An Ontological and Epistemological Paradigm for Clinical Decision Support

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ABSTRACT

This thesis sets out to test the central hypothesis that the paradigm for clinical decision support needs to shift from a technology centred paradigm to a coherent ontological-epistemological paradigm. This was achieved by formalising a coherent ontological and epistemological framework, and then applying it practically to clinical decision support.

Initially the thesis reviews the need for a coherent philosophy in clinical decision support. It then goes on to describe the systematic analysis of established fundamental principles of philosophy, and the formalism of the ontological and epistemological framework. Following this the framework is applied to an analysis of clinical decision making and clinical decision support. The models derived from the analysis are then applied practically to the modelling of the management of acute renal failure patients in the intensive care setting. The results of this modelling are then combined with the decision models as the basis for the structure of a model of the decision making which controls the patient's renal replacement therapy. Finally the models representing the clinical problem and the clinical decision making process are used in the design and development of a prototype renal replacement therapy management system.

The thesis concludes that a coherent ontological and epistemological framework provides clarity and insight during the analysis for and design of clinical decision support tools. The contributions of the thesis relate to the derivation and application of the framework, and the development of the renal replacement therapy management system. Thus the thesis is a foundation for future research in these two areas.

CHAPTER 1

INTRODUCTION

1.1 BACKGROUND

The idea of using computer technology to support the medical decision making process first appeared in articles published in the late nineteen fifties, and experimental prototypes soon followed (Shortliffe, 1987). Shortliffe (1987) defined a decision support system as any computer program containing clinical data or medical knowledge designed to support medical decision making. The original concept of clinical decision support and the articulation of its meaning by Shortliffe reflects a technocentric view in the field. This view has led to many prototype decision tools being developed but an apparent failure to introduce decision support tools widely into medicine (Shortliffe, 1993). This in turn has led to the conclusion that a more problem centred approach is required in clinical decision support development (Coiera, 1995). Heathfield and Wyatt (1993) concurred with this view and proposed that a coherent philosophy was needed to better understand the problem domain, and to broaden the perspective on the development of clinical decision support. However, no such coherent philosophical foundation exists in the domain of clinical decision support. Therefore, if the role of a coherent philosophy in clinical decision support is to be examined it must first be constructed and then applied in the development of an application specific support system. Where the development of a clinical decision support system provides a practical source, application and test for the philosophical framework.

The management of acute renal failure in the intensive care setting requires accurate fluid balance calculations, and expertise in the management of fluid, electrolyte and acid-base balance. The provision of decision support as an source of decision advice in the management of acute renal failure in the intensive care setting is a novel problem. Thus,

developing such a tool using a problem centred approach provides the opportunity for applying and developing the philosophical framework, in addition to making a contribution to the development of decision support for the management of acute renal failure in intensive care.

1.2 HYPOTHESIS

The central hypothesis of this thesis is that the paradigm for clinical decision support needs to shift from a technology centred paradigm to a coherent ontological-epistemological paradigm. The aim of the thesis is to test this hypothesis by addressing the following objectives:

i) To construct a generally applicable philosophical ontology and epistemology as an holistic analytical foundation for clinical decision support.

ii) To apply the ontology and epistemology in an analysis of clinical decision making and of clinical decision support.

iii) To apply the ontological and epistemological framework to a clinical problem analysis, as the basis for the design of a clinical decision support tool.

iv) To analyse the clinical problem of management of acute renal failure patients in the Intensive Therapy Unit.

v) To produce a decision making model for the management of continuous venovenous haemodialysis therapy.

vi) To design and develop a clinical decision support computer tool for continuous haemodialysis management.

Through addressing these objectives the thesis presents a coherent ontological-epistemological paradigm for clinical decision support. Moreover, by presenting a

ontological-epistemological paradigm the intention is to make a contribution to the debate on the philosophical foundations for clinical decision support. Such debate and examination of the philosophical foundation of clinical decision support will produce insight into the field, and give a structure for drawing out knowledge from the development of application specific prototypes.

1.3 THESIS LAYOUT

Chapter two entitled "Reflections on Clinical Decision Support" gives the justification for the philosophical framework developed in the thesis. To achieve this aim the objectives of chapter two are:

i) To give a classic definition of clinical decision support (CDS).

ii) To review the current status of the field of CDS.

iii) To highlight inherent problems prevalent in CDS.

iv) To question the assumptions at the basis of CDS.

v) To justify the need for a coherent philosophical foundation in clinical decision support.

The aim of chapter three, "Ontological and Epistemological Framework for Clinical Decision Support", is to construct an ontological and epistemological framework for clinical decision support. The objectives of the chapter are:

i) To present an analytical structure linking philosophy, methodology, method, techniques and tools

ii) To present a systematic review of the relevant fundamental concepts of philosophy which are used to construct the ontology and epistemology.

iii) To use concepts of philosophy to construct an ontology and epistemology as the basis for an analytical framework in CDS.

iv) To apply the ontological and epistemological concepts to CDS.

v) To characterise the multi-disciplinary nature of CDS in terms of the nature of science, technology and medicine.

vi) To state the ethical codes defining good clinical behaviour.

In Chapter four, "Decision Making and Decision Support", the ontology and epistemology are applied to an analysis of decision making and the role of decision support in the process of decision making. To this end the objectives are:

i) To develop an ontological, epistemological and process model of decision making.

ii) To analyse the clinical decision making process.

iii) To develop a model of the process of rational clinical decision making.

iv) To propose a technique for analysing clinical treatment decisions.

v) To build a conceptual model of clinical decision support with an ontological and epistemological basis.

vi) To define clinical decision support in terms used in the decision analysis.

The Clinical Problem Assessment, chapter five, defines the material clinical problem to be addressed by the introduction of a clinical decision support system. The objectives of the chapter are:

i) To specify the clinical problem as presented by clinicians.

ii) To present the clinical domain knowledge required in the analysis of the clinical problem.

iii) To produce a systems analysis of the clinical problem.

Clinical Decision Making, chapter six, produces a model of the decision making managing a patient's continuous venovenous haemodialysis treatment (CVVHD). The objectives are:

i) To apply the model of clinical decision making to the problem of clinical decision support in the management of renal failure in intensive care.

ii) To produce a protocol for making the CVVHD treatment decisions, and for qualitatively assessing the patient and treatment states.

Chapter seven describes the prototype computer system design and development, and seeks to satisfy the following objectives:

i) To specify the system requirements.

ii) To produce an integrated system design for a complete ITU patient data management system, incorporating the design for a CVVHD decision support system.

iii) To design and develop a prototype information system for the management of an ITU patient's fluid balance.

iv) To specify the other modules required in the information system.

v) To implement the CVVHD treatment decision model using a programming technique which allows for a natural representation of the model.

Chapter 8, the discussion chapter, discusses the main points relating to philosophy,

methodology, method, technique, and tool application in each of the thesis chapters. Finally the conclusion, chapter 9, gives a brief assessment of how the objectives have been met, the contributions made to knowledge, and the possible future directions for the work described in the thesis.

CHAPTER 2

REFLECTIONS ON CLINICAL DECISION SUPPORT

2.1 INTRODUCTION

In the previous chapter the idea that work in the field of clinical decision support (CDS) specifically, and medical informatics in general, has reached a reflective stage was introduced. It is the aim of this chapter to examine this idea in more detail and to justify the need for a coherent philosophy in CDS.

A number of published papers have discussed the reflections on what clinical decision support is and its possible future development. The content of a selection of these papers is summarised below in sections entitled: current status of clinical decision support, and foundations for clinical decision support.

2.2 CURRENT STATUS OF CLINICAL DECISION SUPPORT

Clemmer and Gardner (1992) stated that, "The intent and purpose of medical informatics is to strengthen and improve decision making and patient care." The attempts to improve decision making and patient care have included the development of computer based clinical decision support systems. This use of computer programs in clinical decision support has led to a technology-centred view of CDS. A key paper defining clinical decision support and its characteristics from a technological viewpoint is Shortliffe (1987) which is summarised in section 2.2.1. Another technological view of the current status of and the possible future for artificial intelligence in medicine is given by Shortliffe in "The adolescence of AI in Medicine: Will the field come of age in the '90s?" (Shortliffe, 1993). In "Medical Informatics" Coiera (1995) suggests that there is a need to move away from

the techno centric view of clinical decision support and develop a deeper understanding of the clinical problem domain. In "The role of knowledge based systems in clinical practice", Coiera et al. (1994) goes on to suggest that from a better understanding of the problem domain better user interfaces will result and the educational use of CDS will be realised. The need for a deeper understanding of the problems inherent in the clinical domain is further suggested in the views of physicians on the potential role of CDS in medicine considered in Shortliffe (1989).

2.2.1 Computer Programs to Support Clinical Decision Making. (Shortliffe, 1987)

In this paper Shortliffe offers a definition, used by others (e.g. Miller, 1993), of a medical decision support system (MDSS). MDSS is broadly defined as any computer program designed to help health professionals make clinical decisions. The underlying computer technology used does not affect the categorisation of a computer program as a MDSS. The focus of the definition is that the system should support the clinical decision making process. The decision making processes identified as being generally supported are determining the nature of a patient's disease state, and formulating a plan for reaching a diagnosis or administering therapy. No more detailed description, or model, of the nature of the clinical decision making supported is given in the paper. In an elaboration of the broad definition Shortliffe focuses on the contents and functionality of the computer system. He goes on to state that any computer that deals with clinical data or medical knowledge is intended to provide decision support. The functionality of such a computer system is then broken down into three categories:

i) Tools for information management; for example hospital information systems (HIS) and bibliographic reference sources such as MEDLINE. Information management tools provide the data and knowledge needed by the clinician, but they generally do not help the user to apply that information to a particular decision task. Interpretation is left to the physician as is the decision about what information is needed to resolve the clinical problem. Therefore there is no direct decision advice offered by information management tools.

ii) Tools for focusing attention. Examples include clinical laboratory systems that flag abnormal values and pharmacy systems that advise on possible drug interactions. Such programs are designed to remind the physician of diagnosis or problems that may have been over looked. Thus there is some in-built simulation of decision reasoning and general decision making advice output.

iii) Tools for patient specific consultation. These tools provide customised assessments or advice based on sets of patient specific data. The output of the system is defined in the paper as being either diagnostic or treatment advice for the patient.

Systems of types (i) and (ii) are reported to be operational and commercially available. Whilst the commercial production of the third category of MDSS has not yet matched the production of the first two categories, and it is the development of this type of MDSS that has been the focus of much of the research in the field. To more precisely categorise the third category of decision support tools Shortliffe proposed four further classification criteria:

i) System function, could be either: diagnostic, what is observed to be true about the patient's state, or action guidance, where the action advised could be either a monitoring or treatment action. With regard to the diagnostic decisions, it was reported that many physicians believe that, given a fixed data set, the majority of questions about which they seek consultation deal with what they should do rather than with what is true about the patient. If this belief is accepted as true this implies there is a greater need for action advice systems.

ii) The mode for giving advice; this can be either passive where the clinician goes to the machine and seeks advice, or the machine can actively initiate advice when new data are detected. The second mode of operation has been found to be preferable and relies on the integration of the database function and the decision support function.

iii) Consultation style; this is described as either consultative or critiquing. Passive

decision support systems operate as either consulting, where the program serves as an advisor in response to user enquiries, or critiquing, where the user inputs their own plan for the patient and this is then agreed with or disagreed with using reasoned justification. The critiquing system acts as a second opinion on the proposed action of the clinician. In the active advice mode described in point two the critiquing model can be applied to say drug prescriptions input by the clinician.

iv) Underlying decision methodology. This includes: problem specific algorithms, generally designed by clinicians and then encoded for computer use; Bayesian statistics, these have been used extensively in diagnostic systems; decision analysis adds to Bayesian statistics the notion of decision trees and utility associated with the outcomes that could occur in response to an intervention; and the computer science subfield known as artificial intelligence, in particular expert systems which contain encoded expert knowledge to provide the kind of problem analysis and advice an expert might provide.

Research into producing patient specific advice tools has been continuing for many years, the first papers on the subject of having a computer system to act as a patient specific diagnostic tool appeared in the late fifties. However, despite more than thirty years of research computer-based tools for patient specific advice are not commonly used on a routine basis in medicine. A possible reason for this could be that the complexity of the problem domain and the technology required has been underestimated.

One of the major problem areas for CDS development was labelled human factors by Shortliffe. For example, it has been shown repeatedly that an ability to make correct diagnosis or to suggest therapy similar to that recommended by human beings is only one part of the formula for system success in CDS. One of the categories of human factors identified was logistical problems, such as the placement of a machine, ease of software use, and integration of data stores. These factors are important as it is unlikely that a physician will use a system which places a high data entry burden on them, or which is placed in a remote location. Another human factor centres on the mechanical issues at the user interface; the use of keyboard based interfaces is viewed as an unpopular option, and

it would be better to have a more intuitive interaction. The third human factor identified was the psychology of human-computer interaction: of particular importance is the ability of programs to explain their advice. It is reported by Shortliffe that there is evidence that an explanation capability is mandatory to encourage physicians to use decision support tools. Enough information should be provided to allow the physician to determine whether the computer generated advice is likely to be valid for the patient under consideration. Providing justified advice also gives a CDS system educational potential.

In a later paper (Shortliffe, 1994) ubiquitous computing was identified as a possible way of addressing the problems related to the human-computer interaction. The concept of ubiquitous computing describes a situation where computers become part of the intrinsic world around us. One technique for achieving this goal is to design the structure of a system so that it is a representation of the way people actually work and think. Using such a representation in a system is thought to facilitate a natural communication between the computer and the user. To build such a ubiquitous system the mechanical and psychological issues previously identified by Shortliffe will have to be addressed; in addition to models of clinical working practices and decision making.

Another major problem area in CDS is system evaluation. This is particularly true for expert systems as it is difficult to determine acceptable levels of performance. The technique of using a group of experts to perform an evaluation is inherently problematic, as there may be disagreement even among experts with similar training and experience. This problem is summed up by Shortliffe as there being no such thing as *the* correct answer to a clinical question. Thus the problem of evaluating a system in to demonstrate its effectiveness is a fundamentally difficult one if it must be accepted that advice given by different experts is going to vary. Moreover, any expert system using an expert's knowledge will be unique to that expert, and will be disagreed with on some level by other experts. Thus, it is a problem which goes to the root of the nature of medicine, and any evaluation of a system should include consideration of the differences in expert opinion.

Despite the problems with CDS development Shortliffe believes that the time is now right for expansion in medical informatics because of:

i) The growth in microcomputers and easy-to-use software

ii) The growing distress among health professionals regarding the amount of information they need to practice medicine.

iii) The increasing fiscal pressure that encourages the practice of cost effective medicine, thereby leading clinicians to consider carefully the clinical utility and reliability of tests, procedures, and therapies. This is particularly true when the commitment of resources is expensive or risky.

Thus there is the belief in a growing capability to provide computer based decision support tools and an increase in the potential demand for their services. Having examined Shortliffe's ideas on the what clinical decision support is, and some of the problems associated with human factors in system design, the next paper reviewed describes Shortliffe's later reflections on CDS.

2.2.2 The Adolescence of AI in Medicine: Will the Field Come of Age in the '90s? (Shortliffe, 1993)

In this paper Shortliffe examines the role of artificial intelligence (AI) in medicine and how it may develop in the future. In the twenty years of AI research in medicine there seems to be a failure to introduce AI tools widely into medicine. How this apparent failure may be overcome has lead to many questions being asked about the role of artificial intelligence in medicine (AIM). In fact the general atmosphere in the field is one of self examination, as witnessed by questions raised on the AI in medicine mailing list. These include questions concerning the nature of AIM, the role of decision making models in clinical decision making, the criteria to be used for judging the success of AIM, and the resolution of technical difficulties in AIM development.

AIM is part of medical informatics (MI), and MI exists at the crossover of a number of disciplines, each one with its own experts. This interdisciplinary nature of medical informatics requires a willingness to be eclectic, and to avoid "religious" dedication to any single technique or set of approaches. Shortliffe sums this up thus, "it is in the synergies between AI methods and other techniques that the greatest hope for effective systems may lie." So in Shortliffe's view the development of the field of AIM relies on the eclectic consideration of different ideas and the bringing together of these ideas to satisfy the aims of AIM research. The aim of AIM research is defined as developing tools which enhance the effectiveness of clinical decision making, but which do not replace physicians or offer dogmatic (unreasoned) advice. As with his broad definition of clinical decision support in the first paper the emphasis is on supporting the clinical decision making process.

To enhance the effectiveness of clinical decisions an understanding of the clinical decision making process is required. At present there is remarkably little emphasis on problem solving processes in medical education; the emphasis is on learning medical facts. Yet in Shortliffe's part time clinical practice he finds decision analysis methods and problem solving techniques useful. As an educator he finds simple models of decision making are good for getting the message across, in particular he finds the hypothetico-deductive approach eminently teachable. These experiences seem to indicate that models of decision making could be useful in clinical practice and in support of effective decision making built into decision support systems.

Much of the reflection on the role of AIM stems from its apparent lack of success. In judging success it is pointed out that the criteria used to make the judgement have to be carefully selected. Moreover, AIM research efforts require intermediate goals in the move towards the long term goal of an impact on the effectiveness of patient care. Thus there are many incremental steps of knowledge building to be done before reaching the final solution of an up and running clinical system. Furthermore it was pointed out that formal evaluations of the impact of systems on patient care do require careful consideration and planning, and thus they can distract a research team from development and ongoing system refinement.

The main conclusion of the paper concerns a technical issue in AIM. This is that the limited success in the use of AIM is due to a failure of integration more than any other factor. Thus the existence of an integrated network approach to AIM design is viewed as the main priority. One of the biggest reported problems for the use of past systems is that systems have been designed for single problems and have generally not been integrated into the routine data-management environment of the user. The belief is that physicians will be attracted to computers when they are useful for essentially every patient and when the metaphor for system use is consistent across the varied applications that are offered. So before progress can be made in the field an integration of all patient data management systems (PDMS) and knowledge based systems (KBS) is required. Without the integrated infrastructure in place Shortliffe believes there can be no progress.

This view is a commonly expressed one and it is undoubtedly a technical issue which will have an impact on the use of AIM systems. However, other non-technological issues were articulated by physicians in research described in another paper (Shortliffe, 1989) reviewed in section 2.2.5. Thus it is important to balance Shortliffe's strong conclusions about the significance of an integrated infrastructure against the significance of other non-technological problems that are inherent in CDS.

2.2.3 Medical Informatics (Coiera, 1995)

In this paper Enrico Coiera reviews the progress of the information sciences in medicine. The main lesson he believes that the medical informatics community cannot ignore is that any attempt to use information technology will fail dramatically when the motivation is the application of technology for its own sake rather than the solution of clinical problems. Thus any CDS project must be lead by a clinical problem rather than a technology looking for a clinical application. This implies an understanding of the clinical domain must come before the solution is proposed, be it a technology based solution or not.

From taking the problem centred approach it is pointed out that the potential role of informatics in medicine is vast with the possibilities of studying all the facets of information in medicine. This includes the application of information technology (IT) in

medicine, but it is not exclusively the use of IT in medicine, since medical information and knowledge exist regardless of the use of IT. The possible applications of informatics highlighted include: the design of decision support systems for practitioners; the development of computer tools for medical research; and in the study of the very essence of medicine, its corpus of knowledge.

2.2.4 The Role of Knowledge Based Systems in Clinical Practice (Coiera et al., 1994)

In this paper Coiera specifies guidelines consistent with the problem centred approach recommended in the previous paper. The lack of the utilisation of clinical diagnostic systems led Coeira to recommend the following guidelines for the development of CDS systems in general, and KBS systems in particular.

- There is a need to refocus on the clinical user when developing knowledge based systems (KBS) for clinical practice. Thus during development KBS designers should support clinicians requirements rather than dictate their work practices.
- Designing good user interfaces is not simply a *post hoc* cosmetic nicety, it depends critically on a deep understanding of the problem domain that must be developed prior to commencing system design. The implications of user interactions cannot be conceived of independently of the overall architecture of a system.

- KBS should focus on supporting the patient management process in its entirety not just the diagnostic stage.

- There is a need to build working applications today as well as conducting our research.

- Education for most clinicians is an ongoing process intimately woven into clinical practice. Decision support systems should be built with this type of support in mind, i.e. they should support the education of the user.

Of particular interest is the view that the user interface depends on a deep understanding

and representation of the problem domain. Implied in this is that it is not sufficient to merely have a fancy graphical user interface bolted onto a poorly designed system. Also of note is the potential role of CDS in educating physicians whilst they are practising. Using CDS systems at the point of care has the potential for extending formal education whilst clinicians are practising by encapsulating clinical knowledge and offering it to the user when required during practice. Thus the potential educational role of CDS is an important consideration when developing reasoned justification in a patient specific advice system.

2.2.5 Testing Reality: The Introduction of Decision Support Technology for Physicians (Shortliffe, 1989)

This paper presents a summary of a market research project conducted in cooperation with a pharmaceutical company. The research consisted of six two hour discussion groups amongst six to ten physicians. Consideration of the comments made by physicians is particularly important if CDS systems are ever going to move into routine use. Some of the concerns raised express fears about the way computers could change their working practices. Other issues raised describe problems for CDS related to the very nature of clinical decision making. Finally there are issues raised which support the view that there is a need for the increased use of information technology in medicine.

The fears expressed by the clinicians included:

i) Fear of loss of rapport with the patient. This stems from the fear that a computer would act as a barrier between the physician and the patient, causing the interaction to become impersonal.

ii) Fear of loss of control. Clinicians do not want to be told exactly what to do on all occasions. Their preferred model seems to be to have access to second opinion when they want it.

iii) The fear of change. There is resistance to the introduction of computer based

systems which appear to be largely experimental. The attitude seems to be summed up by a feeling of why should they invest time and effort making changes when what they have now is working.

iv) Fear of legal liability if advice on what action to take is not followed and then a bad outcome results. Or alternatively if the advice offered is complied with and a bad outcome results then the question of who would be liable is another legal problem.

The problems with CDS highlighted which go to the very nature of clinical decision making were expressed in the following points:

i) The belief is that if a problem is messy and difficult to understand and solve for a clinician then surely it will be so for a computer system. Leading to the conclusion that the computer system will not be able to help the physician when faced with a messy problem situation. A quote from one of the physicians in the session summarises the point, "So I think those of us who use database searching use it to retrieve information which we then add to on the basis of things we know and have observed, using thought patterns we can't really quantify or describe so we can't expect the machine to handle it."

ii) There is suspicion of the concept of artificial intelligence, and in particular expert systems. The concerns raised question the very concept of expertise, "(Medical) 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. Having their views distilled in a machine wouldn't give them any more credibility.... When you find an expert who will talk on any one field, you can find another expert who will say something a little different." This quote is consistent with Shortliffe's (1987) point in the above paper where he says that there is no one right solution to a clinical problem.

iii) There seems to be a pervasive attitude in the medical profession towards the use of technology in clinical practice which is summarised by two quotes.

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

(b) "Doctors are resistant to some things but not to something that's easy and useful. You make it easy and useful and great, we'll use it. The problem is to have a computer deal with this huge vast area of knowledge and to expect us to trust what's coming out of that box... But if it saves time and money, doctors will love it."

These quotes seem to make it clear that if a useful, intuitively operated system could be produced then doctors would use it. The problem then is defining and designing a useful and intuitive system.

The issues supporting the perception of the need for information technology were expressed in the following views:

i) The chaos of chart control. Hard copy paper patient records get lost and can be difficult to locate. This is particularly true for patients in large hospitals who have to be seen by a number of different specialists. In the sessions reported in the article this problem did not seem to immediately promote computer databases as a possible solution.

ii) Physicians have a thirst for new information. The need for improved access to current information that is pertinent to quality diagnostic and management decision making was recognised in the article. The use of easily available on line services, such as those evolving on the Internet, are a possible integral solution to this problem.

The problems raised in the paper related to the operation of clinical decision support systems were:

i) Decision support is viewed by some as a dogmatic dictator telling the doctor what to do. A reasoned second opinion is an essential for the operation of a CDS system.

ii) Data entry is a barrier to the use of systems, particularly for writing a patient's history, doctors don't like keyboards. Having a speech driven interface is seen as an important requirement for overcoming this barrier and having usable systems.

The broad range of issues raised above demonstrates the breadth of the field and the complexity of the domain the systems are to be applied in. In particular the complex nature of the clinical field CDS is to be applied in is raised. The need for, and the form of, a foundation to CDS which unifies all the complexities of clinical decision support and which an understanding of the clinical domain can be built on is reviewed in the next section.

2.3 FOUNDATIONS FOR CLINICAL DECISION SUPPORT

Included in the papers reviewed above is Shortliffe's (1987) definition of decision support. The focus of his definition is the computer programs used as decision support tools. This reflects the technology centred view of CDS. This view has led to much of the focus for the future development of clinical decision support being on the technology required. Indeed in the Shortliffe (1993) paper (section 2.2.2) his view of the future development of CDS is that it depends absolutely on an integrated network approach to CDS design. If computer based decision support tools are to be developed undoubtably this and other technological issues do need to be addressed. However, from the other papers reviewed it is apparent that there is a growing realisation in the CDS field that a deeper understanding of the clinical problem, and the role of CDS in addressing these problems, is the primary requirement (Coiera, 1995). Thus when considering the concept of decision support systems there is the need to take a more holistic view of what a decision support system is and to study the system as a whole in order to design effective decision support tools. After all any tool is only part of a larger system in which it is being used to satisfy a purpose. Moreover, the eclectic nature of CDS is complex; it includes elements of clinical medicine and information science. Thus there is a need to question the nature of CDS and from the

questioning to reach a better understanding of the foundations of CDS.

