30	BP 150/90. Start drug treatment.

Case Identifier	3
Sex	male
Ethnic Origin	asian
Age	44
Smoking History	non-smoker
Total Cholesterol (mmol/l and mg/dl)	5 mmol/l or 200 mg/dl
HDL Cholesterol (mmol/l and mg/dl)	1.125 mmol/l or 45 mg/dl
Blood pressure (systolic/diastolic mmHg)	160/94 mmHg
Concurrent Problems	Diabetes mellitus
Concurrent Medication	Metformin
Recommended Drug Treatment	Ace inhibitor, chosen for renal protection
Contraindicated Drug Treatment	none specified
Cardiovascular Risk Assessment	medium
Management Advice: on first visit	BP 130/90. Review and measure cholesterol and urea and electrolytes.
Management Advice: at week 4	BP 150/95. Review and advise non pharmacological treatment.
Management Advice: at week 16	BP 160/94. Fundus screening; chiropody referal; ECG; Full diabetic check; dietician referral.
Management Advice: at week 30	BP 160/94. Start drug treatment.

Case Identifier	4
Sex	male
Ethnic Origin	white
Age	56
Smoking History	non smoker
Total Cholesterol (mmol/l and mg/dl)	6 mmol/l or 240 mg/dl
HDL Cholesterol (mmol/l and mg/dl)	1.125 mmol/l or 45 mg/dl
Blood pressure (systolic/diastolic mmHg)	190/125 mmHg
Concurrent Problems	Mild recent CVA, probably emboli Atherosclerotic arterial disease
Concurrent Medication	aspirin
Recommended Drug Treatment	Ace inhibitor Beta blocker
Contraindicated Drug Treatment	none specified
Cardiovascular Risk Assessment	medium-high
Management Advice: on first visit	BP 190/125. Review in 1-2 weeks
Management Advice: at week 4	BP 174/108. Non drug treatment and general advice.
Management Advice: at week 16	BP 180/114. Prepare patient for the need for long term treatment.
Management Advice: at week 30	BP 140/108. Start drug treatment.

Case Identifier	5
Sex	male
Ethnic Origin	white
Age	52
Smoking History	ex-smoker
Total Cholesterol (mmol/l and mg/dl)	7 mmol/l or 280mg/dl
HDL Cholesterol (mmol/l and mg/dl)	1.125 mmol/l or 45 mg/dl
Blood pressure (systolic/diastolic mmHg)	160/100 mmHg
Concurrent Problems	none
Concurrent Medication	none
Recommended Drug Treatment	Diuretic, because well tolerated, reasonable first choice and cheap.
Contraindicated Drug Treatment	none
Cardiovascular Risk Assessment	medium-low
Management Advice: on first visit	BP 130/88
Management Advice: at week 4	BP 152/104
Management Advice: at week 16	BP 138/98
Management Advice: at week 30	BP 160/100

Case Identifier	6
Sex	male
Ethnic Origin	white
Age	75
Smoking History	non smoker
Total Cholesterol (mmol/l and mg/dl)	6 mmol/l or 240 mg/dl
HDL Cholesterol (mmol/l and mg/dl)	1.125 mmol/l or 45 mg/dl
Blood pressure (systolic/diastolic mmHg)	190/120
Concurrent Problems	Impotent
Concurrent Medication	none
Recommended Drug Treatment	Calcium antagonist, because impotent Ace inhibitor.
Contraindicated Drug Treatment	none specified.
Cardiovascular Risk Assessment	medium
Management Advice: on first visit	no data available
Management Advice: at week 4	no data available
Management Advice: at week 16	no data available
Management Advice: at week 30	no data available

Case Identifier	7
Sex	female
Ethnic Origin	white
Age	51
Smoking History	non smoker
Total Cholesterol (mmol/l and mg/dl)	4.5mmol/l or 180 mg/dl
HDL Cholesterol (mmol/l and mg/dl)	1.125 mmol/l or 45 mg/dl

Blood pressure (systolic/diastolic mmHg)	160/110 mmHg
Concurrent Problems	Hormone replacement therapy
Concurrent Medication	Prempak C
Recommended Drug Treatment	Beta blocker Ace inhibitor
Contraindicated Drug Treatment	none specified
Cardiovascular Risk Assessment	medium
Management Advice: on first visit	no data available
Management Advice: at week 4	no data available
Management Advice: at week 16	no data available
Management Advice: at week 30	no data available

Case Identifier	8
Sex	male
Ethnic Origin	white
Age	60
Smoking History	non smoker
Total Cholesterol (mmol/l and mg/dl)	5.5 mmol/l or 220 mg/dl
HDL Cholesterol (mmol/l and mg/dl)	1.125 mmol/l or 45 mg/dl
Blood pressure (systolic/diastolic mmHg)	180/110 mmHg
Concurrent Problems	Atrial fibrillation
Concurrent Medication	Warfarin
Recommended Drug Treatment	Beta blocker Diuretic
Contraindicated Drug Treatment	none specified
Cardiovascular Risk Assessment	high
Management Advice: on first visit	no data available
Management Advice: at week 4	no data available
Management Advice: at week 16	no data available
Management Advice: at week 30	no data available

Case Identifier	9
Sex	female
Ethnic Origin	white
Age	50
Smoking History	non smoker
Total Cholesterol (mmol/l and mg/dl)	5.5 mmol/l or 220 mg/dl
HDL Cholesterol (mmol/l and mg/dl)	1.125 mmol/l or 45 mg/dl
Blood pressure (systolic/diastolic mmHg)	150/100 mmHg
Concurrent Problems	Carpal tunnel syndrome
Concurrent Medication	none
Recommended Drug Treatment	Beta blocker Diuretic
Contraindicated Drug Treatment	none specified
Cardiovascular Risk Assessment	medium
Management Advice: on first visit	no data available

Management Advice: at week 4	no data available
Management Advice: at week 16	no data available
Management Advice: at week 30	no data available

Case Identifier	10
Sex	male
Ethnic Origin	white
Age	44
Smoking History	non smoker
Total Cholesterol (mmol/l and mg/dl)	4 mmol/l or 160 mg/dl
HDL Cholesterol (mmol/l and mg/dl)	1.125 mmol/l or 45 mg/dl
Blood pressure (systolic / diastolic mmHg)	145/100 mmHg
Concurrent Problems	none
Concurrent Medication	none
Recommended Drug Treatment	Diuretic Calcium antagonist Ace inhibitor
Contraindicated Drug Treatment	none specified
Cardiovascular Risk Assessment	medium
Management Advice: on first visit	no data available
Management Advice: at week 4	no data available
Management Advice: at week 16	no data available
Management Advice: at week 30	no data available

Case Identifier	11
Sex	male
Ethnic Origin	white
Age	45
Smoking History	20 per day
Total Cholesterol (mmol/l and mg/dl)	no data available
HDL Cholesterol (mmol/l and mg/dl)	no data available
Blood pressure (systolic/diastolic mmHg)	160/100 mmHg
Concurrent Problems	none
Concurrent Medication	none
Recommended Drug Treatment	Calcium antagonist Ace inhibitor alpha blocker
Contraindicated Drug Treatment	none
Cardiovascular Risk Assessment	no data available
Management Advice: on first visit	no data available
Management Advice: at week 4	no data available
Management Advice: at week 16	no data available
Management Advice: at week 30	no data available

Case Identifier	12
Sex	female
Ethnic Origin	white
Age	75
Smoking History	no data available
Total Cholesterol (mmol/l and mg/dl)	no data available
HDL Cholesterol (mmol/l and mg/dl)	no data available
Blood pressure (systolic/diastolic mmHg)	180/100 mmHg
Concurrent Problems	Cardiac failure Left ventricular hypertrophy on ECG
Concurrent Medication	none specified
Recommended Drug Treatment	Diuretic Ace inhibitor, because long term prognostic benefits in cardiac failure.
Contraindicated Drug Treatment	none specified
Cardiovascular Risk Assessment	no data available
Management Advice: on first visit	no data available
Management Advice: at week 4	no data available
Management Advice: at week 16	no data available
Management Advice: at week 30	no data available