The remainder of this chapter reviews papers concerned with the philosophical questioning of the foundations of CDS, and with what form the foundations should take. In a paper entitled "Question the assumptions" Coiera (1994) examines strategies for examining the apparent failure of CDS systems. In another key paper by Heathfield and Wyatt (1993) they stated that there is no coherent commonly accepted philosophy to guide the development of clinical decision support. Moreover, their hypothesis is that the definition of a successful methodology for CDS would follow from a coherent philosophy. Heathfield and Wyatt's article provoked several editorial comments. Musen (1993) noted that a philosophy was needed that recognised the systems we hope to build are not isolated computer systems, but whole systems that include health care workers, patients, families, and computers. Thus there is a need for a philosophy which takes an holistic view of clinical decision support systems. J van der Lei (1993) expressed concerns about the form of medical knowledge, and how it could be represented and extracted in a CDS system. Particularly when it has been observed that medical decision making is characterised by a large degree of inter and intra observer variability. This raises the problem of what expert knowledge is and how to use it in CDS. Hence he views a future direction of CDS research being into the nature of medical knowledge and how it can be modelled, validated and applied in the clinical setting. If there was a coherent philosophical foundation for CDS then a strategy for addressing the problem would be through an epistemological study of clinical knowledge. Lanzola et al. (1995) based their generic architecture for a medical knowledge based system on an epistemological model; demonstrating that there is an acknowledgement that models based on philosophical concepts do have a role in CDS development. Szolovits and Pauker (1993) support this notion of having a good philosophy appropriately applied to broaden the horizons in CDS.

In Heathfield's and Wyatt's (1993b) reply to the editorial comments they make it clear that the objective of their paper was to make explicit the need for a systematic and objective review of the current status of CDS. Moreover, they felt that an holistic view of the field maybe required to solve some of the difficulties encountered so far.

The contents of the papers described above are examined in more detail below.

2.3.1 Question the Assumptions (Coiera, 1994)

In this paper two fundamental assumptions of CDS research are presented, and strategies proposed for examining the apparent failure of the CDS research to produce implementable systems. From an examination of the fundamental assumptions of CDS research it is suggested that the assumptions are not a sufficiently robust foundation for CDS research. Confirming the hypothesis that a deeper understanding of the problems CDS is attempting to address is required before being able to design technological tools to alleviate the problems. The two fundamental assumptions presented as forming the base of current research in CDS are :

i) Health care workers require assistance with decision making because they are either prone to error (not effective) or because their efficiency can be improved.

ii) Assistance with decision making can be provided by computer systems that "mimic or emulate at least part of the processes considered to belong to the human intellect".

According to Coiera's view these two assumptions have underpinned research into artificial intelligence in medicine for the last twenty years. During this time the extent of use of clinical decision support tools has not been as wide as originally expected. This leads to the obvious question of why this should be so. Coiera proposes three strategies for explaining the apparent lack of progress in CDS implementation: blame technological problems; question the observation that there has been a lack of progress in CDS, and question the assumptions that CDS is based on. A commonly adopted justification strategy is to explain away failure by blaming the technological tools that we have available to us. This leads to the following explanations and an approach to the problems of CDS of trying to invent bigger and more complex tools than already exist.

i) The decision support technology is immature, and more research is needed before

it is to have a significant clinical impact. This explanation leads to the view that more effort directed towards technological advance will solve all our problems.

ii) Technology is now adequately developed but we lack the appropriate informational infrastructure to support such systems. This is the view that everything depends on the database, without an integrated electronic medical record there can be no decision support. This is true, although holding up the lack of integration as the cause of all the problems with decision support is perhaps masking other causes of these problems.

iii) The third explanation given is that there is resistance to the use of technology within the health professions which requires them to be educated to its benefits, and perhaps to be directed to its use by management. Against this it is argued that clinicians do adopt new technologies where clinical benefit has been established. One of the inherent problems with producing clinical benefit is the complexity of the clinical workplace which requires rigorous systems analysis before any system can be deployed. Finally an important point raised by Coeira is that clinical reluctance to adopt technology says something about that technology, and that clinicians criticisms should be treated as a source of information for learning from.

The second strategy for examining the current difficulties in the field of CDS is to question the observation that CDS systems have not been successful. This was broken down into two explanations:

i) The observation is the wrong one, there are decision support systems which are in use. As evidence of this Coiera cites his list on the world wide web which describes CDS systems which have been reported to be in use. The list describes the current status of each system and gives an index of the systems in use under the headings: acute care systems; decision support systems; educational systems; laboratory systems; quality assurance and administration systems, and medical imaging systems. The majority of the systems identified as in routine use are classified as laboratory systems. In addition to the status listing a brief description of each of the

systems is also available at the web site. A print-out of the contents of the list entitled "Artificial Intelligence Systems in Routine Clinical Use" is included in appendix A.

ii) We have been measuring the wrong thing, our expectations were too high. In other words the wrong criteria have been defined for assessing the success of systems. The argument in this explanation is that it is not just the accuracy of the machine which is important it is the clinical outcomes which are important. Therefore, it is the change in clinical outcomes which should be measured. So, the criteria for measuring the clinical outcome need to be agreed and measured. Then if an improvement in the clinical outcome can be demonstrated the acceptance should follow, because doctors will adopt things which are felt to be useful.

The final one of the three tacks for explaining the apparent lack of success is to question the assumptions themselves. This begins with the proposition that the two assumptions about the needs of the health care workers are wrong. If this proposition is accepted then the CDS community has perceived the needs of clinicians wrongly. When trying to establish the needs for CDS systems, potential users of the system are asked what their needs are. Unfortunately users are expert in what they do but not in what they need. To overcome this problem it is suggested that what we need is to really understand the decision making process we seek to support, and then to understand how this process can be best supported. It is noted by Coiera that in the majority of cases the cognitive study of the problems faced by doctors has been poor. Coiera sums up the problem thus, "a fundamental understanding of the cognitive limitations we seek to support is lacking." When we understand the problems clinicians have in their work then we can better support their needs, but the support needs to be technically feasible. Therefore, it is important to match the technology to the problems found. It is postulated by Coiera that the reason why so many successful expert systems in medicine sit in clinical laboratories may well be that this is where the match for this technology is best.

The conclusion of the paper is that generally CDS research projects have a strong technical content, but are poor in exploring the human element the technology is intended to support.

The paper also reaffirms that it is time to move away from considering only the tool which offers decision support. In the next paper a possible philosophical basis is proposed for the development of CDS. This is based on the assumption that, "a philosophy that is natural for the solution of a problem, or a class of problems will lead to paradigms and models, followed by methods, mechanisms and tools that are consistent with the methodology." (Heathfield et al., 1991)

2.3.2 Philosophies for the Design and Development of Decision Support Systems Heathfield and Wyatt (1993)

This paper reviews the progress of decision support to date and proposes a unified philosophically-based approach to clinical decision support system development. Typically the major reasons given for the low rate of utilisation of clinical decision support systems are: technical difficulties with knowledge representation and reasoning with uncertainty over time; failure to integrate the CDS systems into the information systems of hospitals; and problems of human-computer interaction. The over emphasis on a particular reasoning method such as in AI, is considered by the author to be a contributor to low system utilisation. Another root cause may be that projects are merely theoretical investigations of the problems, not systems for implementation. This could be particularly true for short term projects such as academic research projects where the goals are often to get papers published or construct a PhD thesis. Thus the goals of CDS projects are not solely the implementation of a system. Indeed there are many topics to be studied in the field of CDS including the modelling of human reason in order to understand the process better, and to test the applicability of a new methodology or new concept in the domain (Miller, 1993).

If the goals of CDS projects are more complex than building implementable systems then the observation of the apparent failure in the field should perhaps be questioned as suggested by Coiera in the previous paper. In a similar manner to that proposed by Coiera, the technical explanations for the failure of decision support systems were no longer viewed by Heathfield and Wyatt as convincing due to the dramatic increase in processing power and storage capacity of computers, advances in GUI, and the increase in the number of HIS. Therefore, a prevailing view seems to be that it is not technical difficulties that are holding

back progress in CDS, although this is not a denial of the importance of software engineering techniques and tools in CDS projects. Essentially there is a need for tools and techniques to be part of a coherent philosophy for modelling the problem domain, and not the defining element of clinical decision support.

This leads to the central hypothesis in the paper that the definition of a successful methodology will follow from a coherent philosophy. If the central hypothesis is accepted as true then there is a need for a coherent philosophy covering all aspects of analysis, design and development of a CDS, where a coherent philosophy includes the set of values and beliefs derived from past practical experience which are then applied in future development. At present there is no commonly accepted coherent philosophy to guide the development of clinical decision support systems. Four reasons were identified in the paper for a CDS philosophy not yet existing:

i) A preoccupation with computer artifacts. The majority of time and effort on projects is spent using specific computer tools and techniques. This leads to a view of a problem in terms of the computer tools and techniques that are the most familiar to the designer. In the extreme, the drive to use a specific software technique and tools can drive the analysis of a problem. This would happen whenever the software tool to be used is chosen before the problem to which it is to be applied. So you have a tool and then look for a problem to solve with the tool. Once the problem is found, the solution is then dictated by the tool rather than the problem; the point being that knowledge of specific software techniques and tools should not dominate the problem solving process nor restrict the form the solution takes. However, when the project does reach the stage of system development a good understanding of the tools used is still required. The requirement for good understanding of the domain and the tools applied raises the requirement for multi-skilled individuals, or teams, working on any one system development.

ii) Failure to adopt appropriate models for analysing a problem. This is a symptom of the first problem of using software tools and techniques as the drive in project development. The view in the paper is that a coherent philosophy applied to any

problem will result in the use of models, and thus analytical techniques and tools, that are consistent with that philosophy. Applying philosophy in this way should also lead to the development of novel methods when required. Failure to recognise the natural philosophy of a problem and a preoccupation with computer related artifacts causes tunnel vision, in terms of what can and cannot be accomplished. This may prevent the most appropriate solution being found, particularly where the most appropriate solution to a problem maybe not to use a computer at all.

iii) Lack of a clear language for communicating a philosophy. For a shared understanding to be developed clear concepts are required to express a philosophy. During the development of a system a simple means of communicating between developers and users that elegantly expresses the relevant ideas would be a valuable tool. For example simple graphical representations or prototypes may facilitate better communication between the clinician and the system designer.

iv) A disregard for organisational issues. The organisational environment in which the personnel on the project find themselves is very important. The need to ensure the suitable mix in a development team was highlighted above in point (i) and is vital to a projects progress. The skills required demand a mixture of visionaries as well as people with programming skills. Long term stability is important, and short term contracts do not enable understanding of the problem and potential solutions to be built up, or the trust of the users and their organisation to be gained . This is a particular problem for academic research projects which tend to be funded on fixed short term contracts, with no guarantee of continuity of funding.

So there is a need for a coherent philosophy in CDS to gain a better understanding of the problem domain, and to move away from the blinkered view brought about by a preoccupation with computer artifacts. Having established the need for a coherent philosophy in CDS the next question is what form the philosophy should take. The form proposed in the paper is a development "philosophy". This was defined as a shared perception on how a problem or a class of problems should be solved in principle. It should originate from the basic principles of a discipline, and it is contrasted with a development

method which is defined as explicitly specifying all the steps in the development process. An example of a previous development method for CDS reviewed in the paper is one proposed by Shortliffe and Davis in 1975 which is an eight stage process: system design; development; evaluation of performance; evaluation of efficacy; small scale field evaluation; follow up studies; final amendments; and general release and marketing. It was noted that this has not been generally adopted in clinical decision support system development, and that systems rarely reach the final stage.

Under the heading, "a philosophy for decision support system developers," a series of steps in the form of a development method is described in the paper. Figure 2.1 illustrates that the "philosophy" is in fact a development method, similar in structure to the method described above, containing the beliefs of the authors on how to develop a clinical decision support system. These beliefs are:

i) Establish and clarify the need through rapid prototyping. Formalising the real requirements for a system is hard and often neglected. User involvement is vital at all stages of the prototyping so they can specify their requirements. Rapid prototyping allows for this level of user involvement, and is a popular technique for providing insight into system requirements. The prototype can be built by either using the prototype-discard-reimplement model or the operational prototype, where implementation is in the final language.

ii) Try to use a coherent methodology for modelling the problem. Modelling the application area is a vital precursor to building a decision support system. Using analytical models such as flow charts can contribute to the understanding of the clinical domain. A major challenge for medical informatics is to discover the appropriate analytical techniques. Object oriented techniques are seen as one possibility for analysing the material domain, as the design process seeks to mimic the way in which people form models of reality.

iii) The use of appropriate methods, mechanisms and tools. If there is a coherent model of the clinical problem this will facilitate the choice of appropriate reasoning

methods, techniques and tools. Tools should be chosen on the basis of how consistently they represent the analytical method and model, and on the amount of training that project personnel will need to use them.

iv) Need for evaluation. A system must undergo laboratory testing throughout the prototyping process to ensure safety and usability. This must be followed by field testing to assess its impact both intended and unintended on its users, patients and the health care system. A system must be successfully evaluated before it is commissioned for use.

v) Need for professional approach to implementation maintenance and support. The effort required to develop, maintain and support a system is often severely underestimated. Many clinical systems require a professional approach which is only available from a commercial organisation or a local technical group. For example the monitoring of the system has to continue during routine use to detect unforeseen problems. Furthermore, the system development is an on-going process consisting of correcting software errors, porting to different hardware platforms as necessary, and updating software periodically.

Although there is no explicit philosophy given as a basis for the above development method a need for one is implied in the requirement for a coherent methodology to analyse the problem domain. An explicit philosophy includes views on and models of the nature of reality and knowledge. These models then form a coherent basis on which to build the coherent analytical methodology for understanding the problem domain. The ontology, view of reality, provides a contextual view for analysing the problem, and the epistemology, theory of knowledge, provides a basis for analysing the knowledge of the domain. The epistemology also gives a foundation for constructing a knowledge base. Despite the lack of such an explicit philosophical basis there is undoubtably value in Heathfield and Wyatt's proposed development method, which comes from the authors' experience of developing CDS systems, specifically the ACORN system (Wyatt, 1989).

In summary the paper is a worthwhile attempt to propose a positive solution to some of the problems of CDS system development. It concludes that it is not technical problems which prevent the implementation of CDS it is a failure to appreciate the nature of the decision problems and a mismatch in motivations between developers and users. Although it is likely that novel technology will still be required in CDS systems, it should not be the sole focus for future research. A philosophy of how to build a CDS is central to the development of such systems and also to the discipline of medical informatics as a whole. At present this does not exist, probably because medical informatics is still an evolving discipline in search of an explicit philosophical foundation. The view in the paper is that a coherent philosophy applied to a problem will result in the use of models, and thus analysis methods and tools, that are consistent with that philosophy. Although an explicit philosophy was not given in the development method proposed a need for one was implied.

2.3.3 Critiques of the Views of Heathfield and Wyatt

As mentioned at the start of section 2.3 Heathfield and Wyatt's paper provoked several editorial comments. The comments focus on the evaluation, nature of clinical knowledge, the need for a systemic approach, proposals for the way forward in CDS and requirements for a CDS system.

With respect to the evaluation of CDS technology van der Lei (1993) noted that regular use of computer technology is a trailing indicator rather that leading indicator of success. He used the example of the utilisation of the electronic patient record (EPR) by GPs in Holland. It was observed that despite the form of the EPR for GPs not changing markedly, recently there has been an increase in their utilisation. The situation is similar for CDS and intermediate goals that allow evaluation on a finer level of granularity are required; utilisation is viewed as too late an indicator to be the sole criterion for judging success. This reaffirms the need for goals other than implemented systems in CDS research.

Van der Lei agreed with many of the comments made in Heathfield and Wyatt's development method. However a major issue which in his view is missing is an appreciation of a fundamental problem when constructing expert systems. When

attempting to capture and use expert clinical knowledge there are problems with casting medical knowledge in a formalism. A reason offered for this is that medical knowledge is only in part scientific knowledge. Van der Lei thinks ideally judgements should be based on scientific knowledge, but with limited data this cannot always be the case. Therefore there is an inherent uncertainty in decision making due to lack of data. This is one explanation for the large degree of inter and intra observer variability observed in medical decision making. The question then posed by van der Lei is, "If experts confronted with identical situations yield different judgements, on what foundation shall we build a system?" This issue of disagreement amongst experts also affects the issue of system evaluation discussed above. The issue of medical knowledge is felt to be so fundamental that research into the nature of medical knowledge is seen as an important focus for future work in the field of CDS; in addition to the nature of the knowledge, how to model that knowledge, and how to apply it in different settings. From such cross disciplinary research the anticipated result is insight, and possibly much later CDS systems. Van der Lei goes on to state that when building systems for use the focus will be increasingly on the environment in which clinical decisions are made. This will be partially realised in systems which allow health care workers to communicate and interact, particularly where a team of workers is involved.

Musen (1993) identified two major problems with CDS development to date: namely the computer has not been viewed as part of wider clinical working practices, and that by regarding medical knowledge as a set of extractable propositions that can be stored within a computer our view of the decision making process itself is necessarily narrow. In Musen's view systems that do not integrate into the work patterns of health care providers and that do not address the perceived needs of those providers simply will not be used. The impasse to widespread utilisation of CDS systems has occurred because the informatics community has viewed the purpose of clinical decision aids as that of offering the health care workers "knowledge" that would otherwise be missing. This is held to be a failure to appreciate the nature of decision problems and a mismatch between developers and users motivations. If there is a technical issue that workers in medical informatics have misunderstood it is the nature of medical knowledge itself. There is a need for a philosophy that recognises that the "systems" to be built are not computer systems, but rather systems

that include health care workers, patients, families and computers.

Szolovits and Pauker (1993) also doubt the adequacy of present methods to solve the problems of clinical decision support. Thus they view the work of medical informatics as being in large part basic research that will provide better definitions of the clinical tasks which require support and will provide a new, more flexible set of software tools to address these problems. A good philosophy appropriately applied at the basis of this research will broaden our horizons and not limit our perspectives on some of these possible solutions.

Miller (1993) added the following observations on the nature of the clinical domain and the corresponding requirements for an ideal CDS system. Physicians select human consultations with another physician based on the perception that they have skills and/or knowledge they do not possess. Repeated consultation occurs on the basis of the consultant's apparent accuracy and reliability. As a model for consultation a CDS system needs to display these characteristics. Furthermore, physicians normally check a system against their own knowledge and against certain common sense reality checks, for example whether the system recognises pregnant men as not being possible. Thus the importance of a relevant, effective and up to date knowledge base is paramount. Finally Miller stated that as many of one quarter of all information needs in a clinical setting may require the tailoring of general medical knowledge in patient specific manner; making patient specific advice a paramount requirement for CDS.

In their reply to the editorials, Heathfield and Wyatt (1993b) made clear that the purpose of their first paper was to make explicit the need for a systematic and objective review of the current status of the discipline. Having expressed the need they, hoped to provoke the medical informatics community to take stock of where it is and to plan for the future. Their definition of decision support was "those systems containing and reasoning using medical knowledge." Once more this raises the issues highlighted by van der Lei related to the nature of clinical knowledge and suggests the need for epistemology in CDS research.

In their reply Heathfield and Wyatt go on to state that the primary goal of medical informatics is to help health care workers to improve patient outcomes. As solutions are

sought which satisfy this goal, new approaches need to be tried. In looking for new approaches Heathfield and Wyatt agree that a useful philosophy broadens horizons without limiting perspectives, and that an holistic view of the problem is required. The role of science within a coherent philosophy for CDS is examined in the articles reviewed below.

2.3.4 The Scientific Approach in Clinical Decision Support

As already noted, the focus of much of the development of CDS has been on the engineering of technological tools. The relationship of CDS to science and how science can be used in CDS has not been examined deeply. Two articles have reviewed the status of medical informatics (Lincoln and Essin, 1992, and Seelos, 1992) and suggested the need for the application of science in medical informatics.

Lincoln and Essin (1992) observed through their attendance at major international medical informatics meetings that there seemed to be a lack of challenging fundamental problems which were relevant to the whole community present. This observation led to the belief that medical informatics does not have a scientific basis, which was further reinforced by the observation that there appears to be no framework or set of hypotheses about how chosen tools interact with health care data. Their proposed start point for forming a hypothesis is the observation that the challenging "real world" of health care is filled with non-standard situations as the focus is on patients suffering with non-standard conditions. This raises the fundamental problem of how to model the real world of health care. By focusing on engineering solutions to the problems the underlying science that must be developed to support these solutions is often obscured. This view suggests the need to investigate the role of science in medical informatics and its relationship with engineering. The view in the paper is that by using the scientific hypothesis testing method the foundations of medical informatics can be more clearly stated. It is thought this will produce deeper discussions at meetings and more opportunity for research investigations in the field.

Seelos (1992) thinks the historical development of medical informatics is in the process of advancing from art to science, from craft to methodology. The question according to

Kuhn's theory of scientific revolution is whether a new paradigm for medical informatics has to be acquired in the near future; one which upgrades the discipline from a prescientific era to an advanced scientific stage. Historically medical informatics, generally conceived as the application of information science in medicine, claims to be the science of the nature, the construction and the application of algorithms in medicine. This has lead to a development by accumulation, which is typical of a prescientific era in a discipline. The need to move medical informatics away form this prescientific era is based on two reasons put forward by Seelos:

i) There is a lack of organised knowledge (theory) in medical computing to promote our practical work and to scientifically substantiate appropriate curricula as well as generally accepted educational concepts.

ii) There is an increasingly diverging articulation of the actual paradigm, manifested by differentiation and specialisation.

These two justifications are thought to clearly indicate a deficiency of the traditional paradigm. Thus there is a need for a new paradigm in medical informatics. The new paradigm proposed by Seelos is to adopt a holistic view of the whole health service, and deal with the all the information flows in the health service not just the biological and medical information flows. This systemic approach is labelled comprehensive health care informatics (CHCI). The propositions put forward in support of this paradigm were:

i) IT is instrumental in the sociological organisation which medicine is a part of, therefore medicine cannot ignore the possibilities of IT in health care, e.g. use of the Internet as an information source.

ii) Medical informatics is applied to a complex cross over of different disciplines. Only a mixture of methods from say medicine, IT, economics, statistics, sociology, and legal science is adequate for a comprehensive interdisciplinary statement.

iii) Medical informatics aims to support all the processes of health care in its practical

as well as in its theoretical aspects.

iv) The object produced by medical informatics is a medical information system. This has to contain medical models as well as models of the wider system.

v) Medical informatics has two main aspects: the analysis of the information processes in medical informatics, and the engineering of computer systems to solve problems related to these processes.

vi) The methodology of medical informatics is the application of systems engineering and information management theories to problems in the field of medicine and health care.

Adopting a new approach in medical informatics is further supported by this article. The move towards a scientific age is seen as requiring a new paradigm, namely taking a systemic view of the health care system; this supposedly being scientifically justified by the six propositions above. Such a systemic view is not inconsistent with the need for a coherent philosophy expressed by Heathfield and Wyatt.

2.4 THE NEED FOR AN ONTOLOGICAL-EPISTEMOLOGICAL PARADIGM

Shortliffe's (1987) definition of CDS focuses on the potential role computer programs can play in aiding clinicians in their decision making. The definition goes on to analyse decision support tools from the functional aspect of the computer system, rather than from a model of the decision making process in which the tools are to be used. This is a reflection of the technology centred approach which has been prevalent in CDS. Two papers by Shortliffe (1987; 1993) highlight the fact that despite many years of using this approach to produce patient specific clinical decision support tools they are not commonly used on a routine basis in medicine. This has led to questions being asked about the technology focused paradigm used in CDS.

Coiera (1995) stated that a shift is required in CDS away from the technology focused

paradigm to a more problem centred approach. Specifically Coiera (1994), whilst reflecting on the assumptions on which CDS is based, states that a better understanding is needed of the clinical decision making process that is to be supported. How this may be achieved, and how solutions can be provided for the problems found, is suggested by Heathfield et al. (1991): "A philosophy that is natural for the solution of a problem, or a class of problems will lead to paradigms and models, followed by methods, mechanisms and tools that are consistent with the methodology." This idea is examined further in Heathfield and Wyatt (1993), where they propose that there is a need for tools and techniques to be part of a coherent philosophy for clinical decision support, and not the defining element of clinical decision support. Such an approach is needed to move away form the paradigm which is preoccupied with computer artifacts, and to form analytical models to reach a better understanding of the problem domain. Extending this concept of using analytical models to better understand the problem domain there is also the need to form models of how the proposed CDS solution will impact on the problem domain. The form of the philosophy put forward by Heathfield and Wyatt (1993) is a set of beliefs, derived from their practical experience, on how to develop a CDS tool. In other words their philosophy is another expression of a development method. Although this is not devoid of merit it does not fulfil their identified requirements for a coherent philosophy which forms the basis for a coherent methodology for CDS. Thus the form of the coherent philosophy for CDS is not entirely dealt with in their paper. In the editorial comments which followed Heathfield and Wyatt's paper, van der Lei (1993) suggested that the issue of medical knowledge is so fundamental that research into its nature is an important focus for future work in the field of CDS; in addition to the nature of the knowledge, how to model that knowledge, and how to apply it in different settings. This implies that there is a need for a coherent epistemology, theory of knowledge, to be included within the philosophy for CDS. The need for a coherent epistemology in CDS is further supported by the view of Musen (1993): "If there is a technical issue that workers in medical informatics have misunderstood it is the nature of medical knowledge itself,"; Coiera (1995) stated that applications of informatics in medicine include the study of the very essence of medicine, its corpus of knowledge; the problem of clinical expert knowledge validation by agreement between experts as highlighted by Shortliffe (1987); and in connection with this the questioning of the notion of what constitutes clinical expert knowledge (Shortliffe, 1989).

Thus within a philosophy for CDS there is the need for a coherent epistemology which includes an examination of the nature of medical knowledge. To form a coherent epistemology it needs to be linked to a coherent ontology, as this defines the view of reality of which there can be knowledge.