Case Identifier	13
Sex	male
Ethnic Origin	afro-Caribbean
Age	55
Smoking History	30 per day
Total Cholesterol (mmol/l and mg/dl)	no data available
HDL Cholesterol (mmol/l and mg/dl)	no data available
Blood pressure (systolic/diastolic mmHg)	180/110 mmHg
Concurrent Problems	Dyslipidaemia Impotence Depression
Concurrent Medication	none specified
Recommended Drug Treatment	Calcium antagonist because afro-Caribbean and impotent. Alpha blocker because impotent
Contraindicated Drug Treatment	Diuretics because dyslipidaemia and side effect impotence.
Cardiovascular Risk Assessment	no data available
Management Advice: on first visit	no data available
Management Advice: at week 4	no data available
Management Advice: at week 16	no data available
Management Advice: at week 30	no data available

Case Identifier	14
Sex	male
Ethnic Origin	white
Age	58
Smoking History	ex-smoker
Total Cholesterol (mmol/l and mg/dl)	no data available
HDL Cholesterol (mmol/l and mg/dl)	no data available
Blood pressure (systolic/diastolic mmHg)	145/90 mmHg
Concurrent Problems	Gout Bronchospasm
Concurrent Medication	none specified
Recommended Drug Treatment	Ace inhibitor Calcium antagonist Alpha blocker
Contraindicated Drug Treatment	Beta blocker because bronchospasm. Diuretic because gout.
Cardiovascular Risk Assessment	no data available
Management Advice: on first visit	no data available
Management Advice: at week 4	no data available
Management Advice: at week 16	no data available
Management Advice: at week 30	no data available

Case Identifier	15
Sex	female
Ethnic Origin	white
Age	51
Smoking History	non smoker
Total Cholesterol (mmol/l and mg/dl)	no data available
HDL Cholesterol (mmol/l and mg/dl)	no data available
Blood pressure (systolic/diastolic mmHg)	150/100 mmHg
Concurrent Problems	Diabetes
Concurrent Medication	none specified
Recommended Drug Treatment	Ace inhibitor for renal protection Calcium antagonist Alpha blocker
Contraindicated Drug Treatment	none specified
Cardiovascular Risk Assessment	no data available
Management Advice: on first visit	no data available
Management Advice: at week 4	no data available
Management Advice: at week 16	no data available
Management Advice: at week 30	no data available

Case Identifier	16
Sex	male
Ethnic Origin	white
Age	79
Smoking History	5 per day
Total Cholesterol (mmol/l and mg/dl)	no data available
HDL Cholesterol (mmol/l and mg/dl)	no data available
Blood pressure (systolic/diastolic mmHg)	150/100
Concurrent Problems	COAD
Concurrent Medication	none specified
Recommended Drug Treatment	Diuretic Ace inhibitor Calcium antagonist
Contraindicated Drug Treatment	Beta blocker, because COAD.
Cardiovascular Risk Assessment	no data available
Management Advice: on first visit	no data available
Management Advice: at week 4	no data available
Management Advice: at week 16	no data available
Management Advice: at week 30	no data available

Case Identifier	17
Sex	female
Ethnic Origin	afro-Caribbean
Age	36
Smoking History	non smoker
Total Cholesterol (mmol/l and mg/dl)	7.1 mmol/l or 284 mg/dl
HDL Cholesterol (mmol/l and mg/dl)	1.125 mmol/l or 45 mg/dl
Blood pressure (systolic/diastolic mmHg)	164/98
Concurrent Problems	none
Concurrent Medication	none specified
Recommended Drug Treatment	no data available
Contraindicated Drug Treatment	no data available
Cardiovascular Risk Assessment	low
Management Advice: on first visit	no data available
Management Advice: at week 4	no data available
Management Advice: at week 16	no data available
Management Advice: at week 30	no data available

Case Identifier	18
Sex	male
Ethnic Origin	white
Age	57
Smoking History	15 per day
Total Cholesterol (mmol/l and mg/dl)	7.8mmol/l or 312 mg/dl
HDL Cholesterol (mmol/l and mg/dl)	1.125 mmol/l or 45 mg/dl

Blood pressure (systolic/diastolic mmHg)	160/106
Concurrent Problems	Angina
Concurrent Medication	none specified
Recommended Drug Treatment	Beta blocker Calcium antagonist
Contraindicated Drug Treatment	none specified
Cardiovascular Risk Assessment	high
Management Advice: on first visit	no data available
Management Advice: at week 4	no data available
Management Advice: at week 16	no data available
Management Advice: at week 30	no data available

Case Identifier	19
Sex	male
Ethnic Origin	white
Age	75
Smoking History	ex-smoker
Total Cholesterol (mmol/l and mg/dl)	8.3 mmol/l or 332 mg/dl
HDL Cholesterol (mmol/l and mg/dl)	1.125 mmol/l or 45 mg/dl
Blood pressure (systolic/diastolic mmHg)	176/108 mmHg
Concurrent Problems	Angina Raised creatinine Diabetes Peripheral vascular disease Dyslipidaemia
Concurrent Medication	none specified
Recommended Drug Treatment	Calcium antagonist, because angina
Contraindicated Drug Treatment	Beta blockers, because peripheral vascular disease.
Cardiovascular Risk Assessment	high
Management Advice: on first visit	no data available
Management Advice: at week 4	no data available
Management Advice: at week 16	no data available
Management Advice: at week 30	no data available

Case Identifier	20
Sex	male
Ethnic Origin	white
Age	38
Smoking History	non smoker
Total Cholesterol (mmol/l and mg/dl)	5 mmol/l or 200 mg/dl
HDL Cholesterol (mmol/l and mg/dl)	1.125 mmol/l or 45 mg/dl
Blood pressure (systolic/diastolic mmHg)	166/102 mmHg
Concurrent Problems	Left ventricular hypertrophy
Concurrent Medication	none specified
Recommended Drug Treatment	Beta blocker

	Diuretic Ace inhibitor Calcium antagonist
Contraindicated Drug Treatment	none specified
Cardiovascular Risk Assessment	medium
Management Advice: on first visit	no data available
Management Advice: at week 4	no data available
Management Advice: at week 16	no data available
Management Advice: at week 30	no data available

Case Identifier	21
Sex	male
Ethnic Origin	white
Age	66
Smoking History	10 per day
Total Cholesterol (mmol/l and mg/dl)	9 mmol/l or 360 mg/dl
HDL Cholesterol (mmol/l and mg/dl)	1.125 mmol/l or 45 mg/dl
Blood pressure (systolic/diastolic mmHg)	180/110 mmHg
Concurrent Problems	Diabetes Raised creatinine Dyslipidaemia Peripheral vascular disease Atherosclerotic arterial disease
Concurrent Medication	none specified
Recommended Drug Treatment	Calcium antagonist, recommended for renal protection as patient has diabetes
Contraindicated Drug Treatment	Ace inhibitor, because patient has a raised creatinine and peripheral vascular disease
Cardiovascular Risk Assessment	high
Management Advice: on first visit	no data available
Management Advice: at week 4	no data available
Management Advice: at week 16	no data available
Management Advice: at week 30	no data available

Case Identifier	22
Sex	female
Ethnic Origin	white
Age	85
Smoking History	non smoker
Total cholesterol (mmol/l and mg/dl)	7 mmol/l or 280 mg/dl
HDL Cholesterol (mmol/l and mg/dl)	1.125 mmol/l or 45 mg/dl
Blood pressure (systolic/diastolic mmHg)	190/110
Concurrent Problems	Diabetes Transient ischaemic episodes Atherosclerotic arterial disease Atrial fibrillation