The other reason for having a philosophical ontology for CDS is that it provides the basis for forming the required systemic, or holistic, view of the problem domain and the role of decision support in the domain (Musen, 1993, and Seelos, 1992). By definition the ontology defines a view of the world, thus anything that is perceived to exist within this view must fit into the ontological model in some way. Therefore, an ontology is the starting point for building the model based understanding of the problem domain advocated by Heathfield and Wyatt (1993).

Furthermore, there is a need to consider the multidisciplinary nature of CDS, the two main disciplines being engineering and medicine. Lincoln and Essin (1992) and Seelos (1992) suggest that the role of science in CDS needs to be also included in a systemic analysis of CDS. Therefore the three established disciplines at the core of CDS are science, medicine and engineering, each one being an important ingredient. The role and relationship between these disciplines in CDS are important elements in a coherent view of CDS, particularly in terms of the methodology to be adopted. Through the application of the ontology and epistemology in an analysis of these three disciplines a coherent view of role and relationship of the disciplines in CDS will be formed.

Thus adopting a paradigm based on ontological and epistemological concepts will provide insight into the nature of the problem domain, clinical decision support, medical knowledge, and the role of technology, medicine and science in CDS. All of these have been identified as important factors in shifting clinical decision support away from its technology focused paradigm.

2.5 SUMMARY

This chapter has examined in more detail ideas introduced in chapter 1. Thus this chapter

has examined the technology centre paradigm used in CDS, and proposed that a shift of paradigms to an ontological-epistemological paradigm is required for the development of the field of clinical decision support.

The next chapter shows how the structure of a analytical framework for CDS is built up on the ontological and epistemological foundation. Through a systematic review of fundamental philosophical principles a practical ontology and epistemology are formulated for application to CDS. Also there is a characterisation of CDS in terms of the three established disciplines of engineering, science and medicine.

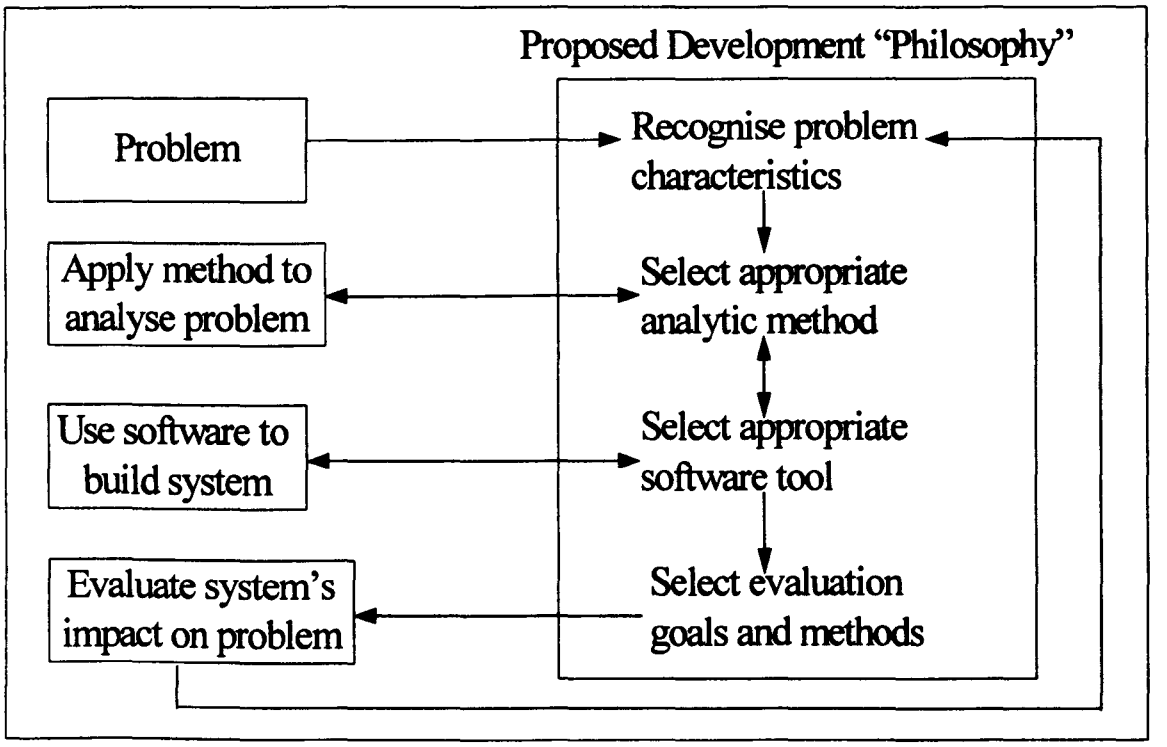


Figure 2.1 Heathfield and Wyatt's development method

CHAPTER 3

ONTOLOGICAL AND EPISTEMOLOGICAL FRAMEWORK

3.1 INTRODUCTION

As discussed in the previous chapter there is currently an absence of any clear philosophical framework in the field of clinical decision support (CDS). This unfulfilled need for a coherent philosophy must be resolved if CDS is to be grounded on a holistic analytical framework. The role of the philosophy in such a framework is to define a coherent basis for building a coherent methodology for CDS. Thus the coherent philosophy is at the base of the analytical framework for CDS. This chapter shows how the structure of the analytical framework is built on the philosophical foundation. In addition to this the chapter also describes the generic ontological and epistemological framework, which forms an holistic analytical foundation for clinical decision support. The construction of the ontology and epistemology is based on a systematic review of the relevant fundamental concepts of philosophy.

With the aim of characterising the nature of CDS beyond the philosophical basis an analysis of the natures of the multiple disciplines (technology, science and medicine) of CDS is presented in section 3.4 of the chapter. The natures of the three major disciplines are presented and analysed using the ontological and epistemological models. Furthermore, with the aim of identifying the influence of each discipline in CDS, models of the relationships between the processes and the knowledge in each of the disciplines are constructed.

3.2 STRUCTURE OF ANALYTICAL FRAMEWORK

Chapter two included Heathfield and Wyatt's (1993) arguments for a coherent philosophy in decision support. In an earlier article Heathfield et al. (1991) summarised the potential power of a coherent philosophy in a analytical framework thus:

"A philosophy that is natural for the solution of a problem, or a class of problems will lead to paradigms and models, followed by methods, mechanisms and tools that are consistent with the methodology."

Unfortunately no definition of paradigms, models, methods, mechanisms, tools, methodology is offered by Heathfield et al.. Neither is their a relational structure made clear in the paper. It is only implied in the quote given that a philosophy is at the foundation of formulating a problem solution. For the levels of analysis built on the philosophical foundation Ackoff (1962) offers a scientific structure for defining them and the relationships between them. Four levels of analysis identified by Ackoff in the applied scientific research process are defined thus:

i) Tools, a physical or conceptual *instrument* that is used in scientific enquiry. e.g. mathematical symbols, computers, random numbers.

ii) Technique, a scientific *course of action*, or ways of using scientific tools; e.g. the use of calculus (technique) to find the minimum or maximum of a curve.

iii) Method, determines the way techniques are selected in science. Methods can be expressed as rules for choosing a technique; for example the method for choosing between techniques for determining the maxima and minima of a curve.

iv) Methodology is the collection of different methods. It involves the study of scientific methods, the objective of which is an improvement in the methods. The method for determining a curves maxima or minima could be one of the methods within a methodology.

Although Ackoff proposed this structure for applied scientific research it does have an analogous application in technology. For example in computer programming, compilers and editors are tools used in software development; whilst techniques define the steps involved in using the software tools to achieve a goal, and methods define how the techniques are selected. Therefore, the same structure will be used for the analytical framework developed here.

The four levels of classification defined above exist within the philosophical framework as depicted in figure 3.1. The most general level depicted in this figure is the encompassing philosophy, and the most specific is an individual tool. Applying rationalism to link the levels of the framework, the philosophy provides the general framework for analysis and for deriving a general methodology. The methodology describes the methods to be used. The methods describe the rules for choosing from the available techniques, whilst the techniques are descriptions of the procedures for achieving pre-defined goals. Which tools are to be used and how is specified in the techniques.

The five levels of figure 3.1 provide a useful framework for analysing problems and the solutions to be adopted. Constructing and then applying the ideas in the framework provides a basis for finding solutions to problems and analysing these solutions. Thus it satisfies the two aims of applied scientific research defined by Ackoff (1962): to find answers to questions, and to develop the procedures used for finding the answers. Thus applied research should lead to a problem specific solution and procedures for more effectively finding solutions to other problems. The philosophical basis defines a generic analytical basis for a group of problems and solutions, whilst at the lowest level the tools applied in a technique to a specific problem provide a problem specific solution.

The flow in the construction of the ideas in the framework is given in figure 3.2. The concepts used at each of the levels of the framework are derived from existing ideas in the relevant disciplines. The two main philosophical concepts used in the analysis are ontology and epistemology. Within the philosophical analysis lie the methods, techniques and tools of science, technology and medicine which are applied in CDS.

The added value of the framework is in the practical application and synthesis of the concepts, as depicted in figure 3.2. Using philosophical models allows for a general high level analysis of the problem. This analysis can then be applied down through the levels of the framework and provides the operational context for the methods, techniques and tools. So techniques are applied within a high level analysis of the problem. There is also feedback from each of the lower levels, for example from tools to techniques. Thus the techniques and tools can be adapted as experience is gained in their application. The practical experience can then feedback to higher levels to adapt methods, methodology and philosophy.

The advantages of this framework for analysis over the commonly used technique centred approach include the more generic levels of analysis. This will give a more holistic view of the problem and will seek the development of techniques appropriate to the problem. This counters the approach commonly used in CDS to date, which is to start with a prescribed technique then to find a problem to apply it to; this being put forward as one of the core reasons for the lack of utilisation of the systems developed to date. Logically this is not surprising; consider the simplified analogy of having a tool box only containing a shiny new hammer. The motivation is to use the hammer, so a problem is sought. The first problem which is found is to secure a screw into a flat wall. The hammer must be used, so the screw is hammered into the wall. The results, if any, are ineffective and nothing can be supported by the screw in the wall. Starting with a technique, or tool, is too much of a bottom up approach. What is required is a top down approach where there is first an analysis of the problem, followed by the development of appropriate techniques and tools. Then by recognising that the problem is to secure a screw into the wall the appropriate tools for the job will then be selected. Thus the framework for analysis proposed in this thesis adopts a top down analysis, beginning with philosophy.

3.3 PHILOSOPHY

An individual's philosophy in the simplest sense is an expression of their view of reality (Ferm, 1969). In terms used in systems science an individual's philosophy expresses their world view, or Weltanschauung. Etymologically, *philos* is Greek for lover, and *sophia*

means wisdom, thus we have philosophy meaning a lover of wisdom. Fundamentally the discipline of philosophy is concerned with expressing a view on the nature of reality, ontology, and the related view on the theory of knowledge, epistemology. These two concepts are at the core of the framework for philosophical thinking. To express the philosophy using established concepts they initially must be understood and then applied in the construction of the framework. Thus the benefit of applying twenty five centuries of philosophical insights to focus and clarify issues in CDS will be realised (Sowa, 1995).

Philosophy does not exist in isolation it is a body of principles and general concepts which underlay a given branch of learning, a major discipline, a religious system, or any important human activity. It includes the application of these principles in the domain of their relevance, e.g. the philosophy of history. A philosophy does not spell out the detailed action to be taken in specific instances; rather it deals with underlying ontological and epistemological concepts which are relevant to whole classes of problems. Therefore, it provides a generic basis for problem analysis. One of the principles for a good philosophy is that it should make a difference in its application. A philosophy which is not usable is sterile and will not make a difference. Thus, the process of thought, dialectic, begins with its foundation in philosophical concepts, and a reasoned argument begins with a philosophical expression of the world view taken.

In addition to the need for a coherent philosophy in CDS there are other benefits to taking a philosophical approach. Firstly, there is the benefit realised from considering what are the foundations of thought in the field of research in CDS; particularly in terms of how the roots of the world view taken, or Weltanschauung, can be expressed in philosophical terms. By questioning these views in a philosophical manner, making explicit the philosophy adopted, and applying the philosophy, a deeper understanding of CDS can be achieved. Secondly there are the epistemological questions raised by the drive to make a contribution to knowledge in the thesis, and the use of knowledge in clinical decision support.

In forming a philosophical root it is helpful to make it explicit, as the author putting forward the argument, and the reader of the argument, can develop their thoughts based on the philosophical root. O'Connor and Carr (1987) sum up the value of this expression thus,

"Language enables us to make our beliefs detailed and precise; it also puts them into permanent and stable form which unexpressed beliefs tend to lack." If beliefs on the root of thought are not made explicit, at best they are only implied and at worst there is no coherent philosophy at all. Such an unexpressed philosophy can leave the foundation of thought stagnant and unquestioned. Contrary to this an explicit philosophy is made available for others to question, a necessary quality of a good philosophy.

There are two main aspects of the thesis which deal with knowledge. The core aim of research is to make a contribution to knowledge; whilst CDS attempts to represent and use clinical knowledge to aid the clinical decision making process. Whenever attempting to deal with knowledge in a meaningful way there is a need to understand and define knowledge. This consideration raises the epistemological questions of what is knowledge, what are the sources of knowledge, the scope of the knowledge, and how can the reliability of knowledge be judged. If an attempt is to be made at representing human knowledge of a domain the answers to these epistemological questions lie at the core of such a representation; the core understanding of the "nature of knowledge" aiding the processes of representing present knowledge and adding to it.

3.3.1 Rationalism

Katz (1993) defined logic as being formalisation of meaning, and without it rational discourse would not be possible. In other words logic is the mental tool used to make sense of the world. The two types of logic commonly defined are:

i) Deductive, or syllogistic, or Aristolean, logic literally means the putting together of propositions. Application of deductive logic is the reasoning from laws and theories to predictions and explanations. For example deductive logic can be used to combine proposition A, All humans are mortal, with proposition B, Jenny is human, to reach conclusion C, Jenny is mortal. If both A and B are true then it follows that the conclusion C is true.

ii) Inductive logic starts with data from observation and proposes new theories and

laws, or propositions which link the data. For example in making a statistical correlation between two variables inductive reasoning is being used to derive the relationship.

Either type of logic can be used to reach a logical conclusion. In addition to the two classical classifications of logic Ferm (1969) described the application of deductive logic in philosophy. Ferm labelled this philosophical logic, which is based on working out some theory or insight and then applying it to show its ramifications and its illumination of the nature of reality. This application of logic is essentially the view taken by Descartes in seeking a philosophical foundation to gain greater insight in to solving a problem (section 3.4.1). Another example of philosophical logic is Hegel's triadic dialectic of thesis and antithesis followed by synthesis; this is described in greater detail in section 3.4.4. Through two conflicting ideas a synthesis of ideas produces a new, possibly better, thesis. The synthesis then becomes the starting thesis for beginning the process again. Applying Hegel's dialectic in a philosophically logical way will, in theory, lead ultimately to an absolute synthesis of ideas. However, as Hegel's critics have pointed out such an absolute synthesis of all ideas has yet to be attained. The use of what Ferm called philosophical logic is discussed in more detail below.

3.3.2 Philosophical Reason

Descartes, a rationalist, believed that any problem needs to be broken down to its simplest factors. It is then in reasoning from the simple to the complex that we gain insight and understanding (Gaarder, 1991). The simplest analysis of a problem is in ontological and epistemological terms. By building on and applying such an analysis it is proposed in this thesis that a deeper understanding of the problem of CDS will be achieved; eventually leading to more robust solutions to the problem, as the problem specific solution is built on the foundation of a coherent philosophy, figure 3.1.

Feinstein (1967) in figure 3.3 expressed in a simplified manner his view of how philosophy can be considered as being at the root of reasoned thinking in medicine. This diagram clearly shows the effect philosophy has on the other levels of thinking and how it impinges

on all that flows from it. The points on the circle are joined by reasoned thought and each of these points impact on each other through this linkage. Although in this simplified diagram Feinstein has shown his view to be that mathematics is the basis for clinical medicine, which is not the absolute view of the author. Despite this disagreement on the detail of the view expressed there is still the clear illustration of philosophy being at the root of reasoned thought. Moreover, the diagram illustrates how the root philosophy can be influenced by the circular nature of the thought process.

Applying rationality the broad concepts of philosophy lead to the development of theories, laws and rules and to the detailed methods of applying them. Without rationality in a philosophy it is not possible to apply the philosophy to situations which are subordinate to it. A philosophy forms an intellectual superstructure or overall strategy which moulds and guides the development of a discipline. By logical combination and extension philosophy forms a larger body of derived principles on which a discipline may find a secure foundation. The discipline provides an intermediate intellectual structure or strategy which moulds and guides the attack on categories of problems. A practitioner, when dealing with an immediate and particular problem, must develop from their knowledge of a discipline a specific attack or tactic which resolves the problem.

Applying the philosophy in the context of the framework in figure 3.1, previously described; the stages to the development of a rational practical philosophy in this framework are:

i) Build the ontological and epistemological framework;

ii) Apply the ontology and epistemology in a generic analysis of CDS ;

iii) Apply the framework to structure the application specific problem analysis and CDS system development;

iv) Evaluate the ontology and epistemology in the light of the practical experience.

The first stage of developing a philosophical framework is to build the ontological and epistemological models.

3.3.3 Building an Ontology and Epistemology

There are a number of ways to construct views of ontology and epistemology. The possible bases for constructing these views proposed by Ferm (1969) are: radical scepticism; eclecticism; a chronological study of past philosophies; mysticism; authoritarianism; deductivism, or positivism. Ferm added to these by proposing a critically evaluative approach, where you take the best of all of the these approaches, but not in an absolutely eclectic manner. To decide which basis to use for building the philosophy here, each of the approaches is briefly considered below.

Pure radical scepticism is the approach which has traditionally been followed in philosophy (O'Connor and Carr, 1987). Radical scepticism takes the stance of doubting the existence of everything, including the very existence of knowledge. Radical scepticism in its most extreme form becomes purely destructive, leaving only doubt and uncertainty. Indeed it was radical scepticism which led Descartes to arrive at the famous words "I think therefore I am." Two of the points of this quote are that the thought process must begin from some start point or set of assumptions, and that radical scepticism doubts the very thought process from which it seems to come. Without any accepted base assumptions there is radical scepticism and doubt, which leaves an incoherent philosophy with no point of origin. Thus, in its purest form radical scepticism does not allow for the construction of a system of thought. Therefore, scepticism will only be used to refine the philosophy developed in this thesis, it will not be the sole basis for it.

The second basis put forward for constructing a philosophy is eclecticism which is based on taking all philosophical ideas and combining them. Considering all the opposing views on philosophy which have been expressed this approach would lead to an inconsistent and incoherent philosophy. A chronological study of philosophy provides an historical context for different philosophical view points. Thus it gives a reference point for a systematic review of philosophical thought.

Another basis used for philosophy building is mysticism, this is based purely on the supernatural experiences of mystics. Despite the sense in which these experiences seem real to the mystic there is a lack of verifiability, and efficacy in these methods for building a philosophy.

Authoritarianism, the fifth basis identified for building a philosophy, is simply basing a philosophy on the word of a figure of authority. Authority is contextual and not universal therefore it cannot be held to be a method for building a general philosophical basis.

As has been discussed above the coherence of a philosophy is based on a reasoned argument, deductivism. It is by the application of reason, or logic, that sense is made of the world and understanding attained. Through the application of logic it is possible to construct an ontology, epistemology and knowledge base. Therefore reason plays a central role in forming an understandable philosophy. The deductivist builds a philosophy based on deductive logic, building on a set of propositions. The main weakness of this method being that the reasoning may begin from untrue propositions, then a false view of reality will be formed. For example, if your propositions are that mice live on cheese and that the moon is made of cheese, then you could conclude by deduction that mice live on the moon. But the original proposition is false and hence the conclusion is false. The positivist view helps to complement this problem by basing propositions on observations of the world as perceived by human senses. So, combining the two it is possible to reason from perceptions of the world.

The importance of using established philosophical concepts for clarity and insight was highlighted above. Therefore, the study of fundamental philosophical theory is relevant to building an ontology and epistemology. The question is how to use the established theory. Of the options proposed by Ferm (1969) radical scepticism, eclecticism, and authoritarianism have been rejected. This leaves a chronological study and a systematic analysis of philosophy theory, with the application of positivist experience from the development of a CDS system. Therefore, the approach taken here will be to build the philosophy using a systematic review of fundamental philosophical theory combined with a brief history of modern western philosophy; whilst the positivist experience from the

development of a CDS system will inform the building process.

3.3.3.1 Criteria for judging a philosophy

When building a philosophy it is important to set up criteria for judging its value. Ferm's (1969) qualities for a good philosophy are that it should be:

i) Generally applicable; a good philosophy should express fully the world view being taken;

ii) Vital; the philosophy should make a contribution to understanding reality;

iii) Coherent, or harmonious; it should not contradict itself;

iv) Disciplined; it should be reasoned and carefully studied;

v) Consistent with material reality;

vi) Capable of being questioned and revised.

Points (i), (ii), and (vi) are generally applicable to all forms of good philosophical ontology and epistemology, whatever the basis used for constructing the philosophy may be. Thus as a minimum criteria set a good philosophy should satisfy these. Points (iii) and (iv) represent criteria that a good rationalist philosophy should comply with, while point (v) is relevant to a building a good materialistic positivist. The approach taken in the thesis is to construct a rationalist philosophy that includes a material element. Therefore Ferm's criteria for a good philosophy apply to the ontology and epistemology described in this chapter.

3.4 A BRIEF HISTORY OF MODERN WESTERN PHILOSOPHY

The purpose of this brief history of modern western philosophy is to give a historical

context to the concepts of philosophy described in the section 3.5 of this chapter. Thus the history begins with a brief discussion of Descartes and finishes with a brief review contemporary philosophy, including existentialism.

3.4.1 Continental Rationalism

3.4.1.1 René Descartes (1596-1650)

Descartes is commonly acknowledged as the founder of modern philosophy (Russell, 1961); where the focus of modern philosophy is on man and his place in the world as we perceive it to exist. Descartes' main concern was with what we can know; certain knowledge. His second great concern was with the relationship between body and mind.

Following the Renaissance the need to assemble contemporary thought into one coherent philosophical system once again presented itself. Descartes attempted to construct a complete philosophical system or edifice by questioning all that had gone before him (Gaarder, 1995). In the view of the rationalists this required the breaking down of a compound problem into as many single factors as possible. Then the root concept for the philosophy is taken from the simplest idea of all. As a rationalist Descartes believed that philosophy should reason from such a root concept up to more complex ideas. Only then would it be possible to construct a new insight. Rationally this has to come through our application of reason, in forming a connected understanding starting from a root idea of philosophical thought.

In seeking the root of philosophical thought Descartes started from the postulate that you should doubt everything. Thus Descartes went beyond the lessons of older philosophies by doubting all that had come before. Then he went on to doubt even what our senses appear to tell us, pointing out that what appears to us in a dream can appear to be real. Radical scepticism of this form had led others to this point but no further. However, Descartes realised the only thing he could be certain of was that he doubted everything. Doubt is an expression of thought, therefore the root idea for his philosophy was that he was a thinking being, and thus he existed. Thus I think therefore I am is the root principle

of Descartes' philosophy.

Descartes was the first of the continental rationalists; convinced that certain knowledge is only obtainable through reason. This conviction is based on the rationalist view that the more self evident a thing is to one's reason, the more certain it is that it exists. According to rationalism whatever we perceive with our reason corresponds to reality, thus in addition to the perceived thinking self there is another out there material reality. During the development of continental rationalism the new physics was offering an increasingly mechanistic view of this material reality. Thus it brought into question the relationship between the body and soul. Previously the soul had been considered to be all pervading in nature. However, the emerging view was that surely the soul could not be explained in such a mechanistic way. This lead to Descartes' second concern of the link between the body and soul.

Descartes maintains that there are two different forms of reality, or two substances (Russell, 1961). One is thought (mind), and the other is extension (matter). Thought was viewed as being quite independent of matter, and vice versa. In Descartes', also referred to as Cartesian, dualism there is a sharp division between the realities of mind and matter. In Descartes' metaphysics it is the existence of God that makes it possible for man to know the world (Marías, 1967). Thus God is the connecting bridge between the two substances of thought and extension. So, the Cartesian metaphysical view consists of the substances of mind and body governed by the infinite God (Marías, 1967).

In the theory of the material world Cartesianism is rigidly deterministic. Owing to the idea of parallelism between the mind and matter mental events were held to be equally deterministic. This combination of the metaphysical view with the deterministic nature of each leads to the occasionalist view, where the clockmaker (god) constantly synchronises the two clocks (thought and extension) which have no direct relationship whatsoever.

As the father of modern philosophy Descartes influenced many of those who came after him, including the other two major continental rationalists Spinoza and Leibniz.

3.4.1.2 Baruch Spinoza (1632-1677)

Spinoza accepted from Descartes and his contemporaries a materialistic and deterministic physics, and sought within this framework to find room for reverence and a life devoted to the good. Like Descartes Spinoza was a rationalist (Gaarder, 1995). Spinoza however rejected Descartes' split between thought and extension. He believed there was only one substance, or reality, and at times he referred to this as God, or nature.

According to Spinoza's philosophy an attribute of the single substance is that which the mind perceives as a constituent of its essence (Marías, 1967). There are an infinite number of attributes of the single substance, God, but only two are perceived a constituents of its essence: thought (cognition) and extension (extension). These essences are the same as Descartes' substances but by labelling them essences of Spinoza has demoted them in the ontological hierarchy.