Concurrent Medication	none specified
Recommended Drug Treatment	Calcium antagonist, because atrial fibrillation.
Contraindicated Drug Treatment	none specified
Cardiovascular Risk Assessment	high
Management Advice: on first visit	no data available
Management Advice: at week 4	no data available
Management Advice: at week 16	no data available
Management Advice: at week 30	no data available

Case Identifier	23
Sex	female
Ethnic Origin	white
Age	81
Smoking History	no data available
Cholesterol (mmol/l and mg/dl)	no data available
HDL Cholesterol (mmol/l and mg/dl)	no data available
Blood pressure (systolic / diastolic mmHg)	no data available
Concurrent Problems	cardiac failure
Concurrent Medication	none specified
Recommended Drug Treatment	Ace inhibitor Diuretic
Contraindicated Drug Treatment	none specified
Cardiovascular Risk Assessment	no data available
Management Advice: on first visit	no data available
Management Advice: at week 4	no data available
Management Advice: at week 16	no data available
Management Advice: at week 30	no data available

11. Appendix 2

Structured Interview to evaluate the prototype E.D.S. system

The first screen is the simulated clinical information system. In a 'real' system, this would be meditel (or what ever system you are using). The menu bar along the top of this screen is the entry point to decision support.

1) question: what is your reaction to this concept ?

_____
_____
_____

Now look at the data in this file, (patients sex, age, ethnic origin, smoking, concurrent problems, concurrent medication, bp, height, weight, cholesterol).

2) question: Is there any patient data missing, that you would consider to be essential before you could manage / treat a patient with essential hypertension ? (what other data would you consider to be essential)

_____
_____
_____

Access patient file.

3) question: Do you accept that this is a realistic / reasonable example ?

_____
_____
_____

Access decision support module

explain how in a working system, a range of diseases would have decision support facilities, hypertension has been developed as an example. show the drop down hypertension decision support system list (main list and health advice list.)

4) question: Do you 'intuitively' know from the words in this list what advice you are going to get ?_____

5) question: would you like to suggest any different words to describe the decision support functions.
drug treatment_____
health advice_____
management advice_____
cardiovascular risk_____
critique_____
drug interactions_____

6) question: does the order of the items in the list convey a message to you ?

7) question: is the order of the items in the list important to you?

8) question: do you like the order of the items in the list?

9) question: what order would you put the items in the main list ?
drug treatment_____
health advice_____
management advice_____
cardiovascular risk_____
critique_____
interactions_____

10) question: what order would you put the items in the health advice list ?
weight_____
cholesterol_____
alcohol_____
salt_____
smoking_____
exercise_____
hormone therapy_____

11) question: would you prefer the items in the health advice list to be incorporated into the main list?

DRUG TREATMENT MODULE

12) question: is the summary of the patient data useful ?

13) question: what patient data would you like on this screen ?

14) question: is the order of the drugs in the display important to you ?

15) question: do you like the order of the drugs in the display ?

16) question: does the order of the drugs in the display convey a message to you ? (e.g. importance / ranking)

17) question : what order would you put the drugs in the display ?
beta blocker
diuretic
calcium antagonist
ace inhibitor
vasodilator
alpha blocker
centrally acting

18) question: is it obvious from the presentation of advice which drugs have been recommended and contraindicated ?

19) question: are there any drugs missing from this list which you would like to see included?

20) question: In this instance, do you agree with the advice ?

21) question: How confident are you in the accuracy of the advice a system such as this can generate?

22) question: Would it be useful to be able to alter the data in front of you, if for example you suspected another concurrent problem, and then ask the computer for another treatment recommendation?

_____
_____
_____

Looking at the items in the list of concurrent problems.

23) question: is the order of the items in the list important to you?

_____
_____
_____

24) question: do you like the order of the items in the list?

_____
_____
_____

25) question: does the order of the items in the list convey a message to you ? (e.g. importance / ranking ?)

_____
_____
_____

26) question: would you like to suggest an order for the items in this list ?
previous MI_____
cardiac failure_____
lvh_____
left ventricular dysfunction_____
angina_____
ischaemic heart disease_____
bradycardia_____
heart block_____
sick sinus syndrome_____
peripheral vascular disease_____
atherosclerotic disease_____
renal failure_____
renal insufficiency_____
raised creatinine_____
renal arterial disease_____
diabetes_____
reduced glucose tolerance_____
dyslipidaemia_____
asthma / bronchospasm_____
COAD_____
migraine_____
depression_____
gout_____
impotence_____

27) question: are there any diseases missing from this list which you consider to be significant in the treatment of a patient with essential hypertension (diseases which would effect your selection of antihypertensive treatment.).

28) question: would you like to make any other comments about this screen ?

From this screen you can access a screen which gives reasons why the computer has generated this specific treatment advice for the patient.

29) question: is it important to you that a system can explain its advice ?

30) question: does the fact that the system provides explanations for its treatment advice improve your confidence in the value / accuracy of the advice generated ?

REASONS SCREEN

31) question: does the explanation make sense to you as a doctor ? (do you understand the explanation?)

32) question: in this instance, do you agree with the explanation ?

33) question: do you have confidence that the explanation is correct / accurate ?

34) question: do you have greater confidence in the advice knowing which references support the advice ?

35) question: how would you like the explanation to be presented ?

36) question: would you like to make any other comments about this screen ?

HEALTH ADVICE

37) question: what are you reactions to this module?

38) question: do you like the idea of discreet modules or do you find this cumbersome and time consuming?

39) question: can you envisage using such a module in your normal working pratice.

MANAGEMENT ADVICE

40) question: is the summary of patient data shown here sufficient ?

41) question: what additional patient data would you like to see ?

42) question: do you think that this is a useful feature of a decision support system for essential hypertension.

43) question: can you envisage yourself using such a system?

44) question: the information this module provides is taken from the world health organisation flow charts.....would it be useful to provide a diagram of this flow chart here ? (an additional button, which contains a screen with a diagram?)

45) question: do you feel more confident in the advice, knowing the source of the advice (WHO 1993) ?

46) question: would you like to make any other comments about this screen ?

CARDIOVASCULAR RISK MODULE

47) question: would you consider using a module such as this ?

48) question: you can change the patient data in this screen (e.g. smoking to non smoking, or raise or lower the bp or cholesterol), and ask the computer to generate another cardiovascular risk. do you think you would ever do this ?

49)question: how confident do you feel that the system is generating a correct answer?

50) question: do you feel more confident knowing the source of the advice (Anderson 1991) ?

51) question: In your opinion how useful is it to know the cardiovascular risk of a patient with essential hypertension ? and, does this effect your management ?

52) question : would you like to make any other comments about this screen ?

CRITIQUE MODULE

53) question: can you envisage yourself using such a module as this ?

54) question: if you were to use this module, would you use it:-

a) with the patient
b) before seeing the patient
c) after seeing the patient
d) some other time (please specify)
e) in conjunction with other members of the health care team.

55) question: does the explanation make sense to you as a doctor?

56) question: in this instance, do you agree with the explanation ?

57) question: do you have confidence that the explanation is correct ?

58) question: do you have greater confidence in the advice knowing which references support the advice ?

59) question: how would you like the explanation to be presented ?

60) question : would you like to make any other comments about this screen ?

INTERACTIONS MODULE

61) question: can you envisage yourself using such a module as this ?

_____

62) question: if you were to use this module, would you use it:-

a) with the patient
b) before seeing the patient
c) after seeing the patient
d) some other time (please specify)
e) in conjunction with other members of the health care team.

63) question: does the explanation make sense to you as a doctor?

_____
_____

64) question: in this instance, do you agree with the advice ?

_____
_____

65) question: do you have confidence that the explanation is correct ?

_____
_____

66) question : would you like to make any other comments about this screen ?

_____
_____
_____

GENERAL QUESTIONS

67) question: is the advice generated quickly enough? _____

68) question: could you envisage using this system if it was incorporated into your existing clinical information system?_____

69) question: which modules would you use routinely ?

a) drug treatment
b) health advice / patient education
c) management advice
d) cardiovascular risk
e) critique
f) interactions

70) question: what other types of advice would you like to see provided to assist a gp in the treatment of a patient with essential hypertension.