Spinoza's metaphysics, or ontology, is the best example of "logical monism"; the doctrine that the world as a whole is a single substance, none of whose parts are logically capable of existing alone. Spinoza thought that the nature of the world and of human life could be logically deduced from self evident axioms. The whole of such a view is difficult to accept; it is incompatible with modern logic and with scientific method, where facts are linked to observations. Empirical data is the source and expression of such facts. Moreover, the concept of substance is one which neither philosophy, or science can currently accept (Russell, 1961).

In Spinoza's logical monism there is only one clock (God) with two visible faces, or attributes. Thus there is no communication between the two attributes only correspondence. There is strict parallelism between the two attributes of the single substance. Just as there is an exact correspondence between ideas and matter, so there is a strict parallelism between the soul and the body. Thus mans' mind and body is governed by the deterministic natural law that he must follow. This lead to Spinoza's belief that only one type of freedom remains open to man: knowledge. The knowledge he speaks of is the knowledge of God. The intellectual love of God is for Spinoza the culmination of both

philosophy and human life. When a man knows what he is, he knows that he is not free and does not feel constrained or coerced, but determined according to his essence; therefore, reason is freedom.

3.4.1.3 Gottfried Wilhelm Leibniz (1646-1716)

Like Descartes and Spinoza, Leibniz based his philosophy on the concept of substance (Russell, 1961). However, he held that extension cannot be an attribute of substance. After rejecting extension the only possible essential attribute remaining was soul. Thus according to Leibniz the metaphysical structure of the world consists of an infinite number of souls , or monads (Marías, 1967). Monads are the basic substances, substances without component parts, which group to form complex things. These elemental monads cannot decay or perish through disintegration, nor can they be built up from parts. The monad is force; or force of representation. Every monad actively represents or reflects the entire universe from its own perspective. This representation of the universe is active; it is the monad's purpose, tendency; a desire that arises from the monad's ontological basis itself, from its own reality. Everything that happens to a monad arises from its own being, from its internal possibilities; the monads are completely insensitive to external influences.

Thus Leibniz proposes a pluralist multiplicity of substantial monads which contain strictly within themselves all their ontological possibilities. Monads are windowless, which leads to the problem of how can there be communication in such a pluralist reality. This problem is overcome by saying that the internally defined reality and purpose of each monad is in harmony and defined by God. This concept was labelled pre-established harmony by Leibniz. Using the clock analogy once more in pre-established harmony there are many clocks; the clockmaker (God) has made them in such a way that they remain in harmony without any further interference or synchronisation. Thus God is the source of all knowledge when he made the monads. We only have knowledge of all things around us by the action of God. Thus the only windows the monads do have all open up to God, not to each other.

From Descartes to Leibniz there is an almost unquestioned acceptance that God does exist.

This is seen as central to giving unity to the ideas that they express, and despite the fact that God and philosophy are separate, each of their philosophies features God in some central controlling way. This unifying idea of a single deity at the centre of everything came increasingly into doubt during the eighteenth century. Especially the ideas that all knowledge is *a priori* and that the source of knowledge is God.

3.4.2 British Empiricism

The British Empiricists were: John Locke; George Berkeley, and David Hume (Gaarder, 1995). By definition an empiricist derives all knowledge of the world from what the senses tell us. This view was summed up by Aristotle thus, "There is nothing in the mind except that which was first in the senses" (Gaarder, 1995). To the empiricists if we do have an idea that cannot be related to experienced facts then it will be a false conception. Thus, the empiricists criticised the seemingly previously contrived philosophical systems, which by their maxim seem to be based on pure fantasy.

3.4.2.1 John Locke (1632-1704)

Locke may be regarded the founder of Empiricism; the doctrine that all our knowledge (with the possible exception of logic and mathematics) is derived from experience (Russell, 1961). Locke is viewed as being less dogmatic than the rationalists.

All knowledge is viewed by Locke as coming from experience. Prior to experience the soul is like a clean piece of paper on which nothing has been written, no knowledge is innate (Marías, 1967). Locke classified two classes of perception: external perception of physical states by means of the senses, or sensation; and internal perception of physical states, or reflection, where reflection operates on the material introduced by sensation.

Built on these perceptions there are two levels of ideas: simple ideas which are formed from a single sense or from several senses simultaneously, or from reflection, or finally from a combination of sensation and reflection; and complex ideas which are the result of the activity of the mind, which combines or associates simple ideas; memory being the basis

on which complex ideas are formed. Simple ideas leave an impression on the mind, memory, which are then later associated with other ideas to form more complex ones. Thus all ideas proceed from experience by means of successive abstractions, generalisations and associations.

Locke distinguishes simple ideas with objective validity (primary qualities) from those which have only subjective validity (secondary qualities). The primary qualities (number, figure, extension, motion) belong to the bodies and cannot be separated from them; the secondary qualities (colour, odour, taste) are subjective sensations of the man who perceives them. In Locke's view sense data (primary qualities) we receive cannot be subjective because we do not control them. In Locke's view space and time are qualities of the external world and thus they are perceivable.

Locke's empiricism limits the possibility of knowledge, with respect to the potentially infinite knowledge of God which went before in rationalism. Moreover, in Locke's view there is no *a priori* knowledge from God. Locke is also generally suspicious of metaphysics. He thinks in terms of concrete detail rather than of large abstractions. His philosophy is built up in piecemeal fashion rather than the grand design of a complete system as proposed by the rationalists.

Locke's system is viewed as being so full of paradoxes that it is logical inconsistent with itself. Thus it cannot be wholly true, by the rule of coherence. Russell (1961) even states that Locke's philosophy is wrong. Locke's drive is to propose a philosophy which is credible with common sense and to move away from the grand metaphysical systems of the rationalists. Generally the British Empiricist philosophy is more piecemeal than the continental rationalist style.

In Empiricism, a comparatively modest conclusion is drawn from a broad survey of many facts (Russell, 1961); whereas in Leibniz for example a vast edifice of deduction is pyramided upon a pin-point of logical principle. In Leibniz if the principle is completely true and the deductions are entirely valid then all can be held to be true, and the system can be said to hold. However, if there is the slightest flaw in the fundamental principle or in

the deduction then the whole system can be said to fall. On the contrary in Empiricism the base of the pyramid is on the solid ground of observed fact, and the pyramid tapers upwards not down to a single point of a fundamental principle. Consequently the pyramid of ideas is more stable and a flaw here or there can be rectified without real disaster. Within the British Empiricist movement the heirs of Locke include Berkeley and Hume.

3.4.2.2 George Berkeley (1685-1753)

Berkeley, an Irish Bishop, also based his philosophy on what he perceived, and thus was an empiricist (Gaarder, 1995). Locke's theory of ideas lead Berkeley into the realm of metaphysics (Marías, 1967), although for Berkeley matter does not exist. Moreover, primary and secondary qualities are just as subjective; all qualities are the content of perception; there is no material substance behind the ideas. The existence of matter is exhausted in it being perceived. The entire material world is but a representation, or perception. According to Berkeley the only thing which does exist is the spiritual self which we have an intuitive certainty of. Physical science establishes laws or connections between phenomena, which are understood as ideas. These ideas proceed from God. Thus we literally live, move and exist in God.

The denial of the material world is viewed by Russell (1961) as being his major contribution. However, Russell does see fundamental problems with this view. On the one hand Berkeley argues that we do not perceive material things, only qualities of them, such as colour, or smell, or sound, or hot/cold etc. Then he goes on to say that these things are merely mental and cannot be associated with an extended cause. In this he is relying on the fact that everything is mental, but nothing is both mental and material. Russell's fundamental criticism of this view is that if something is an object of the senses, some mind is concerned with it; but it does not follow that the same thing could not have existed without being an object of the senses.

In terms of the form of ideas Berkeley does not believe general ideas exist; he is a nominalist. For example there cannot be a general idea of a triangle as it is either equilateral, isosceles, or scalene, whereas the general idea does not involve such

distinctions.

3.4.2.3 David Hume (1711-1776)

Hume is one of the most important among philosophers, because he developed to its logical conclusion the empirical philosophy of Locke and Berkeley, and by making it self-consistent made it incredible (Russell, 1961). This view is shared by Gaarder (1995) who saw Hume as tidying up all the woolly concepts that went before him. Hume's intention was to investigate every single idea to see if it corresponded to reality; as perceived through the senses. He sought the answer to the question: from which impression does this idea originate?

Hume broke perceptions down into two different types: impressions, the initial perception of say a burn; and ideas, the recollection of a burn (reflective memory). An impression is more strong and lively than an idea, and both can be either simple or complex. Every simple idea has a simple impression which resembles it, and vice versa, although complex ideas need not resemble impressions (Russell, 1961).

For example the complex idea of heaven compounded up from pearly gates and streets of gold, all of which have been put together from simpler impressions of an earthly concept. He also examined the idea of God and came to a similar conclusion that he is the compounded idea from our relationship with our own father, and from concepts of infinite intelligence, goodness etc.

Hume opposed all ideas that could not be traced back to corresponding sense perceptions. Hume did not believe in the unalterable ego. In his view there is no underlying personal identity beneath or behind these perceptions and feelings which come and go. This was as Hume perceived his own ego, "I never catch myself at any time without a perception and can never observe anything but the perception." (Russell, 1961)

With regard to the laws of nature Hume's view is that it is meaningless to say that we have experienced the laws of nature. We have merely experienced what we interpret to be their

affects. For example it is not possible to experience that a stone will always fall. It is usual to say the stone will fall because of gravitation but we have never experienced such a law. The only experience we have is the perception of stones falling.

Hume's view on the law of causation is that just because one event is observed to follow another does not mean it is caused by it. For example thunder appears to follow lightning thus it could be assumed that lightning causes thunder. However, lightning does not cause thunder; they are both caused by an electrical discharge. According to Hume, causal connection only signifies a relationship of coexistence and succession. When a phenomenon repeatedly coincides with another or succeeds it in time, by virtue of association of ideas we call the first cause and the second effect, and we say the latter occurs because the former takes place. In Hume's view no matter how many times this is observed it does not allow us to affirm a causal link in the sense of an absolutely necessary condition.

Hume's rejection of the concept of cause and effect leads to a sceptic's view that knowledge cannot achieve metaphysical, or absolute, truth. What Hume is proposing is that all we have is subjective impressions which we build ideas upon, thus there is no absolute knowledge. Russell (1961) states that Hume's scepticism is something that has not been refuted fully since; that is the scepticism which springs from his rejection of the concept of cause and effect derived through observation (induction); although Kant, following in Hume's footsteps, did attempt to address this issue by investigating the problem from its roots upwards.

3.4.3 The Romantic Movement

From the early part of the eighteenth century to the present day philosophy, art and literature and even politics, have been influenced positively or negatively by a way of feeling which was characteristic of what, in a large sense, may be called the romantic movement (Russell, 1961). Historically Romanticism reacted against the inherited rationalism, and is said to be Europe's last common approach to life (Gaarder, 1995).

The first great figure in the movement was Jean-Jacques Rousseau (1712-1778). Prior to romanticism prudence was regarded as the supreme virtue; intellect was valued as the most effective weapon against subversive fanatics; polished manners were praised as a barrier against barbarism. By the time of Rousseau many people had become tired of safety and wanted excitement. The romantics aimed at vigorous and passionate individual life.

The romantic movement as a whole is characterised by a substitution of aesthetic for utilitarian standards. They valued what they considered to be beautiful: the tiger over the utilitarian earth worm. The romantics liked the strange (e.g. ghosts and pirates) and this is most commonly expressed in fiction. They felt inspired by what was grand, remote and terrifying. For example the romantics favoured the middle ages over science.

The romantics admire strong passions of whatever kind, no matter what the consequences may be. Hence the type of man encouraged by romanticism is violent and anti-social, an anarchic rebel, or conquering tyrant. In the view of the romantic movement, by throwing off the social constraints introduced by morality, man can then be true to his passions and by doing so elevate himself to a God like status. Revolt of solitary instincts against social bonds is the key to the philosophy of the romantic movement.

They had a strong belief in nationalism which sprung form the belief that friendly relations towards others is based on a belief that friends can be regarded as a projection of oneself. In love the consequence of this idea is incest between blood relatives. Only by having friends that are a projection of oneself is it possible to break through the conflict of self and social constraints. Hence the popularity of nationalism amongst romantics.

In its extreme form Romanticism can be viewed as reactive and morally corrupt, and a view that the majority seemed to lose by the time they were thirty years old. Russell (1961) sums up a fundamental problem with romanticism thus, "Man is not a solitary animal, and so long as social life survives, self-realisation cannot be the supreme principle of ethics."

3.4.4 German Idealism

3.4.4.1 Immanuel Kant (1724-1804)

As a scholar of philosophy Kant was familiar with the rationalism of Descartes, Spinoza and the empiricism of Locke, Berkeley and Hume (Gaarder, 1995). Kant felt that each view was too monolithic and he sought to form a view which acknowledged that both reason and sensation play a part in the formation of knowledge. He sought to create a transcendental theory of knowledge, where this knowledge is to be the bridge between the ego (mind) and the things (matter).

In Kant's view ideas are ideas of things, thus there are two elements of an idea. Kant draws a distinction between things as they appear to us, phenomena, and things as they are in themselves, noumenal. The noumenal is not knowable, all that is knowable are the observed phenomena. The view formed of the observed phenomena is shaped by the *a priori* knowledge of the mind. Kant labelled his view the Copernican revolution in thought, as he saw it as being similar to the shift brought about by Copernicus' discovery that the Earth revolves around the Sun.

Kant identified space and time as our two forms of intuition, and these forms are *a priori*. Thus space and time precede everything we experience. So everything is perceived as a series of processes in space and time. In Kant's phenomenalist view what we perceive will first and foremost be perceived in space and time.

The *a priori* knowledge of space and time shape our sensory experience, perceptions, of the world around us (the ego). These perceptions are then further interpreted according to twelve *a priori* concepts defined by Kant. The twelve concepts are divided into four sets of three (Russell, 1961):

i) Of quantity: unity, plurality, totality

ii) Of quality: reality, negation, limitation;

iii) Of relation: substance and accident, cause and effect, reciprocity;

iv) Of modality: possibility, existence, necessity.

As can be seen these include the relational *a priori* concept cause and effect. Thus Kant deals with Hume's scepticism by saying that causality is an *a priori* relational concept that the mind imposes on the observed phenomena.

So the two elements that contribute to man's knowledge of the world are: the external conditions that we cannot know of before perceiving them, the source of knowledge; and the internal conditions of the mind, space, time and causality, which describes the form of knowledge. The important development from Kant's philosophy was that of Hegel (Russell, 1961).

3.4.4.2 Georg Wilhelm Friederich Hegel (1770-1831)

Hegel was the culmination of the German idealist movement that started with Kant (Russell, 1961). In addition to being influenced by Kant, Hegel was also influenced by the Romantic movement (Gaarder, 1995).

Hegel saw three stages in the development of knowledge: thesis; antithesis, and synthesis. The start point for this dialectic process is the thesis, then in response to this the antithesis is generated followed by the synthesis of the thesis and antithesis. Thus in the dialectic process it is through the negation of arguments and the development of antithesis and synthesis that ideas logically develop. Each synthesis of the dialectic process contains all the earlier stages; as it were in the "solution" of each stage of the process. As an example of this process Descartes rationalism can be considered to be the thesis; Hume's empiricism the antithesis, and Kant's phenomenology the synthesis. Kants synthesis then becomes the new thesis to be refuted. Thus, Hegel's triadic dialectic can be used to describe historical change in ideas.

Applying Hegel's dialectic demonstrates the subjectivity of truth. All knowledge is human knowledge, and in Hegel's view human knowledge is constantly expanding and progressing through history. The only fixed point philosophy can hold onto is history. There are no

timeless truths. Hegel distinguishes mere information from conceptual knowledge, in which the concepts of things are described.

3.4.5 More Recent Western Philosophy

Influenced by the above philosophers, more recent movements extended and expanded on the ideas reviewed above. In contemporary thought the human person and human activity remain at the main centre of philosophical interest. Within contemporary thought there are several different movements. These include: pragmatic; empiricist; linguistic; idealist; vitalist; phenomenological; existentialist and metaphysical (Walsh, 1985).

3.4.5.1 Pragmatism

According to William James (1842-1910) the whole function of philosophy ought to be that it makes a difference to our lives when applied in our daily actions (Marías, 1967). In his published writing he spoke of human intelligence as an active, selective agent of adjustment whose function is to guide action (Walsh, 1985). According to James' pragmatic theory truth is what works, what turns out to be right. True ideas are those which work, which lead to success, and which give various kinds of satisfaction. To be true ideas must prove consistent with other ideas conformable to existing fact, and subject to experimental corroboration and validation. Theories thus become instruments not answers to enigmas.

Thus according to James' view truth is relative to human desires and aims. Truths are human valuations. To recognise something as true or false is to recognise it as useful or useless to mankind. A belief is true when it has been verified that it "works" for man. Although in a broader sense James does not mention what the common goal, or purpose, of man is. James' critics thought that utility can be a sign of truth but it is not the (formal) constitutive cause of truth (Walsh, 1985).

John Dewey (1895-1952) is another member of the pragmatic school of thought. The true function of philosophical thinking according to Dewey lies in its being directed to resolving indeterminate or problematic situations by effecting changes in the environment and in man

himself (Walsh, 1985). Dewey's view hinges on the idea that thinking and acting are intimately related in man's attempt to adjust and survive in his environment. Thus thinking is seen as a natural biological power whose function is instrumental in solving problems.

In Dewey's view for each problematic situation the true hypothesis is the one which transforms the problematic situation. Thus, knowledge is derived through verifying ideas in practice. Moreover, there are no absolute or first truths that are given or known with certainty.

3.4.5.2 Positivism

The law of three states is the basic proposition of Auguste Comte's (1798-1857) positivist philosophy (Marías, 1967). According to Comte there is a progression in thought from the theological to the metaphysical and finally to the positive.

Theological could perhaps be more accurately referred to as the religious or mythical state. The theological or fictitious state is provisional and preparatory. This state, in which the imagination predominates, corresponds to the infancy of the development of Human thought. At the centre of this view are supernatural causes and explanations for events.

The next state is the metaphysical or abstract state and it is essentially critical and transitional. It is the intermediate stage between the theological and the positive. In it absolute knowledge is still sought. Metaphysics seeks to explain the nature of beings, their essences and their causes. In the previous state God is viewed as being at the centre of everything, the creator and controller. In the metaphysical state this is substituted for nature. However, this unity is weaker and the character of the metaphysical state is critical and negative, and merely a preparation for the next state.

Finally the positive or real state is the definitive one. In it imagination is subordinated to observation. Positivism seeks only facts and their laws. Not causes or origins of essences or substances; all that is inaccessible (Marías, 1967). Positivism relies on the positive that which is given; it is the philosophy of the datum. This is the final state in which the mind

eventually seeks only the laws of phenomena.

The positive spirit is relative. The study of phenomena is never absolute, but relative to our organisation and our situation. The loss or gain of a sense would completely change our world and our knowledge of it. Knowledge must incessantly come nearer and nearer to the ideal limit fixed by our necessities. The goal of knowledge is rational foresight: see in order to foresee, foresee in order to provide (Marías, 1967).

3.4.5.3 Neo-positivism:

Ernst Mach (1838-1916), an Austrian physicist and philosopher, is widely regarded as the father of logical positivism and as the real master of the Vienna circle (Walsh, 1985). Mach developed the empiricism of Berkeley and Hume into a philosophy of radical empiricism. In Mach's view scientific theory is simply a device for predicting the course of our sensations of things. He views sense experience as the basis and origin of all scientific knowledge. Applying this view the only scientific theories or hypothesis that are admissible are those that can be tested in sense-experience. As the scientific laws so admitted are based on sense experience they can only be considered to be summary descriptions of phenomena.

Jules Henri Poincaré (1854-1912) a philosopher of science stated that theories are convenient rather than true (Walsh, 1985). One theory or suggestive model may be superseded by another theory which is more fruitful than the first. In his view theories are conventions that depend on the scientists free choice between alternative ways of imaging or explaining the natural world.

In Moritz Schlick (1882-1936) view scientific knowledge seeks to know the relations between physical magnitudes; thus metaphysics must be denied the status of scientific knowledge. The meaning of a proposition is in whatever observations or experiences show whether or not it is true. A proposition only has meaning if testable or confirmable propositions can be derived from it.

Karl Popper (1902-1996) contradicted this view of verification through positive verification when he pointed out that it is falsifiability not verifiability that is the essential criterion for the scientific character of discourse, and this is the hallmark of science (Walsh, 1985). Thus our present scientific knowledge is simply that body of knowledge which so far, in history, survived all sustained and systematic attempts to falsify it. Scientific theories eventually become provisionally accepted by successful submission to empirical tests. Thus, falsifiability distinguishes the empirical theories from the non-empirical.

3.4.5.4 Existentialism

Existentialist philosophers include Martin Hiedigger (1889-1976) and John Paul Sartre (1905-1980) (Gaarder, 1995). Existentialism starts from humanity itself; it is humanistic. Man must decide for himself how to live. Existence is the key word in relation to the position that man finds himself in. We each have to find our own way to live and work it out for ourselves, through our conscious human thought. We are totality responsible for everything we do. There is no eternal truth out there guiding us and telling us what to do. We are totally free to make our own choices. Our freedom obliges us to make something of our lives, and not just to join the flock. We each one of us perceive a situation according to what our interests in the situation are.

3.4.6 History of Modern Western Philosophy Summary

The purpose of this section has been to provide a historical context for the philosophical concepts systematically reviewed and applied elsewhere in the thesis. Thus this section gives a historical reference point for the ontology and epistemology described in sections 3.5 to 3.11.

3.5 ONTOLOGY

Having established the basis for building a philosophy and the required qualities of a philosophy, the first component in any philosophy to be considered is ontology. According to Ferm (1969) ontology, the nature of reality, can be analysed by addressing two

questions:

i) How many realities are there?

ii) What is the nature of each of those realities?

In considering the answers to these questions the ontological view sought will be the one which best represents a meaningful basis for an analysis of the CDS problem.

3.5.1 Number of Realities

In terms of the number of realities these can be broken down into three views:

i) The monist view considers there to be a single reality.

ii) Dualism takes the view that there are two realities.

iii) Pluralists see the world as consisting of multiple realities.

There are a number of implications attached to each of these views, in particular the level of analysis and abstraction in each of the views. The monist view of reality involves the most analysis and abstraction of experience to arrive at the one unifying view on reality. At the other extreme the pluralist sees reality as being made up of many different experiences none of which are related, each representing its own reality. The dualist views requires some degree of analysis of experience down to one of the two views of realities, but not to the extent of attempting to put all these experiences down to one unifying experience. This implication is considered in more detail below in an analysis of each of the views.

3.5.1.1 Monism

Monism considers there to be one single unifying reality of all things, everything is of this

one reality. An example of monism being Spinoza's logical monism described in section 3.4.1.2. Central to the concept is the ordered and united universe, in which everything is interrelated or tied in together. This whole in which everything is united has qualities which cannot merely be considered by studying the sum of the parts in it. Essentially it expresses an holistic view of the world, and is traditionally seen as the system builders view of the world. However, expressing a system in monist terms is a denial of another world which the system model is merely an abstraction of. Therefore for effective systems thinking and system model testing there has to be a reconciliation of the abstracted or idealised system and its material manifestation. The testing of a system model against its physical manifestation is fundamentally an admission of the dual nature of reality. Therefore, in terms of ontology, systems building is not an expression of a single monist reality.

The strongest point in favour of the monist view is an epistemological one. This is essentially that all it is possible to know about reality is held in the mind, therefore there is only one true reality and this is held in the mind. However, such a monist view assumes that reality can only be exist in the mind, and takes no account of the reality which exists regardless of and beyond the ideas and perceptions of the mind. Another criticism of monism expressed by Ferm is that monism represents the supreme sophisticate putting all sorts of "humpty dumpties" together even though they are not related.

Monism represents an over analysis of reality and an over simplification, a denial of the existence of an "out-there". Moreover, it does not represent an ontology which is meaningful when considering the activity of systems modelling. Therefore for this thesis monism will not be taken as the basis for constructing an ontological model.

3.5.1.2 Dualism

The dualist view is that reality can be analysed down to two realities, existing together. The exact nature of the realities is not fixed. The most orthodox natures of dualism are mind and body, Descartes' the thinking world and the extended world (section 3.4.1.1). These two realities are fundamentally real and separate, although there is an interaction

between the two realities. It is this interaction between the two realities in dualism which leads to doubt over the existence of two opposite and exclusive poles. Leading many dualists back into the monist analysis of reality. However, when considering the mind and body natures of a dualist view of reality it is possible to see how the two can be real and separate.

Applying the dualist realities of the mind (idealist) and body (materialist) to the process of building a system, the abstraction of the material reality occurs in the idealist reality. There is then an expression of the idealised abstraction back in the material reality, followed by a comparison of the material system expression with the original material reality the system abstraction is attempting to represent. At the most fundamental level this process could be used to describe the process of the mind's conceptualisation of material reality, and the expression of the conceptualisation in language. A simple example of such a model formulation is the drawing and subsequent use of a road map. The road map is merely a conceptualisation, and simplification, of the material road system which does exist regardless of the existence of the map. The map is a material manifestation of an idea of how to represent the material reality of the road system. Therefore, dualism represents a system builders view of reality.

3.5.1.3 Pluralism

Pluralism is fundamentally centred on the idea that we have many different experiences and that each separate experience defines reality, a view expressed in existentialism. The belief is that we live in a fortuitous world, a world of chance, where nothing is planned and anything could happen. The world is viewed as a mess made of many separate people, phenomena and ideas.