_____
_____
_____

71) question: thinking back to the first drop down menu showing the hypertension decision support modules, would you like to suggest any different words to describe the decision support functions?

drug treatment_____
health advice - weight_____
- cholesterol_____
- alcohol_____
- salt_____
- smoking_____
- exercise_____
- hormone therapy_____
management advice_____
cardiovascular risk_____
critique_____
drug interactions_____

72) question: overall do you find the system easy to use ?

_____
_____
_____

73) question: overall do you find the advice is useful ?

_____
_____
_____

74) question: overall is the way in which the advice presented acceptable to you as a doctor?

_____
_____
_____

75) question : would you like to make any other comments about this system?

_____
_____
_____

12. Appendix 3

12.1 Summary of Input Devices

Class of Device	Specific Example	Description	Key Features
Keyboard	QWERTY	Uses the most common arrangement of alphabetic keys.	Required when the data to be input are highly variable. Many people are trained for using it. Very slow for those not trained.
	Dvorak	Similar to the QWERTY keyboard, but keys allow for more efficient input.	People familiar with the QWERTY keyboard need retraining.
	Alphabetic	Similar to the QWERTY but with the arrangement in alphabetical order.	Often thought to be suitable for people untrained in keyboard use, but tests show that it is no faster for an untrained user to locate a letter than either of the two previous keyboards.
	Chord	Various arrangements. To form words (usually in a short hand type notation), several keys are pressed simultaneously.	Can be extremely fast when used by a trained operator. Often used to record transcripts of court hearings, Parliament etc. Requires training to use and to read the output.
	Numeric	Number keys, arithmetic operator keys, decimal point and enter key.	Good for very fast keying of numeric data. Trained operators can reach a very high speed. Untrained users find it easy to use.

Automatic scanner	Bar code reader	Pen or gun like device that 'reads' black and white printed or magnetic bar codes when passed or held over them. Versions also exist that are embedded into work surfaces.	Suitable where the amount of data is limited and is not subject to rapid change (e.g. ID numbers such as product codes). Requires constant user operation with one or both hands. May also require one hand to hold the object.
	Optical character reader (OCR)	Device that reads characters automatically.	Can handle a variety of data. Characters need to be well formed (handwritten characters may be misinterpreted). No user involvement required once the documents have been positioned.
	Document reader	High speed scanner that reads whole pages.	Useful for inputting large amounts of text.
	Magnetic ink character recognition (MICR)	Device that interprets characters written in special ink.	As for OCR, but more reliable.
	Optical mark reader (OMR)	Device that detects the position of marks made on documents	Specially designed forms are required so that the marks are correctly located. No user involvement is needed once the marks have been made.
Dataglove		Wired glove that allows the wearer to grasp objects in 3D space.	Used for manipulating objects and gesturing. The range of task possibilities is currently being explored.

Footmouse		A form of pedal that pivots.	The direction in which the pedal is moved causes a cursor on the screen to move correspondingly. Suitable for coarse movements. Leaves hands free for other tasks.
Gesture devices		Small transmitting device held by the user and a receiving device associated with the computer.	The receiving device places the position and movement of the transmitting device in space. Facial gestures may be used in conjunction with speech systems for confirmation of requests.
Graphics tablet		Flat panel that is placed on a table near the computer display. The tablet surface represents the display.	Movement of a stylus or a finger across the surface causes a cursor to move across the screen or a line to be drawn. Very good for graphical input.
Joystick		Small stick that can be moved in any direction within a fixed socket.	Often used to position a cursor. Requires a high level of concentration. Fine control is limited where fine grip is not possible.
Light pen		Pen that emits a light beam when a button is pressed.	Good for pointing and simple input. Has to be used against a vertical plane, so is not always very accurate. Difficult to use where grip is weak.

Mouse		Continuous input device that has one or more buttons for discrete input. Unlike the trackball or joystick it is not fixed, so the user can move it around on a flat surface.	The most common and popular of these devices. Highly versatile. May be optical, in which case a special pad must be used to track movement. Objects are manipulated by pressing control buttons embedded in the mouse.
Touch-sensitive screen or tablet		Special screen that detects the position of a finger touching it.	Relatively 'vandal-proof' and cannot be removed. Needs frequent cleaning. Very easy for people without any prior computer experience to use.
Trackball		Rotatable ball embedded in a surface in a fixed socket.	Can be moved by drawing the fingers or the palm of the hand over the surface, or by flicking. Less force is required than for a joystick. Fast, and does not require a good grip for accurate use.
Video		Video camera and digitizer for recording pictures.	Necessary if video images are required.
Speech recognition	Isolated word recognition	Can deal only with individual words	Limited vocabulary. Pauses between words must be longer than normal. Users need training.
	Continuous speech recognition	Can recognise words within strings of words	Less limited vocabulary, but works by recognising words from a continuous stream of speech. More prone to error

			than isolated word recognition systems but does not require special training of users.
	Speaker dependent	Can be used by individually identified speakers only.	System must 'learn' to recognise the speaker, who must 'train' the system. Easier to implement and more secure than speaker-independent systems, but may still have problems, e.g. if a speaker has a cold.
	Speaker independent	Attempts to deal with all users.	Attempts to deal with a wide range of vocal and speech characteristics. More difficult to implement and more prone to error than speaker dependent systems.
Eye and head movements	Electro-physiological sensing	Records muscle movement.	Electrodes have to be secured to the skin to detect muscle movement and are therefore subject to general body movement. May be uncomfortable and confining. Not well suited to the tracking of very small targets or to fine control.
	Photo-electric reflection	Records movements in reflected light from the eye.	User must maintain a stable image on the central part of the retina. This is not easy to achieve. Not well suited to the tracking of very

			small targets or to fine control.
	Head movement tracking	Light weight headset similar to a telephonist's. Transmits ultrasonic signals to a measurement unit on top of the computer.	The keyboard is a display on the screen of a computer. The system detects slight movements of the user's head and moves the cursor accordingly. To operate a key, the user locates the cursor on the key and then blows on a blow switch (a switch activated by a burst of air) in the headset 'mouth-piece'. This device can be used by even severely disabled people.

12.2 Summary of Output Devices

Class of Device	Specific Example	Key Features
Visual output	Microfiche or microfilm	Card sized rectangle of film which records frames in a grid (fiche) or a continuous strip of film with frames. Each frame is equivalent to a sheet of paper. Suitable for longer term storage of high volume data. Requires magnifying readers and special equipment to make copies.
	Plotter	Used for producing diagrams, maps and other precision continuous output. Can often produce coloured output through the use of different pens.
	Printer	Many kinds available. Dot matrix and character printers vary greatly in quality of printing. Inkjet and laser printers offer high-quality output but may be expensive. Some printers provide colour.

	Visual display unit (VDU)	VDU's vary in their ability to display colour and in the resolution and quality of the characters and graphics displayed. Some types of screen are not easily adaptable to graphics output or provide only one character type.
	Video	Video output is now becoming available and promises to have a big impact. For example, error messages and instructions can be issued by a video of a person talking to the user rather than by a cryptic message.
Non-visual output	Speech output : concatenation	Segments of human speech are recorded digitally and later re-assembled and played back to produce the desired words and sentences. Tends to be limited to applications requiring vocabularies of fewer than 200 words. Examples include the speaking clock and information such as details about changed telephone numbers and call diversions.
	Speech output : synthesis by rule	The synthesis of words and sentences is dictated by rules of phonemics and rules that relate to the context of a sentence or phrase. Used in conjunction with a database this method has the potential to produce a much larger range of responses than speech produced by concatenation. Pitch and tone can be varied but the speech produced can sound synthetic.
	Electronic forms of output	Includes output on disk, digital transmission of messages and facsimile transmission direct from a computer.
	Tactile output	Output using the sense of touch (e.g. Braille) is of particular interest to blind users.