To a pluralist a totality is merely an abstract, the parts are not really parts they exist, as they are observed, in there own space in a whole. Thus it is the least analytical of the three views on the number of realities. In this existentialist extreme there is no analysis, or reason, merely existence, or being. In a way it represents an anti-intellectual ontology; where intellectual activity is normally centred on analysing, understanding and linking

observations under unifying theories. Under this philosophy there is no necessity in the concept of scientific law and order no absolute underlying unity which ties it all together. For example, the law of gravity is merely a description of the observation of objects in space, there is no underlying unity. Thus, as a philosophy for intellectual endeavour it does not provide a useful basis; particularly when considering systems modelling which by its very nature involves some analysis, abstraction and unification of the experiences of the material world.

3.5.2 Nature of Reality

Within any reality its nature can be thought of as being either (Ferm, 1969):

i) Idealist, essentially reality is a set of ideas.

ii) Materialist, everything is matter.

iii) Dynamist, all is energy, movement and flux.

iv) Neutralism, none of the above apply to reality it is nothing in particular.

So, the question now is what is the nature of the realities in the two realities which are to be adopted in the dualist ontology. The dualism combined with a descriptive view of the nature of the realities is fundamental to an expression of a world view. Thus it sets the context for the analysis which follows in the thesis.

3.5.2.1 Idealism

An idealist reality is akin to human thought, or the human mind. Reality is based on a world of ideas, the world is in the mind of the beholder. Ferm (1969) classified four essences of idealism; these are outlined below and their possible role in decision making is assessed.

i) Reason is of the essence, rationalistic idealism is the application of logic. For example by the application of deductive reasoning formulating new ideas. In this view man is a purely rational being. As an ideal rationalism can form the basis for decision making.

ii) Emotion is of the essence, romanticism, or affectivistic idealism, views moods at the root of human ideas not reason. Moods are viewed as closer to the nature of man than his rational processes. This is an unsystematic view of idealism, since feelings are spontaneous. Reality is something which is experienced and felt rather than understood. Such romanticism does not feature in the philosophy of science, although it does undoubtedly affect human experience of life. Thus decision making could be influenced by romanticism.

iii) Impulsive irrationality is the essence, voluntaristic idealism views ideas as being driven by man's will; for example the drive to reproduce, the drive for survival. In voluntaristic idealism the will is fundamental, it shapes reason and dominates the passions. It is this inner passion which drives us on to achieve other things, choice is the determining factor in life. These choices have no foundation in rationality as there is only the passion in us all which drives us on. From an epistemological view we go on without knowing all the answers, because not everything is a justified true belief, or known, it is merely a belief. In this view there is not a belief on the nature of reality, and therefore no application of philosophical logic. Any decision to take an action, or make a choice, is only consistent with a deep internal drive. There is no considered application of logic, only pure impulsiveness.

iv) The totality of the self is the essence; here the idealist reality is a totality of personality. It is not simply rational or emotional or voluntaristic, but a mixture of all three. This analysis of the idealist reality relies on considering its nature as being akin to that of personality with all its different facets. Thus decision making can be influenced by application of rationalism, emotion or free will.

The most holistic of these views on the nature of an idealist reality is the totality of

personality. In this analysis of the nature of idealism all of the essences described in one to three constitute the total nature of idealism. For example, man uses his powers of reason to solve problems rationally, he has emotional responses to situations, and takes action to ensure his continued survival. Thus, all essences of idealism are involved in an idealist reality. However, in terms of intellectual pursuit man strives to display rationalistic idealism, to the extent that this nature of idealism is held in highest regard and the others are often dismissed rather than acknowledge. Although, when considering decision making in the idealist reality of the mind all of the essences describing its reality influence the process of decision making. Analysing the decision making process on different levels can illuminate this further. For example, a man decides to work to earn money to eat and survive, voluntaristic, on another level his emotional response to his environment may affect how effectively he makes decisions, romanticism, and finally when faced with a technical problem he may apply deductive reasoning to solve it, rationalism. Thus voluntarism influences the perception of a need which drives an action, romanticism defines the emotional context of the decision making, and rationalism defines a mental process which can be applied when seeking the solution to a problem. Which of the categories of idealism have an influence will depend on the stage of the decision making process.

3.5.2.2 Materialism

Materialist reality is akin to the physical world. In materialist reality matter is fundamental, both its function and its form. An example of a materialist view of reality is the atomic view of all matter in the world consisting of atoms. Under this theory all matter can be broken down into its constituent atoms. For scientists with a monist view of reality, the nature of the reality is material. In this view the mind function and form is explained in terms of a brain consisting of many nerve cells and with electrical impulses travelling between them. In a material reality it is science which will give us our understanding and knowledge of the material reality. The materialistic monist believes the only thing truly real is the physical world that we inhabit. Although through observation this does seem to be a reasonable explanation of reality, it is a denial of the involvement of the mind in the conceptualisation of the material world.

3.5.2.3 Dynamism

Dynamism views the nature of reality as pure energy, neither spiritual or physical. The world is in a constant state of flux or change. Heraclitus expressed this view by stating that everything flows, all is flux, the only thing unchanging is the flux. Reality is seen as a dynamic process which is available to us in our non-intellectual, non-analytical, immediate insights. Dynamism is a reality in which activity systems are in action and reaction to one another. Under dynamism with its constant flux systems exist in an unstable manner. The fact that a system can be identified implies there is sufficient stability for the observation to be made and that not everything is in a constant state of flux. Epistemologically this is a expressed in the need to gather reliable knowledge of reality. Reliability implies that there is some consistency. Therefore, for reliable knowledge there must be stability and consistency.

Dynamism does offer a view though on how the dual realities of mind and body can interact with one another; where to the observer the mind and the body are entities with sufficient stability to assess them as systems in an idealist level of abstraction. The movement between the two realities being by a dynamic transference of energy from the idealist to the material reality, and vice versa. Such dynamic change is then observable in the material reality.

3.5.2.4 Neutralism

A neutral reality has no character of force. It is not any of the previous three in nature. Reality only exists in pure experience, it just is. There are no entities, patterns or forms. There is no idealist analysis or judgement of the world around us just experience. There is no material existence, or dynamic interaction in the world. As for pluralism, this existentialist ontology offers no analytical basis for a decision making or for systems modelling.

3.5.3 Ontological Model

The analysis of ontology was to firstly consider the question of the number of realities and then the nature of each of these. There are three classifications for the number of realities: monist or single reality; dualist or double reality, and pluralist or multiple reality. The nature of a reality may be either: idealist, all ideas; materialist, all matter; dynamist, all constant flux, or neutralist, there is no nature. The ontological model is to be applied to an analysis of systems modelling, decision making and decision support. The criteria for deciding which philosophical concepts to include in the model is related to how well the concepts apply to systems modelling and decision making.

Monism, in an idealist sense, is traditionally seen as the system builder's view of the world. However, expressing a system in monist terms is a denial of the material world which the system is merely an abstraction of. Therefore for effective systems thinking and system model testing there has to be a reconciliation of the abstracted or idealised system and its material manifestation. Testing of a system model against its physical manifestation is an admission of the dual nature of reality. Therefore, in terms of ontology, systems building is not an expression of a single monist reality.

A pluralist analysis of reality is essentially the existence of a number of neutralist realities all existing at an experiential, or existentialist level. The application of such a concept to systems analysis would not provide any greater insight than that which is immediately observable.

Dualism takes the views that there are two separate and distinct realities. The most orthodox natures of dualism are mind and body, Descartes' the thinking world and the extended world. Applying the dualist realities of the mind (idealist) and body (materialist) to the systems modelling process. The abstraction of the material reality occurs in the idealist reality. There is then an expression of the idealised abstraction back in the material reality, followed by a comparison of the material system expression with the original material reality the system abstraction is attempting to represent. Therefore, dualism represents a system builders view of reality. Movement between the two realities is by a

transference of energy across a dynamic bridge from the idealist to the material reality, and vice versa. The dynamic interaction, or processing filter, between the two acting as a cross over point, as depicted in figure 3.4; examples of the filters being human perception for observing matter, and language used to express what exists in the mind. Thus the ontology can be viewed as an idealist reality, encompassing all the essences described above, interacting with a material reality. This view of reality modelled in figure 3.4, will form the basis for an analysis of the epistemology to be used, and as a philosophical model of the decision making process.

Ontologically decision making is a process involving the interaction of the idealist and material reality. In the idealist reality actions are decided on and then converted by a process in the dynamic bridge into actions. The actions then cause a disturbance, or reaction, in the material reality which is observed and converted back into ideas for adding to the next decision making cycle. This is a general model of decision making applicable to all categories of decision, including intuitive and rational based decisions.

3.6 EPISTEMOLOGY

The ontological model gives a framework for building up an epistemology, the theory of knowledge. The ontology defines the realities which there can be knowledge of, and where knowledge can exist. Knowledge is thus a function of a view of reality as it can only exist within this view, and is knowledge of the realities portrayed in the ontology.

Epistemology is useful in the context of understanding the nature of knowledge, and using this understanding to analyse its role in decision making and knowledge based systems. Important aspects of knowledge are its truth and validity, which will also be covered in this section. O'Connor and Carr (1987) define the four key concerns of epistemology as follows:

i) Giving an account of the nature of knowledge.

ii) The sources of knowledge, with the nature and modes of acquiring knowledge.

iii) To defend criteria for judging knowledge against radical scepticism, which questions the very existence of any knowledge.

iv) The scope, or context, of the knowledge of the realities expressed in the ontological view.

Katz (1993) defined epistemology as the study of what knowledge is, how it can be obtained, and how it can be validated. This three part definition corresponds to the first three parts of the definition by O'Connor and Carr. O'Connor and Carr add to this the importance of the scope of the knowledge in an ontological context. Therefore, in defining an epistemology for decision support the four aspects of knowledge to be considered are its: nature; scope; sources, and validity. Each of these aspects of knowledge will be considered in the following sections.

3.7 NATURE OF KNOWLEDGE

Knowledge can be defined in different ways:

i) Knowledge is a rich form of information, often expressed as facts, rules, relationships, assumptions, tasks, etc. (Tansley and Hayball, 1993)

ii) Knowledge is relationships, facts, assumptions, heuristics, and models derived through the formal or informal analysis or interpretation of data. (Shortliffe, 1990)

iii) Knowledge comprises a set of formulae, rules, or heuristics that can be used to create information from data (or other pieces of information). (Deutsch et al., 1994)

iv) Knowledge is commonly understood as justified true belief. (O'Connor and Carr, 1987)

The first three definitions come from the development of knowledge based systems.

Hence, the emphasis in these definitions on the representation of knowledge as a form of information. Combining these three definitions of knowledge representation into one; knowledge can be represented as rich information which contains facts, rules, assumptions relationships, heuristics and models. The emphasis here is on the expression of knowledge in the material reality. Such a representational definition does not describe the nature of knowledge in a philosophical manner, that is it is not a general definition of knowledge, and there is no mention of any judgement of the truth of knowledge. Therefore this definition is too restricted in its applicability, and a more general definition is needed.

A philosophical definition of knowledge provides the basis for a definition which could be useful in knowledge based system development. Such a general definition includes the fundamental aspects of the nature of knowledge. With a better understanding of these fundamental aspects it will be possible to analyse more fully the complexities of dealing with the concept of knowledge. For example an appreciation of the subtleties of knowledge could aid in structuring the process of knowledge elicitation from a knowledge source. Furthermore, when seeking to make a contribution to knowledge there needs to be an appreciation of the nature of knowledge.

The definition which does satisfy the criteria for a philosophical definition of the nature of knowledge is the fourth one as quoted by O'Connor and Carr. Here knowledge is expressed as justified true belief. This definition of knowledge uses the concept of belief to define the nature of knowledge. So before considering the criteria for judging what makes a belief knowledge, the concept of belief is analysed.

3.7.1 Belief

Traditionally there are two philosophical models of belief: the mental model, where belief is viewed as a mental occurrence of the believer, and the behaviourist model, where belief is viewed as the material expression of behavioural dispositions. Both types of model are process models, the mental model describes the acquiring of a belief, whilst the behaviourist model represents the expression of belief. The mental models exist in the idealist reality, and the behaviourist model is a material model. An ontological view of the

two models is given in figure 3.5.

3.7.1.1 Mental model of belief

In his mental model of belief Hume summed up belief as a "lively idea related to or associated with a present impression". In arriving at this definition Hume was attempting to address the question of what is the process involved in moving from perception through to belief of how future similar events will occur. Such a model of belief could be considered to be a model of the acquisition of knowledge.

Extending Hume's lively idea Cook Wilson's mental model considered belief as two separate acts:

i) Entertaining the proposition P;

ii) The assenting to or adopting of the proposition.

The first act entertaining a proposition involves formulating and then considering the proposition without making a commitment either way on whether the proposition is true or false. To adopt the belief entertained then involves accepting the belief. The basis for judging the belief varies according to the criteria for judging it. Beliefs are held after the assenting stage of the process described in the definition. Therefore, the more propositions someone entertains and assents to then the more beliefs they will acquire. If the propositions in question are domain specific and linked with each other in a logical manner then a set of linked beliefs will be formed. Where these beliefs constitute knowledge, the beliefs gained through experience form a knowledge base of domain expertise. Thus, the notion of expertise through exposure to propositions under the mental model does reinforce the notion of using experts as a source of knowledge in knowledge based system development.

The acquiring of belief, or knowledge, is only one aspect of belief. There is also the aspect of belief concerned with holding, or having, a belief. The behaviourist model attempts to

describe how the beliefs held are expressed in actions.

3.7.1.2 Behaviourist model of belief

The behaviourist model states that beliefs manifest themselves in the action of an individual. Braithwaite's theory of belief in action interprets belief, as in I believe in proposition P, as the conjunction of two propositions:

i) I entertain P,

ii) I have disposition to act as if P were true.

The problem with the second proposition here is in the connection of an action with the belief that P is true. Even when considering an individual expressing a belief P there is no absolute technique for saying they do definitely hold the belief. An individual's actions and words can lie about their belief. However, in a more general sense some propositions do have a direct impact on actions. For example when trying to find a set of keys, if you believe the keys were left in the top drawer, your action will be to look in the top drawer. Therefore, held beliefs do influence actions, but not always in a transparent way. This problem of identifying held beliefs is fundamental to the problem of knowledge elicitation when developing a decision support system.

Taking decision support to be advising on the choice of an action from several alternatives there needs to be a link in the system between the system knowledge and the system recommendations. By having a transparent link between the knowledge and the advice offered deductive justification of the advice is made available. The link between these two is normally determined by an expert knowledge source. This raises the question of how does the expert interpret their own connection between held beliefs, or knowledge, and the actions they normally perform. This is one of the very fundamental problems of knowledge elicitation of expert knowledge. Any knowledge elicitation does require some acceptance of the behaviourist model as being true.

3.7.1.3 Belief summary

In summary there are two models of believing, acquiring belief and expressing a belief. The mental model theories above attempt to analyse the first category, whilst the models based on action attempt to describe the second. These can be combined by considering firstly the building or accepting of a belief, and then the acting or using of a belief. The first stage will be an actively mental one where the proposition is questioned against previously held beliefs before it is added to them. Then once a "map" of beliefs is constructed, and held in memory, these will be used in the reactions to problems faced by an individual. This model of beliefs can then be applied to knowledge, as knowledge has been defined as a type of belief.

In developing a model of knowledge the mental models of belief confirm that knowledge is formed and stored in the idealist reality, and expressed and put to use in the materialist reality. Therefore, it is possible for knowledge to exist without there being any material expression of the knowledge. This reinforces the point that a definition of knowledge which only describes an expression of knowledge is not describing its absolute nature. The mental model provides a basis for the analysis of how knowledge, or expertise, is acquired. The behaviourist model can be used to provide insight into the process of knowledge elicitation.

3.7.2 Truth

The distinction between belief and knowledge needs to be made, as not all beliefs can be considered to be knowledge. Knowledge, a justified true belief, can withstand critical examination. Specifically, to be classified as knowledge a belief must be able to be judged true according to the criteria for truth described below. In the context of using knowledge in decision support the concept of truth is fundamental to an assessment of validity of the knowledge, and in assessing the "true" state of matter when offering decision support.

Ontologically truth exists as a concept in the idealist reality. Truth is a judgement made in the idealist reality; truth does not exist outside this reality. In the material reality matter

cannot know truth. It is only when matter is being observed through the application of perception and ideas that truth about matter can be said to begin to exist. To put it another way truth is a quality assigned to knowledge and knowledge only exists in the reality of ideas, therefore truth can only exist in ideas. For example, consider a scientific experiment running in a laboratory isolated form all observers. Running in isolation the material reality of the experiment contains no concept of what is true. Matter by nature does not contain ideas or make judgements. The truth value of the results of the experiment can only be judged when observation of the results are made. The judgement will be made according to observation and interpretation using previously held ideas, or concepts. This judgement will depend on the observer's perceptive skills, their knowledge base of ideas and their analytical ability. To sum up truth exists in the mind of the beholder. Therefore, any truth will have a subjective element. This is a fundamental problem when trying to construct an "objective" knowledge base.

One implication of the view of an idealist truth is that there is no universal truth in the material reality waiting to be discovered. Any laws concerning the behaviour of matter are idealistic interpretations of observations.

The three aspects of analysing truth, as attached to a belief are:

i) The acquiring of a true belief, applying the mental model of belief.

ii) How can truth be expressed, applying the behaviourist model of belief.

iii) How can the truth of a belief be tested.

Acquiring a true belief involves the process of:

i) Entertaining proposition A.

ii) Testing the truth of the proposition and finding it to be true or false.

Following this process a knowledge base will be added to. The expression of a truth follows a similar two stage process:

i) Entertaining a proposition A as being true.

ii) Expressing, or behaving, in accordance with the belief that A is true.

In both of these processes there is some judgement on the truth of a proposition. Therefore, a proposition can be viewed as the truth carrier or truth bearer. To publicly test such a proposition there needs to be some expression of the belief before this can be done.

3.7.2.1 Expression of truth

Some truth bearers are essentially linguistic but they need not always be. For example an action may be an expression of an internally held truth. However, the expression of truth by action is limited. A large number of truths rely on language to express them.
So, what is the nature of the linguistic truth bearer, the proposition. A statement of truth is an affirmation about some observed material phenomena, for example, there is a black cat lying on the mat. The levels of truth in this statement are first that it is a correct description of a possible state of affairs. In other words is it coherent with the present world view, do cats lie on mats. The second level of truth is the context of the statement, or the space and time being referred to by the statement. A proposition can be regarded as the cognitive content, or meaning, of a statement of truth; each of the meanings, or interpretations, of a statement being represented by an individual proposition. For the above statement three propositions can be analysed as representing the meaning of the statement: the cat is black; the cat is lying down, and the cat is on the mat. So, propositions are the breakdown of the meanings of a sentence, and are subject to the same tests of truth as any truth statement. Their value is in expressing one of the facts or meanings of a statement. Thus they are more precise than general sentences and offer an object which can be tested for truth in the public domain.

Redundancy theory address the problem of how truth can be expressed in language. The

basic representation of truth is a proposition, "Snow is white." If such a proposition is represented by P, redundancy theory holds that to say, "P is true" is the same as simply stating," P", or "P is false" is the same as "Not P". Therefore, adding true and false does not add meaning to the proposition as they are merely adjectives which do not add meaning to the proposition and are therefore redundant. Therefore to express a truth it is sufficient to state,"P," it is not necessary to state,"P is true."

3.7.2.2 Truth tests

The judgement of truth, or a proposition, can be philosophical or non-philosophical. The categories of truth test which do allow for critical reflection, or the philosophical criteria for truth are:

i) Coherence theory is concerned with the knowledge being consistent with what is known already. In this theory harmony of ideas is the essence of truth, the emphasis is on building a systematic body of knowledge. Applying this theory depends on the knowledge base and the logic used to judge the coherence of the proposition under test. The theory's most fundamental assumption is that the knowledge base already in existence is true. Thus, this test should not be considered to be a revealer of absolute truth, but a test of the consistency of a proposition with what is already known. Coherence testing can be considered to be the "it makes sense" test of truth. In other words if there is no logical contradiction of the proposition under test with that which is already known then the proposition makes sense.

ii) Correspondence theory, is the correspondence of a proposition to a fact or an observation of material phenomena. Under this theory a proposition represents one entity, the expression of a truth, and the other entity is a fact, the observation of matter. It is the correspondence of one entity to the other which acts as a test of truth. This can be thought of as the correspondence of truth bearers, propositions, with truth donors, or physical observations. An illustrative example of this theory is a map which corresponds to the material terrain which it represents. Here the

map is synonymous with the proposition and the area it represents synonymous with the facts. The testing of the "truth" of the map will rely on firstly the interpretation of the map, using the concept of the language of a map, and then a visual test of its correspondence with an observation of the observed surroundings. Obviously the interpretation of the map as a true representation of an area will depend on the skills of the user of the map. Thus, the interpretation of facts is governed by perception, and moulded by the concepts, or ideas, through which reality is interpreted.

iii) Pragmatic theory states that if an idea works then it is functionally true. This theory was developed by the pragmatists William James and John Dewey (section 3.4.5.1). To the pragmatist a true statement is one which is useful; a true theory is one which works in practice. Therefore, this theory is concerned with measuring the utility of propositions to assess their truth. The utility of any idea, or proposition, is a matter of judgement and dependent on a set of goals. Therefore, subscribing to this theory involves the adoption of the view that truth is always contextually dependent on a purpose. As there is no universal context or purpose then pragmatism holds there is no universal or absolute truth. Moreover, truth is fluid and open to change, revision and new plateaus. Therefore knowledge of the world is constantly changing and evolving. Both humanistic pragmatism, where the truth satisfies the goals of the human race, and the experimental scientist, or positivists, subscribe to this view of truth. To the pragmatist the more a truth works the more certain it becomes.

The judgement of a proposition about material reality will involve the application of the correspondence theory, as an observational test, and the coherence theory as a logical test of the proposition. The pragmatic test can be applied as another level of testing applying correspondence and coherence to judge if a pragmatic purpose has been satisfied. The tests of truth outlined above allow for critical reflection on the truth of a proposition, thus they provide a philosophical test of truth. Moreover, they can be applied to testing the validity of any knowledge base containing propositions on the material reality.

The non-philosophical criteria for judging truth, which are not by nature open to philosophical question, are:

i) Truth from an authority; the authority could be a church, parent, social group, or one of many more sources. One fundamental problem with this criteria for truth is that different authorities disagree on the truth of propositions. Therefore, accepting as true without question a proposition from a single authority is not the basis for obtaining a philosophical truth.

ii) Truth appealing to feeling, an emotional response to a proposition which gives a feeling that it is true. The problem with linking truth to feeling is that emotions can be very unstable. Thus, the context of a truth becomes dependent on a fickle emotion.

iii) Truth by general agreement of a group; truth is whatever the majority of people believe to be true. There have been many cases through history where the once commonly held belief is now almost universally agreed to be false, for example the notion of the earth being flat. Therefore, just because the majority of people believe a proposition to be true does not make it true.

iv) *A priori* or self evident truths are truths which are prior to experience and are an expression of the nature of the mind. To set a proposition as self evident does not leave it open to philosophical reflection.

v) Intuitive truth is truth as revealed to an individual by some inner insight. The intuition being something beyond reason makes it difficult to question the validity of the truth.

All of the last five categories of truth are non-philosophical because they lack critical reflection and can border on the dogmatic. In its purest form dogmaticism makes no room for question. Thus any truth which can be classified in this way, and has not been subjected to any critical analysis is not valid as a rational source of justified true belief; although, the

five non-philosophical bases of truth can be used as a source of propositions which are then tested using the philosophical tests of truth. Thus the source of propositions to be entertained can be philosophical and non-philosophical. However, the philosophical tests of truth act as the test for forming a reasoned and validated knowledge base. In a practical sense the three philosophical truth tests offer a basis for the validation of propositions in a clinical knowledge base.

3.7.3 Summary on Nature of Knowledge

Knowledge is defined as justified true belief. The mental model of belief offers an understanding of how knowledge is acquired by the process of entertaining a proposition or idea and then the assenting to or adoption of the proposition. The behaviourist's model of entertaining a proposition and then acting as if the proposition were believed, offers an insight into how knowledge is applied.

The major distinction between belief and knowledge is the concept of truth. Truth is a judgement formed on a belief, and so exists in the mind of the believer. A truth may be expressed in a tested proposition, where a proposition expresses a single meaning of the form "the snow is white". For a proposition to be analysed as true it needs to be tested according to coherence, correspondence, or pragmatic theory. Only then can a proposition be defined as a justified true belief, or knowledge.

In the development of knowledge based systems there are the two stages of knowledge acquisition and knowledge utilisation. Knowledge acquisition can be seen as a process described by the mental model of belief, with a test of truth before the belief is adopted as knowledge. Knowledge utilisation can be described by the behaviourist's model, particularly where a proposition is acted on in an explicit and transparent manner. The testing of the truth of the knowledge acquired and utilised is embedded in each process. In acquiring knowledge the truth of a proposition should be tested before being added to a knowledge base, then when the knowledge is utilised it can then be tested again and modified if necessary. Thus knowledge as it exists in the idealist reality, in an open system of ideas, is a dynamic entity.

The testing of truth during knowledge acquisition could be performed according to correspondence theory and coherence theory. Applying correspondence theory, a fact which corresponds to the proposition could be looked for. Applying coherence theory the knowledge can be tested for logical consistency with the established knowledge base. How the observations are performed, and the coherent knowledge base used, are important considerations when applying these tests in practice. In the clinical domain the observations will have to be performed by a suitably qualified person, and the wider the agreement that can be reached on the observed facts the greater the power of the test. The established knowledge base used to test for coherence needs to be fixed and agreed upon. One possibility is to test clinical knowledge for coherence with established physiological and pathophysiological knowledge. Then if the proposition is contradictory to this knowledge it can be rejected. However, testing a piece of clinical knowledge referring to patient treatment against this knowledge does represent only a shallow test of the knowledge. Finding an established deeper clinical knowledge base is difficult partly due to the dynamic nature of clinical knowledge. This is a fundamental problem when applying coherence testing to new clinical knowledge.

Knowledge, once acquired, can then be further tested when utilised. Providing knowledge can be linked to an action, then a proposition can be tested by applying the pragmatic test of knowledge. This is fundamentally testing whether or not the knowledge works, or satisfies perviously defined purposes. For example if an ethical purpose of clinical decision support is to improve patient care, then a pragmatic test of a knowledge base used in decision support would be to see if it improves patient care. Following the pragmatic test there needs to be a reappraisal of the knowledge used, in a similar manner to how the knowledge was judged in the first instance. So there is a feedback loop back into the knowledge base; thus knowledge can potentially be updated and changed in a dynamic manner.

When assessing knowledge it should be remembered that truth is always contextual, both in terms of its acquisition and utilisation. Therefore there is no absolutely true knowledge only degrees of belief. The belief which is nearest to absolute is that which is held to be most true, and most justified is normally the most unshakable or most absolute, but all

knowledge is contextual according to the "map" of belief which already exists. To use the analogy of the map, a new piece of knowledge has to have its place clearly marked on the map so its interrelation to other knowledge is clear. On such a map we could have propositions representing fixed places on the map, and the connecting roads could be seen as being analogous to the reason used to connect these propositions. However, just as places and roads can change it is important to remember the dynamic nature of knowledge. Throughout history there have been examples of commonly held knowledge, for example the sun revolves around the earth, which are now considered to be false, and hence are no longer on the knowledge map. Therefore, when defining and testing knowledge the context of formulation and application should be defined also. How to define the context, or scope of knowledge is considered below.

3.8 THE SCOPE OF KNOWLEDGE

The highest level for an analysis of the scope of knowledge is ontologically. It has been established above that knowledge exists in the idealist reality and is expressed in the material. The existence of a reality is established by the knowledge we have of it. Therefore, at the highest level there exists knowledge of all aspects of the ontological model. This is depicted in figure 3.6 as an encompassing ellipse within which there is conceptual knowledge. Within this ellipse are all the concepts used to make sense of reality. This category of knowledge defines the knowledge base used to make judgements on the coherent truth of all new propositions. A systems model could be considered to represent conceptual knowledge when it is being used to make sense of a specific domain. For example conceptual knowledge of diseases is used in the process of making clinical diagnoses. Within the realm of concepts of the whole of reality it is useful to define two further categories of knowledge:

i) Knowledge of the state of a reality, for example knowing a patient has a high concentration of potassium in their blood.

ii) Know how, which is knowledge of how to perform an action or make an observation.

These latter two categories of knowledge will be influenced by the conceptual knowledge. For example any interpretation of the state of matter is dependent on our knowledge of the concepts of matter. This is clearly demonstrated in a specialist domain such as nephrology where the concepts of normal kidney function will be an influence. In clinical care conceptual knowledge will determine what monitoring actions are taken, and then know defines the way the actions are performed. This implies some previous experience, or knowledge gathering, to learn how to perform the activity and observational techniques. The interpretation of observations into ideas on the state of reality will be influenced by the conceptual knowledge used to interpret the observations to form knowledge of the state of reality. So, knowledge of the state of reality is dependent on information gathering, the know how needed to gather the information and the conceptual knowledge used to interpret the information.

3.9 SOURCES OF KNOWLEDGE

Two main classifications of the sources of knowledge are rationalism and empiricism, one from sensation and the other from reflection. These classifications originate from two of the major movements of modern philosophy: continental rationalism and British empiricism (section 3.4). Rationalism, or "getting at the essence", is founded in the reason of the mind. As a source of knowledge rationalism in its purest form takes the view that all knowledge comes from the application of reason and does not have to involve experience. Implied in rationalism is *a priori* (from what is prior) knowledge, that is prior to experience. A proposition is *a priori* if its truth can be established by means independent of empirical investigation or observation. At the other extreme is empiricism which takes the view that all new knowledge comes from experience. This is *a posteriori* (from what is posterior) knowledge, referring to the view that all knowledge must follow experience via the senses.

The problem with these two extreme views is that one precludes the other. Immanuel Kant (section 3.4.4.1) agreed with the empiricists in that he believed all our knowledge of matter is founded on experience. However, he extended the ideas of the empiricists by stating that it is our reason which determines how the world is perceived. The concepts of the world

already held, *a priori* knowledge, influence the way sensory observations of matter are interpreted . For example the concept of states of the material world existing in space and time is an *a priori* concept recognised by Kant, and applying this concept to sensory observations means they are interpreted as phenomena in space and time. Interpreting experience in this way means that the mind can never "see things exactly as they exist in the material sense" but that knowledge of matter only represents an expression of the way in which phenomena are experienced. Another expression of this idea is that there are two worlds that which we observe (phenomenalism) and that which is the noumenal (real) world. This view has been labelled phenomenalism, all that we can know of material reality is as it appears to us. Beyond the application of reason in perception Kant also specified the use of concepts to make sense of perceptions in a coherent reasoned manner, for example in the categorisation of perceptions into groups. Thus there is the application of rationalism to the categorisation of perception according to *a priori* knowledge.

Ontologically as an analysis of the source of material knowledge, Kant's view is consistent with the model of ontology proposed above. In this ontological model the observational boundary, or filter, between mind and matter can be used to represent the noumenal world on the material side and the phenomenalist world on the idealist side. The phenomena perceived are then interpreted using conceptual knowledge in the idealist reality. According to Kant the two stages are interdependent on one another and one without the other does not lead to new knowledge. The Kantian epistemology is also illustrated in the model describing the scope of knowledge. Here know how is applied to sensations to form perceptions and conceptual knowledge is applied to these to form new knowledge. The process of knowledge building in this way is illustrated in a process model, figure 3.7. Thus, to build a knowledge base specific to a domain of reality requires experience of events in that domain and the required *a priori* conceptual knowledge to form knowledge from the observations. For a knowledge based system to emulate knowledge formation it needs to contain the structure for interpreting observations, conceptual knowledge to judge the observations, and the necessary process logic to form new knowledge.

3.10 VALIDITY OF KNOWLEDGE

Considering the process of knowledge acquisition, storage and application, as depicted in figure 3.8, an analysis of the validity of knowledge of material reality can be considered at the acquisition stage and the application. Knowledge is valid at the acquisition stage if it complies with the description of knowledge given in the section on the nature of knowledge. Thus, if on acquisition knowledge is tested for truth according to the above criteria it can be labelled valid. The test of truth or validity in the application stage is the pragmatic truth test. Thus if the application of the knowledge satisfies a practical purpose it can then be judged to be valid. In the field of technology the emphasis is on the testing of knowledge in its application. This is discussed in more detail below in the consideration of the philosophy of technology.

The judgement of knowledge validity is a function of the idealist reality the knowledge exists in. In other words the validity of knowledge is dependent on the context of the idealist reality it is being interpreted in. In addition to the idealist context there will also be a material context which knowledge is acquired in and applied to. Applying the *a priori* concepts of space and time means the context of material phenomena will be defined in terms of space and time.

For knowledge based systems applied in decision support they exist to aid the solution to a practical purpose. Therefore, the emphasis is on the pragmatic test of knowledge validity. However, if the applied knowledge has not first been tested for truth in its formation this could invalidate its application.

3.11 EPISTEMOLOGICAL MODELS

The four aspects of epistemology to analyse knowledge here are the: nature; scope; source, and validity of knowledge. The broad definition of knowledge is a justified true belief. This can be expressed in the form of a proposition. A proposition in application to material objects is of the general form object A is B, where B is a property of A.

Knowledge as justified true belief requires firstly the act of believing followed by the judgement of truth. Two models of belief have been proposed: the mental model, and the behaviourist's model. The mental model applies to the acquisition of a belief, or knowledge. Firstly mentally entertaining a proposition and then subscribing to the belief. The behaviourist's model is concerned with the connection of holding a belief and then acting in accordance with that belief. This leads to a three stage model of knowledge acquisition, storing and application, figure 3.8.

The criteria for judging truth can be categorised as philosophical and non-philosophical. The philosophical criteria allow for critical testing of truth. Whereas the non-philosophical require a degree of unquestioning acceptance, and in extreme cases can be dogmatic. The philosophical tests for truth are the correspondence test, the coherence test, and the pragmatic test. Broadly the correspondence test is concerned with supporting a proposition with an observable fact. The coherence test using the current knowledge base to test for logical coherence of a proposition with other knowledge. The pragmatic test is concerned with testing the utility of ideas to test their truth. If a proposition is proven to meet a practical purpose then it is held to be true pragmatically. All of these tests of truth can be applied in building a knowledge base.

Knowledge is formed in the idealist reality, but applies to both the idealist and the material reality. Here the interdependence of ontology and epistemology is apparent. An ontology is defined by what is known of reality, the realities it is possible to have knowledge of are defined by ontology. An analysis of the scope of knowledge of reality is represented in figure 3.6. At the highest level conceptual knowledge defines a view of reality and provides the context in the idealist sense for interpreting other knowledge. The lower level knowledge is knowledge of the states of reality and know how on interaction between the two realities. Knowledge of the state of material reality is normally defined by some quantitative or qualitative measurement technique. Thus know how is applied in applying the technique to gain knowledge of the state of matter.

The source of knowledge has been traditionally been viewed as empirical or rationalist. However, these two views contradict each other and each one taken in isolation does not

adequately describe all sources of knowledge. Kant proposed a compromise to this conflict in the form of phenomenalism. Phenomenalism takes the view that all observations of matter are the result of the application of *a priori* knowledge to form perceptions. The *a priori* knowledge includes the concept of interpreting observations, or sensations, in terms of the *a priori* concept of space and time. The perceptions formed in this way are then rationally processed using other *a priori* conceptual knowledge into new knowledge. Thus the source of knowledge is both empirical and rational.

The validity of knowledge is judged according to the criteria for truth discussed above. Applying the model of stages of knowledge developed above this judgement can be made at the stage of knowledge acquisition and knowledge application, where the context of the idealist and material reality in which they are made determine the judgement of validity.

3.12 THE MULTIDISCIPLINARY NATURE OF CLINICAL DECISION SUPPORT

A characterisation of the multi-disciplinary nature of CDS needs to consider many elements. The structure of these elements is shown in figure 3.9. At the root of figure 3.9 is the generic philosophy described above. The remaining elements of CDS illustrated in figure 3.9 are more specifically related to the domain of interest. According to Shortliffe's (1987) definition of clinical decision support the production of a computer decision support tool is the aim of CDS development. Hence, the drive to use technology in CDS to produce decision making tools means that technology plays a role in defining the nature and central methodology of CDS. The application domain for the technological artifacts of CDS is a medical one, thus the nature of medicine is relevant, particularly the ethics defined in medical philosophy. A large part of the knowledge base of medicine and technology is based on scientific knowledge thus the nature of science is an element in the nature of CDS. This section will consider the nature of these three remaining disciplines and model the relationship between them.

3.12.1 Technology

Technology comprises the sum of the resources which increase the efficiency of human

activity, e.g. trains and telecommunications. All societies can be said to apply technology in relation to their problems of food, shelter, and transport. The instrumental function of the technological process is to direct the use of resources according to human purposes. Thus the technological process is always limited by the availability of resources. Technology is driven to satisfy the defined purpose of the material artifact, or tool, being constructed. When judging success the criteria used are essentially ones of corroboration, mainly social and legal. Seeking corroboration involves demonstrating that the defined social purpose has been satisfied within the legal framework. The criteria applied when judging a technological artifact include: durability; reliability; sensitivity; pragmatic effectiveness; cost effectiveness; rapidity of production; or a combination of these or similar better criteria. In summary technology is concerned with the efficient use of resources to satisfy a material social need.

3.12.1.1 Ontology and epistemology of technology

Technology aims to produce material artifacts to solve material problems. This involves the processes of the abstraction of the problem into a set of ideas and an abstract representation of the design of the artifact. These characteristics of technology are summarised in the ontological model of technology in figure 3.10. Materially technology exists in the material problems and in the material artifacts it produces. The idealist abstraction or representation of these material factors exists in the mind. The link between the two is in the realisation of the design of material artifacts and in assessment of observed material phenomena.

Epistemologically technological knowledge exists in the mind as justified true belief. The major test of the truth of the belief and the validity of the application of the knowledge is a pragmatic one. The scope of technological knowledge is represented in figure 3.11. The how to knowledge covers techniques for how to realise ideas in practice and how to assess the material problem and artifacts. For example knowledge of how to produce a car more cheaply. There is also knowledge of material problems and artifacts derived from the observation of material phenomena. The conceptual knowledge includes the ideals guiding good practice which will be influenced by the ethical codes of the culture within which the

technological activity is taking place. Asimov (1974) defined a set of ideals for the engineering design process:

i) NEED; design must be a response to individual or social need which can be satisfied by technological factors.

ii) ECONOMIC WORTHWHILENESS; the goods or service, described by the design, must have a utility to the consumer that equals or exceeds the sum of the costs of making it available to them.

iii) FINANCIAL FEASIBILITY; the operations of designing, producing and distributing the good must be financially supportable.

iv) OPTIMALITY; the choice of a design concept must be optimal among the available alternatives; the selection of a manifestation of the chosen design must be optimal among all permissible manifestations.

v) DESIGN CRITERION; optimality must be established relative to a design criterion which represents the designer's compromise among possibly conflicting value judgements that include those of the consumer, the distributor and his own.

vi) ECONOMIC WORTH OF EVIDENCE; information and its processing has a cost which must be balanced by the worth of the evidence bearing on the success or failure of the design

vii) MINIMUM COMMITMENT; in the solution of a design problem at any stage of the process, commitments which will fix future design decisions must not be made beyond what is necessary to execute the immediate solution. This will allow the maximum freedom in finding solutions to sub-problems at the lower levels of design.

In the domain of CDS an additional ideal of design is that it must perform in accordance

with medical ethics. Codes of medical ethics are described in the section on the nature of medicine. The principles underpinning the design process are (Asimov, 1974):

i) PHYSICAL REALISABILITY; the object of a design is a material artifact or service which must be physically realisable.

ii) MORPHOLOGY; design is a progression from the abstract idea to the concrete material. This gives a vertical structure to a design project.

iii) DESIGN PROCESS; design is an iterative problem-solving process. This gives a horizontal structure to the design process.

iv) SUB-PROBLEMS; when attending to the solution of a design problem, there will be uncovered a substratum of sub-problems; the solution of the original problem is dependent on the solution of the sub or unforeseen problem.

v) REDUCTION OF UNCERTAINTY; design is a processing of information that results in a transition from uncertainty about the success or failure of a design toward certainty.

vi) BASIS FOR DECISION; a design project is terminated whenever confidence in its failure is sufficient to warrant the non-commitment of resources necessary for the next phase.

vii) COMMUNICATION; a design is a description of an object and a prescription for its production; therefore, it will have existence to the extent that it is expressed in the available mediums of communication.

The vertical structure of the design process, highlighted in point two above, progresses from an idealised abstraction to a material manifestation and is defined by the system development cycle, or design process. The traditional top to bottom waterfall model of this process follows the following stages:

i) Requirements analysis, abstracting the users material needs the artifacts produced are to satisfy.

ii) The design phase, production of the design ideas.

iii) Development phase, building a prototype and validating its operation.

iv) Evaluating the artifact produced in the users environment.

v) Commissioning the operation of the technology.

vi) Post commissioning maintenance and upgrades.

How the waterfall model is applied will depend on the size and complexity of the project undertaken. The horizontal structure of the design process, described above as an iterative problem solving process, means that although the above process may describe the order the tasks start; there is iterative movement within each of the stages and between them. So for example during the development phase of the project it may be necessary to reassess the requirements for the system.

3.12.1.2 Science and technology

Science and technology are terms which are sometimes used synonymously. However, there are important distinctions as well as similarities between them. The aims of each discipline distinguishes them clearly:

i) Progress in science aims to increase knowledge

ii) Progress in technology aims at creating new artifacts to increase effectiveness.

Thus the intended product of scientific enquiry is knowledge, while technology seeks to produce tools to solve problems. To sum up this fundamental difference: science is to

understand, whilst technology is to engineer. The nature of scientific problems is a problem of not having adequate knowledge to explain an observed scientific phenomena. A technological problem is defined by a set of material goals which are not satisfied by the observed phenomena. In science a given material reality is investigated, and in technology a material reality is created according to a design. Figure 3.12 shows the scientific and the technological processes operating in parallel to one another. The nature of the scientific process and the knowledge it produces are discussed in section 3.12.2.

Pure science is a method of investigating nature by the experimental method in an attempt to satisfy the need to know. The task is to understand nature. The relationship between science and technology in figure 3.12 shows the scientific task of understanding nature operating in parallel to technology. The parallel nature of their operation means the two processes can operate independently from one another. However, there is some crossover between the two where scientific knowledge is applied in technology, and technological artifacts are used in the scientific experimental procedure. Examples are given below to illustrate the central ideas of figure 3.12.

There is not always a direct link between scientific and technological progress. For example how to make a car more cheaply does not add to scientific knowledge. Moreover, new scientific knowledge will not be utilised in technology until a social purpose requires it. It may be that there is no technological use for scientific knowledge, for example knowledge of the existence of a star in the milky way.

Tools can be used in tasks without any scientific theoretical knowledge of how the tools perform the tasks, e.g. it is possible to know that a drug cures a certain illness without knowing exactly all of the in-vivo biochemical reactions involved. Moreover, tools can be designed without knowledge of the scientific laws which describe their behaviour. Anthropologically there are societies with technology but nothing recognisable as science; but there are no societies without technology. Moreover, scientific explanation is not a prerequisite to the understanding or solution of a technological problem.

Technology presupposes nature can be manipulated and modified to serve human needs,

science presupposes a regularity in nature; and technology has to take account of economical and social factors which science does not. One impact of this is that technological artifacts have to comply with certain safety standards, these standards do not impact on the product of the scientific process. The reason for this is technology seeks social and legal corroboration whilst science does not. Science may even seek to refute the corroborated view point.

However, the drive for technological progress can often lead to investigation of the related pure science problems, for example in semi-conductor devices. So scientific discovery can be technology-led. Where the scientific knowledge produced has a direct impact on the application of technology. Also scientific progress can be dependent on the technological tools available for experimentation, for example in the development of measurement technology in physics.

A scientific understanding of the technological problem and of the resources being applied to it can aid the process of effective technological design. Therefore application of scientific knowledge in technology does constitute effective practice. This is particularly true where there is novelty in the problem and the methods required to solve the problem. The innovation required in a novel situation can be informed by and include the use of science. Although the goal of technology is not a better understanding of nature, it is satisfaction of a material need; therefore in the design task technology is the master and science the slave.

The application of science in technology is to solve the sub-problems that require solution before reaching the final design solution. This could involve the application of science at all stages of the process including the problem analysis.

3.12.2 Science

Seelos (1992), and Lincoln and Essin (1992) confirmed the need for a more scientific approach in CDS. In the context of the technological goal of CDS, science is an important procedure and source of knowledge for the medical problem domain and the technological

solution. Scientific knowledge and the scientific method are often used without question. However, in adopting a philosophically rationalist approach to the domain of CDS it is necessary to examine the meaning of these terms and how they can be applied in the domain. Moreover, a world view incorporating science can be more fully expressed by examining the basic concept of what science is.

Scientific thought grew out of natural philosophy, thus despite the two now seeming to be separate subjects they are closely related. Here the ontological and epistemological bases for science are discussed, as are the main ingredients of the scientific method. The use of science in research is well established, the scientific age has existed for many years now. Lastrucci (1967) sums up the position of science thus:

> "....in the competitive arena of opposing logical and methodological systems, all presumably devoted to the discovery of truth, scientific method has become the strongest intellectual tool that man has devised for furnishing verifiable and predictable answers to questions of demonstrable fact."

So if science is to form part of the world view for CDS the first question to be answered is "what is science?" Lastrucci (1967) defined science as:

> "An objective, logical, and systematic method of analysis of phenomena, devised to permit the accumulation of reliable knowledge."

In Lastrucci's definition reliable knowledge refers to knowledge which permits better predictions than could be made by chance or guesswork alone. In this definition the product of science is a set of reliable justified true beliefs. Ackoff (1962) defined the products of scientific enquiry as:

i) A body of information and knowledge which enables us to control the environment in which we live.

ii) A body of procedures which enable us better to add to this body of information and

knowledge.

These two sources agree science is essentially a knowledge building methodology, concerned with the interpretation of perceived material phenomena. Ackoff's definition adds that the application of the knowledge is to better control the world we live in.

3.12.2.1 Ontology and epistemology of science

Ontologically science exists within the dualist view represented in figure 3.4. The view expressed in this model is the view of the author, and does not represent a traditional monist materialist view. Within this ontological model science focuses on the interpretation of material phenomena. In the idealist reality exist the abstracted concepts and constructs, or theories, on the nature of matter. The dual of idealism is matter which is the source of phenomena studied. The product of the study of the material phenomena is an expression of the abstracted scientific knowledge. Therefore there is a bias in science towards materialism. However this does not preclude the study of material manifestations of ideas, as in psychology.

Although science exists within an ontology its main focus is epistemological. An analysis of the epistemology of science can be broken down into four stages as for the description of philosophical epistemology used above. These four stages are the: nature; scope; source, and validity of scientific knowledge.

Scientific knowledge has been defined above as reliable knowledge, or in philosophical terms reliable justified true belief. Reliable refers to being able to make predictions more accurately than by chance or guesswork alone. A central tenet of the description of scientific knowledge is the interpretation of scientific truth. Lastrucci (1963) defined three concepts which define the structural levels of truth in scientific knowledge as:

i) Postulates define the fundamental assumptions which must be accepted before the logical reasoning can begin, therefore they are not knowledge, they are purely beliefs which define the idealist context of the map of knowledge.

ii) Propositions, discussed in earlier in the philosophy section, are not reducible logically and are of the form the snow is white.

iii) Statements of fact are propositions which have been verified by observation of material phenomena.

Scientific reasoning begins from a set of *a priori* postulates and hypotheses in the form of propositions and seeks observations of material phenomena to confirm or deny the propositions. The point of the establishing a scientific truth rests on establishing material facts. Where a material fact is supported by objective evidence. The testing of the truth of individual propositions is based on:

i) Logical positivism, the belief that propositions have factual meaning only when they can be confirmed by empirical evidence. This is an application of the correspondence truth test discussed above.

ii) Pragmatism states the ultimate test of the value of an idea is its usefulness in satisfying a practical purpose. Pragmatism as a test of truth applied to an idea, or proposition, is discussed above.

The primary test of these two is logical positivism, or correspondence theory, as in the empirical experimentation of science. In terms of the application of science to a wider social purpose the pragmatic test is applied.

The level of scientific truth attributed to a proposition will depend on the available empirical evidence. Absolute truth for all time and space is not obtainable as any scientific proposition relates to current perceptions of phenomena and these can change over time. Lastrucci (1963) states that truth is relative to the state of knowledge at the time; based on the available evidence, facts, and the logic used to form the knowledge base. Therefore the expression of scientific truth is fluid over time and a statement of absolute truth is never achieved. An analogy for truth in science is of a proposition measured on a spectrum of truth, with absolute falsehood at one end and absolute truth at the other. Scientific

propositions contain probable truth represented by a point in the spectrum. The greater the weight of empirical evidence there is to support the proposition then the higher the probability of it being true.

Potential future human experience is infinite, or not totally predictable, and new experiences can lead to a new interpretation of phenomenon and thus a reinterpretation of present knowledge. Science allows for this as an open system of ideas. The impact of this characteristic being that science is willing to accept new ideas or truths and discard old ones. A closed system of ideas does not accept any new ideas and has a fixed knowledge base, such as religious dogma in certain philosophies.

Thus science adds a new concept to the level of truth in a knowledge base and relates it to the weight of evidence supporting a proposition; allowing for the concept of degrees of truth in the evaluation of a knowledge base.

The second aspect of scientific epistemology is the scope of knowledge. Lastrucci's definition of science states that the central concern of science is the interpretation of material phenomena. Considering the model of knowledge scope in figure 3.13, the scope of scientific concepts of matter, know how and material state knowledge is targeted to this goal. The emphasis being on scientific conceptual knowledge of matter, know how of procedures for controlling and measuring material phenomena, combined with knowledge of the state of matter.

Scientific conceptual knowledge is broken down into classifications of objects. The classifications are expressed in concepts and constructs. Where concepts are an idea or a generalised idea of a class of objects, and constructs are a structure expressing an orderly arrangement of concepts into a single whole. The concepts and constructs used to classify objects are expressed in declarative definitions. Reducing knowledge into classes using definitions is central to scientific thinking. Thus a scientific conceptual knowledge base is founded on definitions of the concepts and the constructs. The required qualities of a definition are:

i) It should be inclusive of all things denoted by it yet exclusive of all things not denoted by it, i.e. it must be precise and distinctive.

ii) Definitions should not be circular, i.e. not referring to themselves.

iii) Definitions are more clear if they are stated in the positive not negative. i.e. do not form a definition around what lies outside the classification.

iv) Definitions should be clear and unequivocal.

The source of scientific knowledge on the material phenomena has its roots in philosophical thought. In the philosophy section describing the source of knowledge it was argued that phenomenalism is the source of knowledge. Applying phenomenalism, conceptual knowledge is used to interpret sensory observations of the material world. The *a priori* conceptual postulates that are the foundation of scientific reasoning are those given in Lastrucci (1963):

i) All events have a natural cause. Naturalness, while including man, refers to objects, conditions or events which exist or operate independently of man's manipulation of them due to forces existing beyond his creation of them.

ii) Man is part of the natural world, when studying man scientific thinking can be applied just as it be would for any other natural object.

iii) Nature is orderly and regular, events do not occur haphazardly. The natural world can be observed to obey certain "natural laws" abstracted by man to help him to understand the whys of the world. Thus the attention of the scientist is focused on seeking the qualitative and quantitative relationships which exist between and among natural phenomena.

iv) Nature is classifiable as uniform, which leads to taxonomy (functionally arranged classifications). These classes are necessary to represent the large mass of

knowledge which is growing all the time.

v) Nature is permanent; a lump of coal studied today will be similar enough to permit valid generalisations to be made about it to hold true for a period of time.

vi) All objective phenomena are eventually knowable; there are no intellectual limits placed by nature on man's search for knowledge.

vii) Nothing is self evident; science seeks objective, empirical verification of facts, it cannot accept facts merely based on custom.

viii) Truth is relative to the existing state of knowledge; truth in science is simply the best professional judgement available at any given time. Knowledge changes in quality and quantity, necessitating the reappraisal of phenomenon. Proof in science is always only within the bounds of the experimental technique.

ix) All perceptions are achieved through the senses; all knowledge is acquired from sensory perceptions. Empirical demonstration is the ultimate test of the validity of all theoretical speculations about objective phenomenon and the resultant predictions.

x) Man can trust his perceptions, memory, and reasoning as reliable agencies for acquiring facts. Accepted rules of reasoning and sensorial perceived data take precedence over mere mental notions or ideas.

These postulates define the world view and characteristics of science. Furthermore, consideration of these postulates is important when assessing the validity of the application of scientific knowledge. In the context of the application of scientific knowledge these postulates need to be valid to the perceptions they are applied to. The validity, or truth, of any scientific knowledge is only within the context of the scientific experiment used to evaluate its truth. Beyond the confines of the scientific experiment the validity of the direct application of the knowledge requires further testing. An important test of the validity of

the application of scientific knowledge being a pragmatic one. Where the context of the application will determine whether or not the knowledge proves to be valid in the pragmatic sense.

3.12.2.2 Scientific procedure

Ackoff's (1962) essential characteristics of scientific procedure are:

i) A procedure for answering questions, and

ii) A procedure for developing more effective procedures for answering questions and problems later.

Thus there are two main aims to the scientific procedure. The first is in finding the solution to the question being faced, and the second is optimising how the solution is achieved. Fulfilling the second aim involves discussing the ways work should be done in the future in the light of what has been found during the research period. This then enables an improvement in the research procedures employed. Ackoff's four levels of elements used in the scientific research process were defined in section 3.2. These have been applied to building a philosophically based scientific framework for the analysis of CDS.

The framework is being proposed to promote a top down approach in CDS beginning with an analysis of the problem. This rational approach of firstly defining the problem is endorsed by Ackoff's and Lastrucci's analysis of the stages of scientific research. During the technological process of building a CDS system the scientific procedure is used to develop knowledge of the problem and potential solution of the problem. The six phases of applied research defined by Ackoff give a structure for performing the process when it is directly applied to aiding the solution of a material problem:

i) Formulating the problem;

ii) Constructing the model;

iii) Testing the model;

iv) Deriving a solution from the model;

v) Testing and controlling the solution;

vi) Implementing the solution.

The first three stages of this process are defined in more detail by Lastrucci's eight stage process of more pure scientific research:

i) Formulation of the problem by a statement of an empirically testable proposition, forming a hypothesis;

ii) Literature search for relevant data and methods;

iii) Research design, including the selection of techniques and the rationale for their choice;

iv) Determination of the boundaries of the investigation;

v) Gathering data and processing it into workable form;

vi) Interpretation of the data;

vii) Verification of the interpretation, conclusion. By either:

a) confirming or questioning the results of other studies.

b) confirming or rejecting the original hypothesis.

viii) Presentation of findings in a report.

As stated above the aim of the scientific process outlined above is to produce reliable knowledge. Therefore, the scientific method is applied where a empirically testable proposition is presented. The problem of CDS is mainly a technological one, although there are issues relating to knowledge building methodology within the technological problem.

3.12.3 Medicine

Medicine is essentially an ethically driven activity, where a clinician seeks to act for the good of the health of their patients. Ethics are encapsulated within a philosophical view and they represent a particular type of knowledge governing decision making and behaviour in the clinical domain. For example a basic ethic of medicine is the Hippocratic oath, where it is stated to always act in the interest of continuing the life of the patient wherever possible. It is this ethical knowledge base, or code, which is the core knowledge base for defining acceptable clinical activity. The ethics in a philosophy for clinical decision support need to be consistent with the ethical principles applied by the human decision makers using the decision support. If the advice offered by a decision support system is not in ethical agreement with the user then it is unlikely that the user will accept this advice. Hence, the ethical principles expressed in the philosophy of medicine form an important part of any clinical decision support system. The source of an ethical code, or set of ethical postulates, is complex and not purely rational. In a domain such as medicine, ethics are defined by medical associations and colleges, and upheld by ethics committees. These definitions are encapsulated in doctors' ethical oaths, some of which are described below.

In addition to operating within a set of ethical codes, the medical process shares characteristics with the technological process; mainly in the function of the two processes being to effectively solve a material problem using a limited pool of available resources. Similarly clinical practice is informed partially by science but not exclusively; although the study of medical science is a reliable source for an understanding of the conceptual knowledge base of medicine.

Medical science takes a mechanistic materialist view of the body. A person is reduced to

a set of constituent parts, which are then subjected to scientific investigation and treatment; hence the splitting of the medical profession into specialisms such as nephrology and neurology. The approach is mechanistic in that there is always an underlying assumption of cause and effect. This is manifest in the often asked question: what factors have caused the state of health A to be followed by the state of disease B. The deterministic approach leads to the approach of attempting to detect findings, signs and symptoms of disease. The subsequent action then concentrates on treating the symptoms to return the patient to health state A. The advantages of applying mechanistic materialism in medical science include: advances in the treatment of infectious diseases; surgical removal of diseased areas, and the prevention of illness through immunisation. However, by applying scientific classification, medical science treats people as though they belong to homogenous groups, seeking to represent an individual as a unique occurrence of the universal. A weakness of this approach is that it does not allow for the heterogenous nature of individuals presenting with different symptoms.

Extending the ideas of mechanistic materialism leads to the belief that it is possible to explain all the biological processes in the body in physio-chemical terms. These processes can then be represented in a series of haemostats which respond to their surroundings in an appropriate controlled way according to the information received. This idea has been applied in compartmental modelling, where sub-systems of the body are represented by biochemical mass storage compartments. However, unlike in a machine, not all the physio-chemical processes in the body are known. Therefore, using this approach cannot be used to represent the complete body in physio-chemical terms. Moreover, the description of the body in completely physio-chemical terms is highly complex, and often impractical to apply to routine clinical decision making.

The clinical activity may be informed by medical science but it does not explain the whole activity, although the conceptual classifications used in medical science and clinical practice are related. The activity which goes beyond that explained in the mechanistic view is studied through practical clinical experience of solving the problems of actual patients. The knowledge base gained from this activity can be expressed as a set of conditional propositions guiding the decision making. The truth of the propositions is judged using the

tests of truth described in the earlier philosophy section: coherence; correspondence, and pragmatism. Due to the variability of individual clinical experience the practical knowledge base varies between individuals more than the medical science knowledge base. An ontological and epistemological analysis of the clinical activity which produces the practical knowledge base is given below.

3.12.3.1 Ontology and epistemology of clinical practice

The dualist ontology applied to clinical practice has the patient state in the material reality and the clinical decision maker in the idealist reality (figure 3.14). The clinical decision maker observes phenomena of the patient state and then by applying their prior conceptual knowledge make decisions regarding the actions to be taken. The view of the patient state is abstracted by the clinician according to the observed phenomena and their prior knowledge of patient conditions. Further analysis of the ontological model of clinical decision making is the subject of the next chapter.

The nature of clinical knowledge is the same as the definition given in the philosophical definition, justified true belief; implying there has been a judgement of truth of a proposition. Ultimately the truth test of the knowledge relating to a clinical action is whether it has fulfilled a pragmatic purpose, where the purpose of a clinical action is to act in the interests of the health of the patient. The clinical actions are guided by codes of ethics which act as set of ideals to define good behaviour. In addition to the ethical codes the scope of clinical conceptual knowledge covers treatment and monitoring techniques, over and above scientific medical knowledge of the body. Applying the concepts of phenomenology to clinical experience the source of clinical knowledge is observed phenomena of patient state and the effect of treatment interventions. The valid application of knowledge to a patient is one of the more difficult aspects of clinical judgement due to the individual nature of each patient. Every case is different, and it is rarely possible to make generalisations about all patients with disease X or requiring treatment Y; hence the use of specialisms in medicine to build up detailed specific knowledge about specific categories of patient problems and their treatment. Further analysis of how knowledge is applied in a rational model of clinical decision making is discussed in the next chapter.

3.12.3.2 Ethical codes

As mentioned above medicine is essentially an ethically driven activity. These ethics are enshrined in ethical codes. The oldest of the ethical codes recognised by medicine is the Hippocratic oath, Hippocrates having lived between 470 and 360 B.C. (Orr and Pang, 1993). This has been developed by medical colleges and organisations since to take account of the social context it is to be applied in. The international code of medical ethics of the world medical association, 1949, encapsulates most of the Hippocratic ideals and adds some relevant to modern day practice. This code defines the general duties of doctors as follows:

- A doctor must always maintain the highest standards of professional conduct.

- A doctor must practice his profession uninfluenced by motives of profit.

- Any act, or advice which could weaken physical or mental resistance of a human being may be used only in his interest.

- A doctor should certify or testify only to that which he has personally verified.

The following practices are deemed to be unethical:

- Any self advertisement except such as expressly authorised by the national code of medical ethics.

- Collaborate in any form of medical service in which the doctor does not have professional independence.

- Receiving any money in connection with services rendered to a patient other than a proper professional fee, even with the knowledge of the patient.

The code then goes on to define the duties of doctors to the sick:

- A doctor must always bear in mind the obligation of preserving human life from conception. Therapeutic abortion may only be performed if the conscience of the doctors and the national laws permit.

- A doctor owes his patient complete loyalty and all the resources of his science. Whenever an examination or treatment is beyond his capacity he should summon another doctor who has the necessary ability.

- A doctor shall preserve absolute secrecy on all he knows about his patient because of the confidence entrusted in him.

- A doctor must give emergency care as a humanitarian duty unless he is assured that others are willing and able to give such care.

The duties of doctors to each other prescribed in the code are:

- A doctor ought to behave to his colleagues as he would have them behave to him.

- A doctor must not entice patients from his colleagues.

- A doctor must observe the principles of "The Declaration of Geneva" approved by The World Medical Association.

The final duty mentioned is the international code of medical ethics is that doctors should observe the principles of the declaration of Geneva. The declaration of Geneva was first adopted by the World Medical Association in 1948, following the inhumane atrocities of the second world war. It was subsequently updated in 1968 by the World Medical Assembly. The declaration was intended to replace the outdated Hippocratic oath and it states:

At the time of being admitted as a member of the medical profession:

I solemnly pledge myself to consecrate my life to the service of humanity;

I will give my teachers the respect and gratitude which is their due;

I will practice my profession with confidence and dignity;

The health of my patient will be my first consideration;

I will respect the secrets which are confided in me, even after the patient has died;

I will maintain by all the means in my power, the honour and the noble traditions of the medical profession;

My colleagues will be my brothers;

I will not permit consideration of religion, nationality, race, party politics or social standing to intervene between my duty and my patient;

I will maintain the utmost respect for human life from the time of conception; even under threat, I will not use my medical knowledge contrary to the laws of humanity;

I make these promises solemnly, freely and upon my honour.

The principles above guide the clinical activity, thus they form an important part of the clinical decision making knowledge base. Any clinical decision making, including that in decision support systems, should not contradict these ethical principles. Thus when building a clinical decision support system the above principles constitute a core set of propositions defining the system operation. For example in the international code of ethics it is stated that when a doctor has insufficient ability to deal with a situation another doctor should be summoned. The impact of this on CDS systems is that the boundary of operation

of a system must be clearly defined, and when it is beyond the scope of the system to offer advice this should be clearly stated. The right of the patient to confidentiality stated in the declaration of Geneva, requires the secure storage and transmission of all patient data in a CDS system.

3.12.3.3 Relationship of clinical practice to science and technology

Figure 3.15 shows the relationship between science and medicine. This is similar to the relationship between science and technology described above. The two processes operate independently, but scientific knowledge can have an impact on clinical practice. Also, clinical needs can define the need to gain further scientific knowledge. Clinical practice is fundamentally different from the scientific experiment, in that the clinician is not conducting a controlled repeatable experiment (Feinstein, 1967).

The relationship between technology and clinical practice is that technological tools can be used to perform clinical actions during the monitoring and treatment of patients (figure 3.16). Moreover, as a social need clinical practice can define the purpose for a technological artifact.

3.13 SUMMARY

The systematic review of philosophical concepts, and the construction of the ontological and epistemological models in this chapter have provided a foundation for the rational analysis and development of clinical decision support. The philosophy developed is the foundation of the analytical framework shown in figures 3.1 and 3.2. These figures illustrate how methodology, method, technique and the application of tools can be built up from a philosophical basis.

Ontologically a dualist view has been adopted for use at the most generic level of analysis. A model illustrating this view is in figure 3.4, the nature of the adopted dualities are idealism and materialism. Linking the two is the dynamic interaction between ideas and matter.

Clinical decision support systems involve the use of knowledge in their development and within their structure. Therefore an understanding of knowledge from an epistemological view point is fundamental to the development of CDS systems. Analysing the nature, scope, source and validity of knowledge has provided a framework for this understanding. Consideration of the testing of truth within the nature of knowledge provides the basis for evaluating knowledge. The three tests which allow for philosophically critical testing of truth are: coherence testing; correspondence, and pragmatic testing.

Clinical decision support is primarily a technological process, therefore the driving goal is the material need to be satisfied by the artifact produced. However, technology, science and clinical practice all have an influence on the development of CDS systems. The nature of each of these disciplines has been analysed in order to model how they interact. Figures 3.12, 3.15 and 3.16 show how the three separate processes have an impact on each other and how they may influence each other.

The philosophical models and framework proposed in this chapter will be used in the next chapter as the basis for an analysis of clinical decision making and the role of clinical decision support in the decision making process.

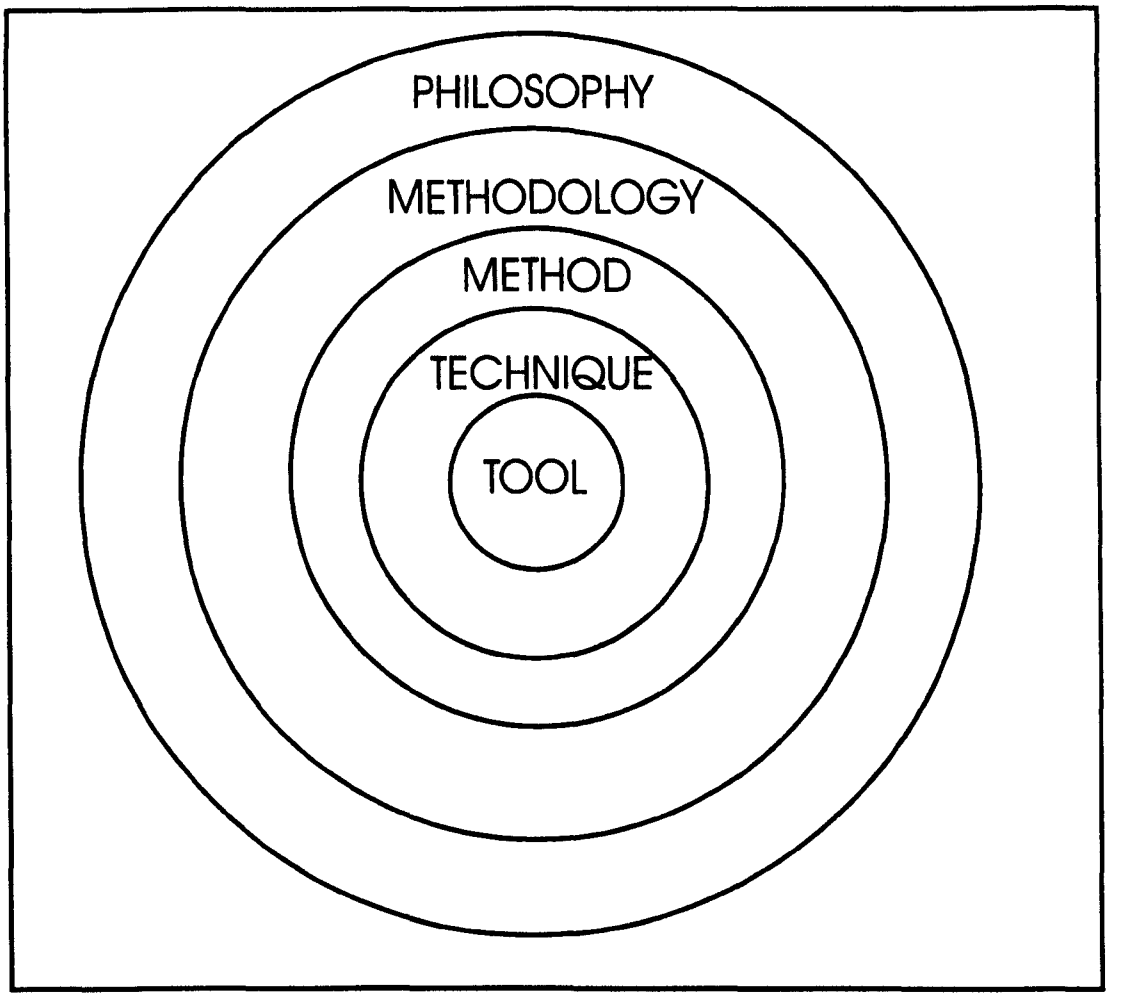


Figure 3.1 Contour map of analytical framework

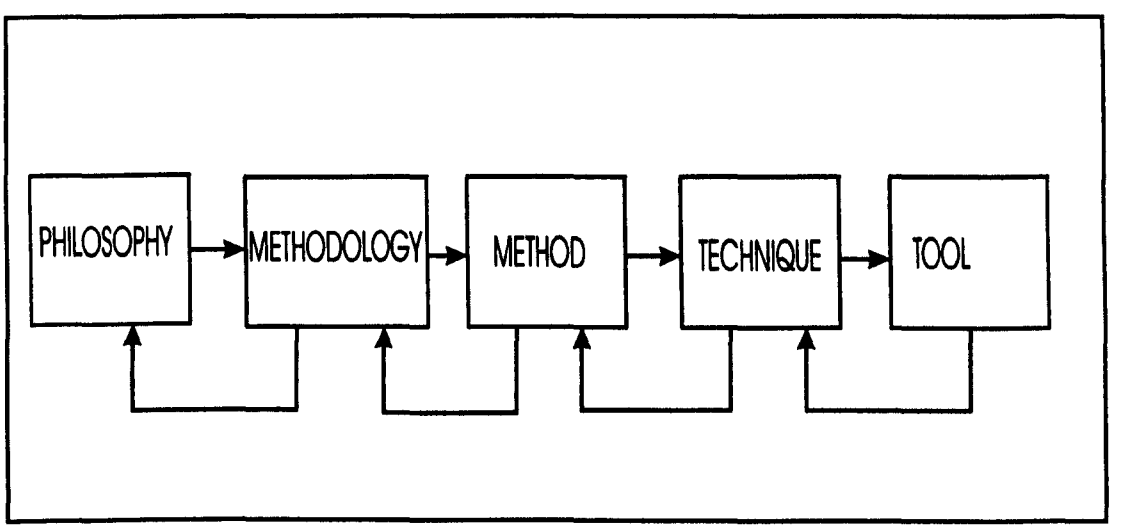


Figure 3.2 Framework for analytical process

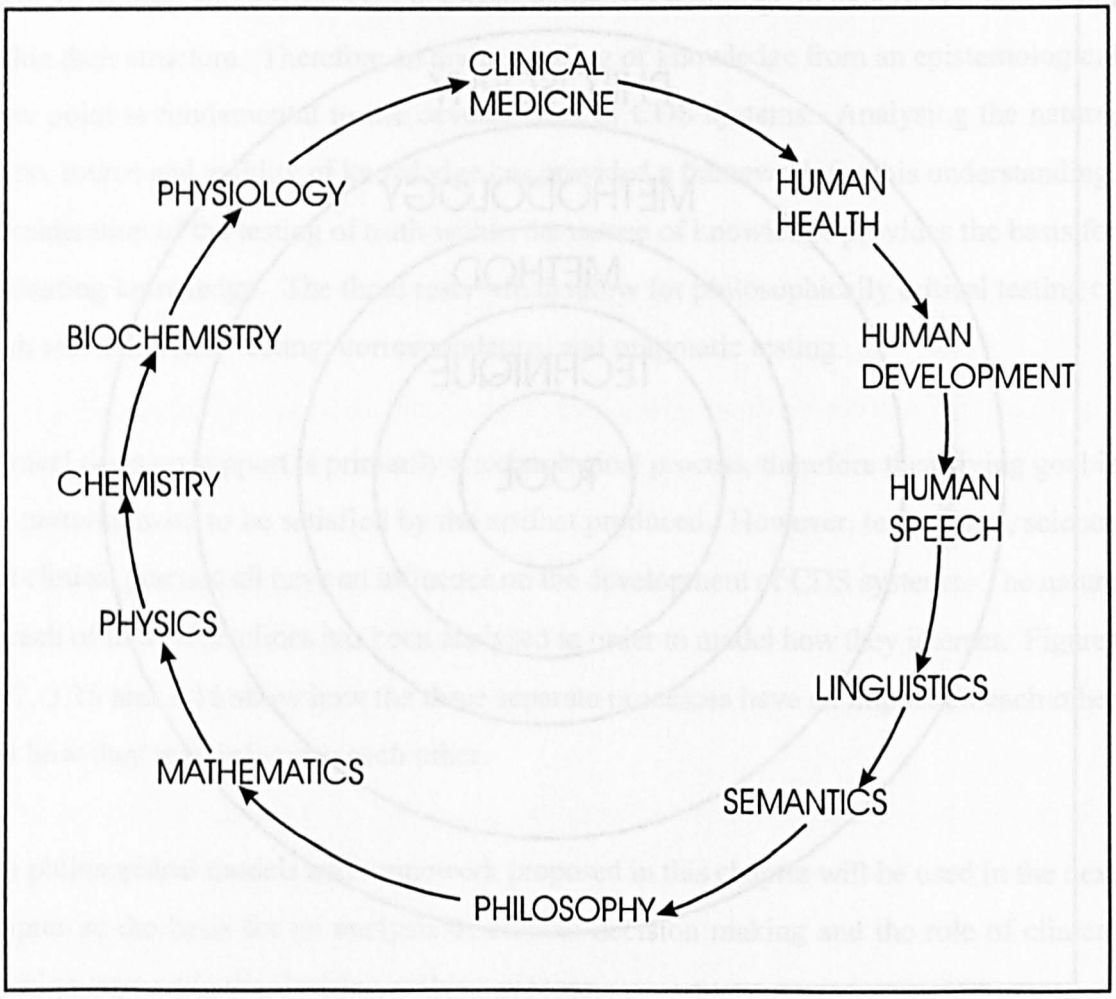


Figure 3.3 Feinstein's circle of reason

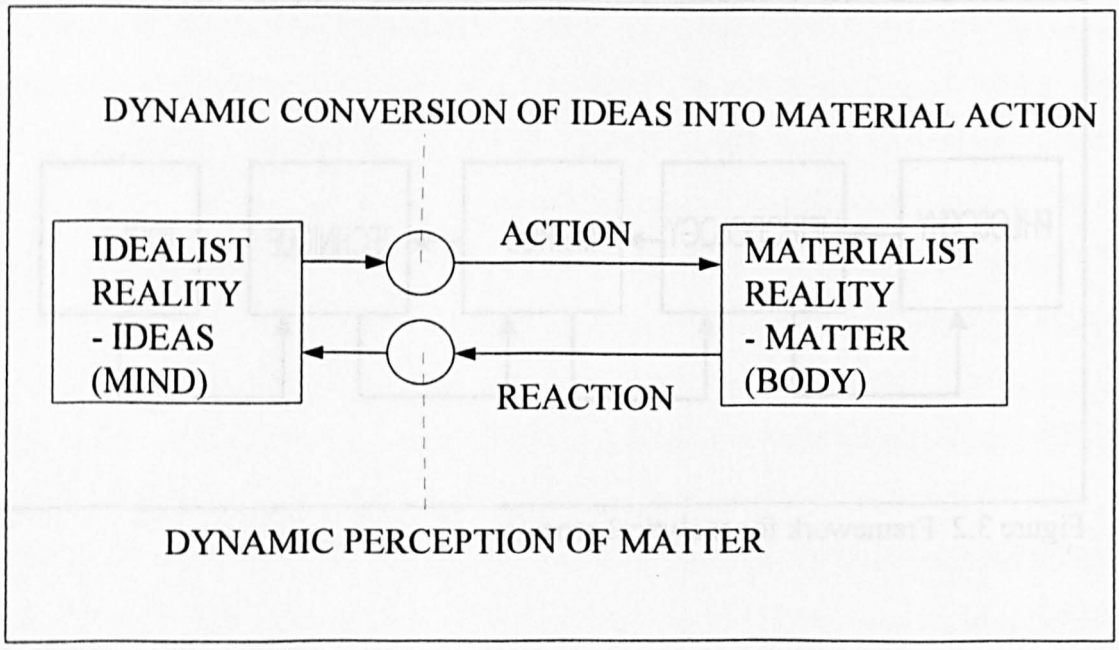


Figure 3.4 Philosophical ontology

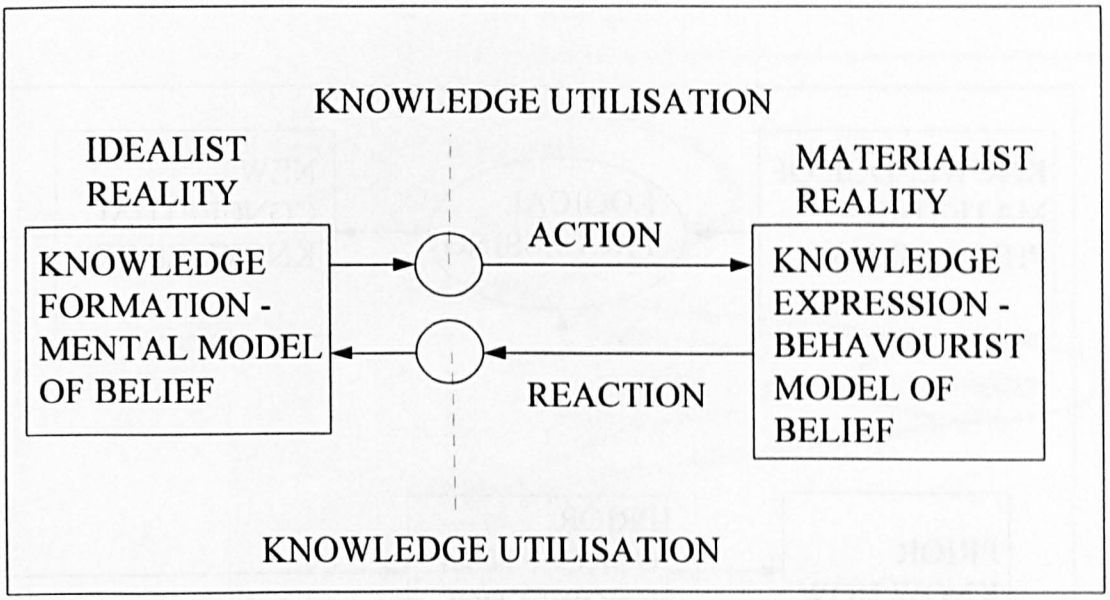


Figure 3.5 Ontological model of knowledge formation, use and expression

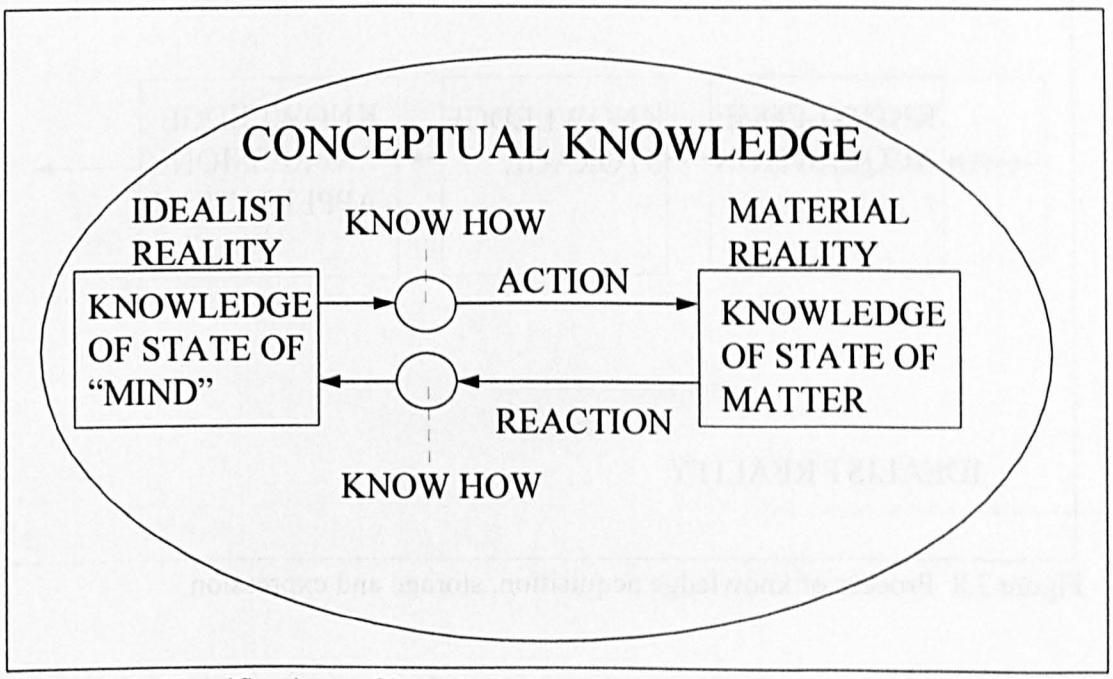


Figure 3.6 Classifications of knowledge

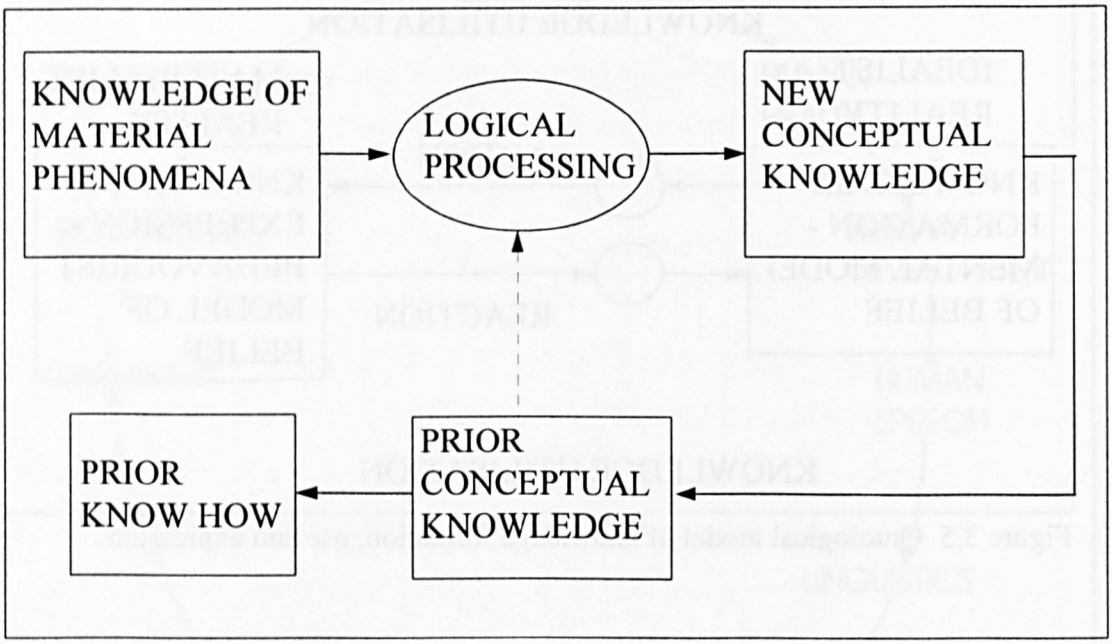


Figure 3.7 Phenomenalist model of knowledge formation

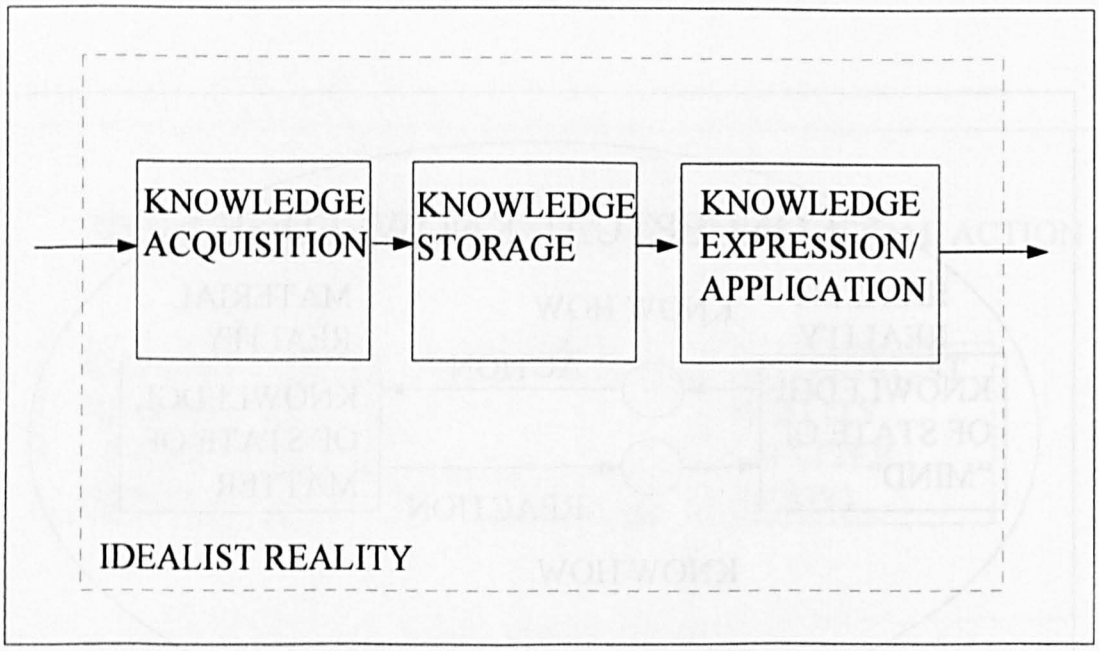


Figure 3.8 Process of knowledge acquisition, storage and expression

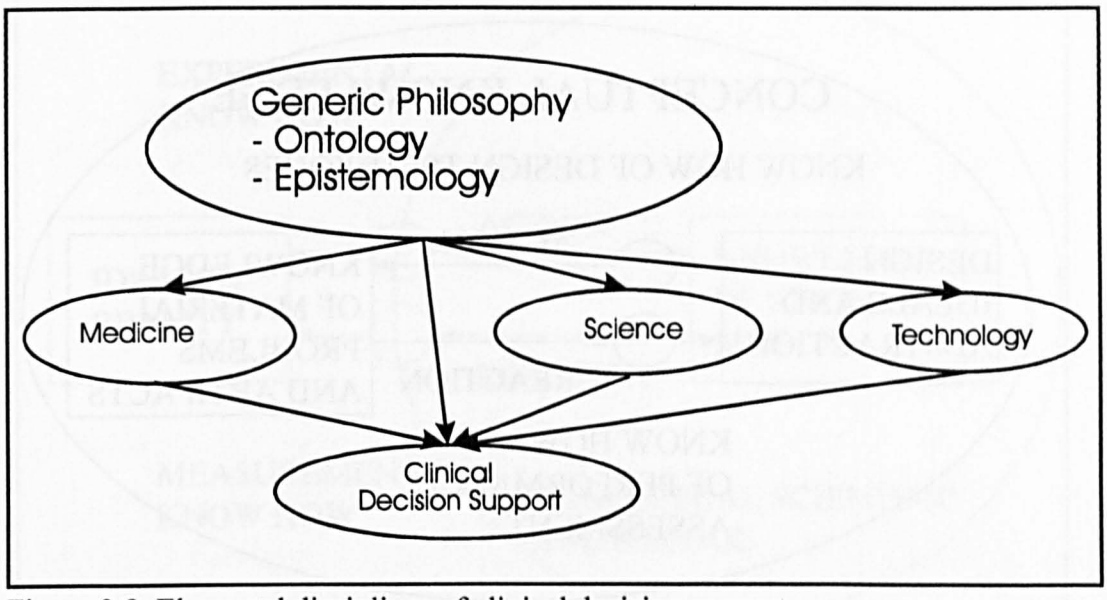


Figure 3.9 Elemental disciplines of clinical decision support

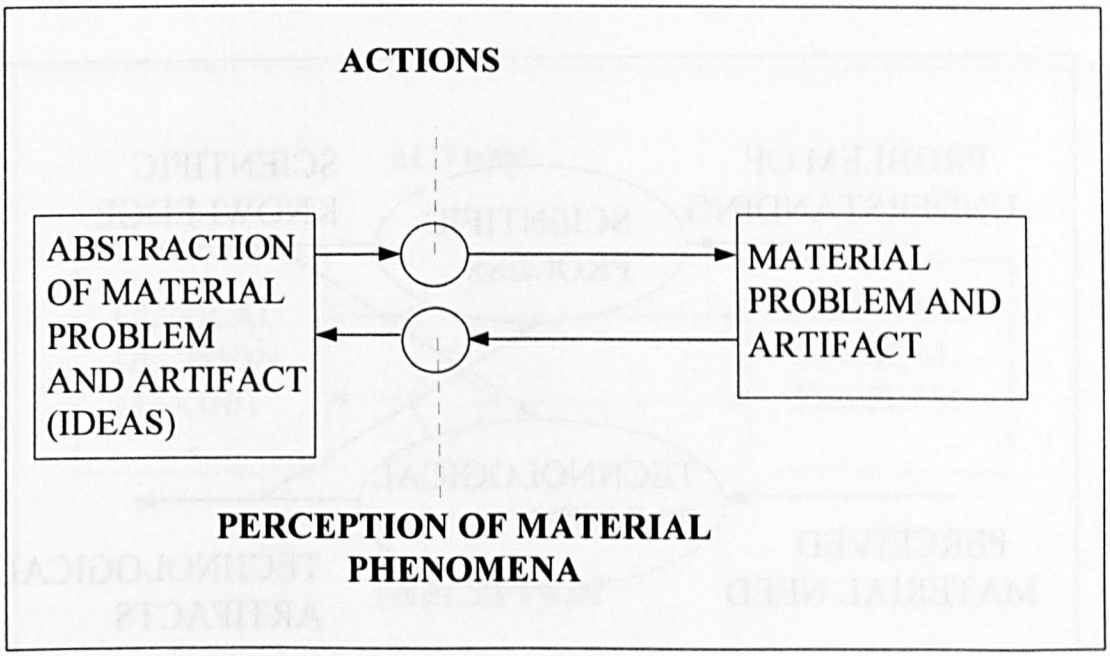


Figure 3.10 Ontology of Technology

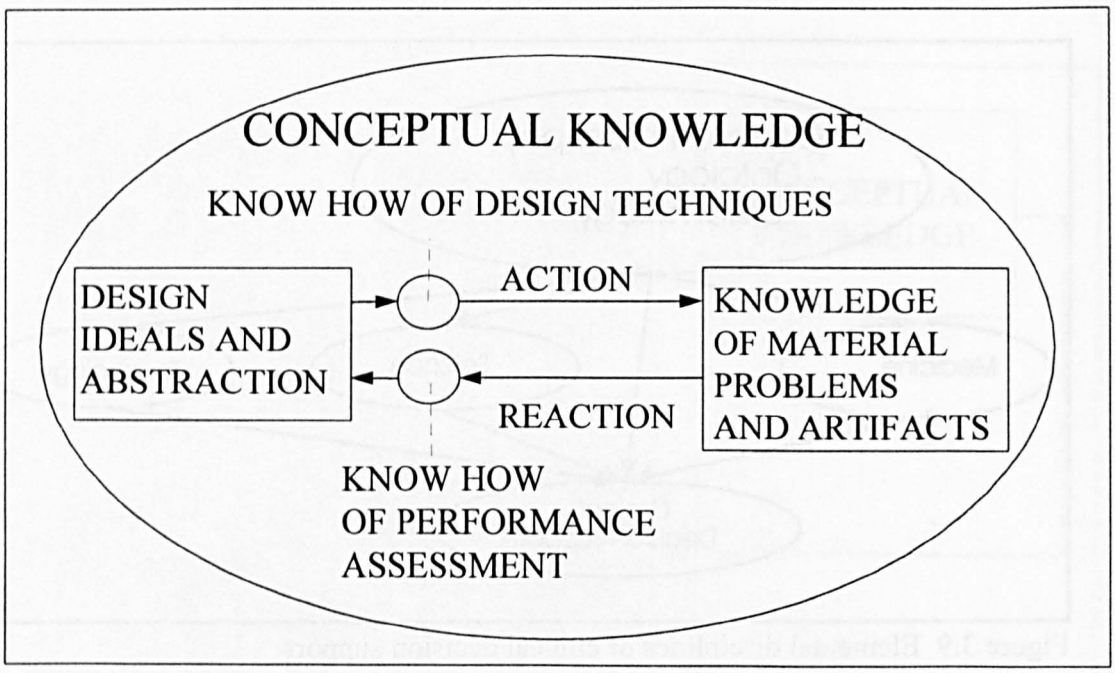


Figure 3.11 Scope of technological knowledge

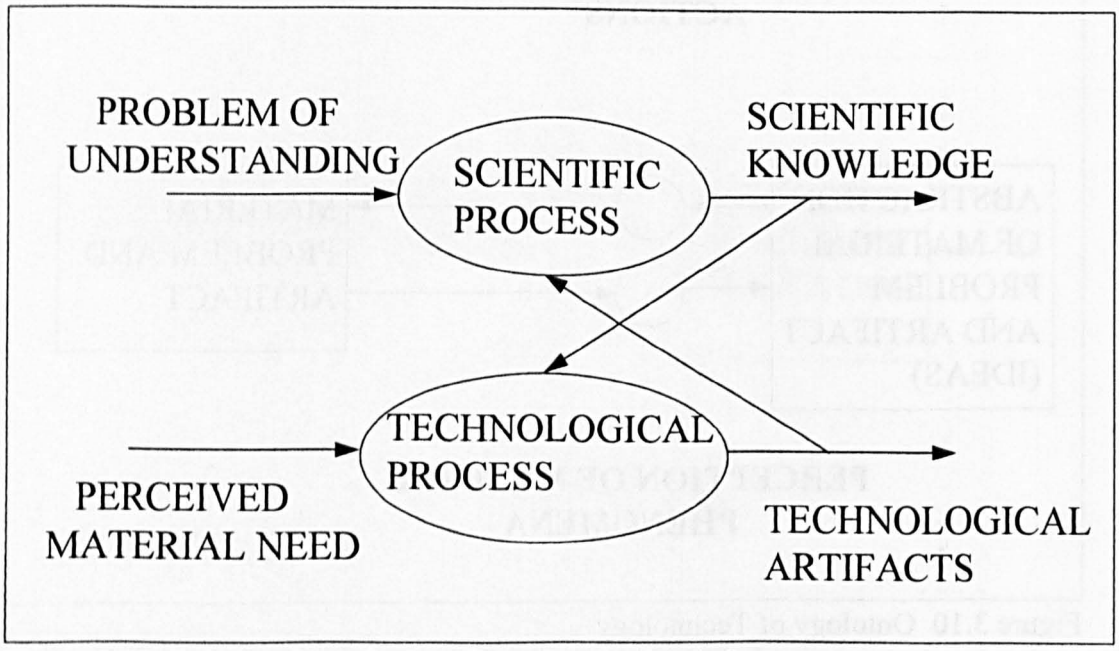


Figure 3.12 Relationship of scientific and technological processes

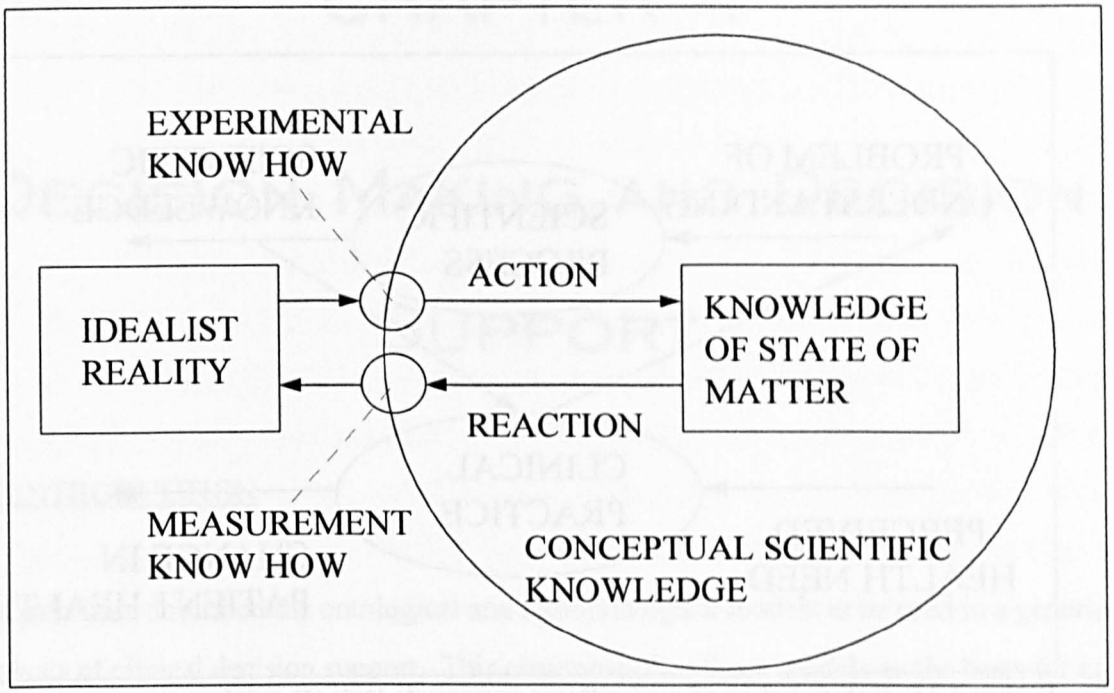


Figure 3.13 Scope of scientific knowledge

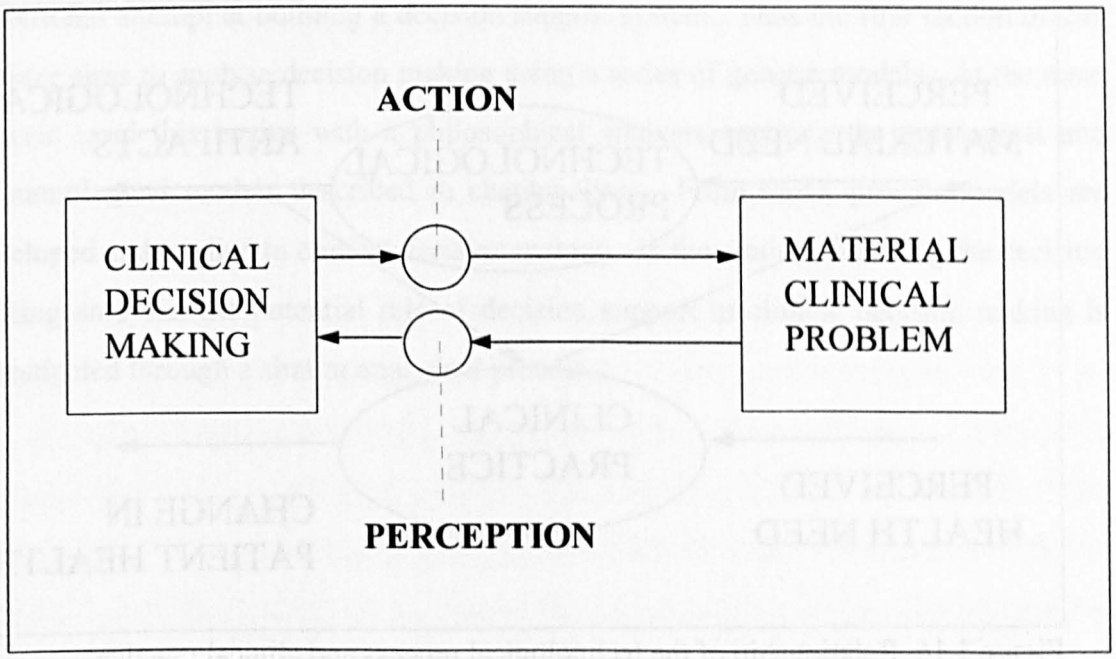


Figure 3.14 Clinical ontology

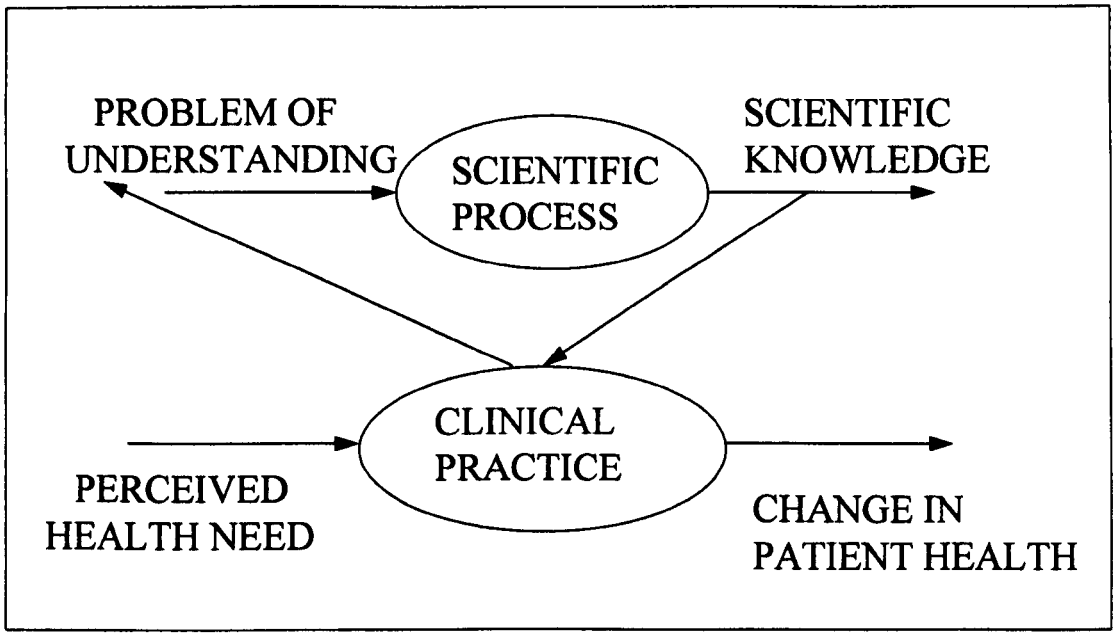


Figure 3.15 Relationship of scientific process and clinical practice

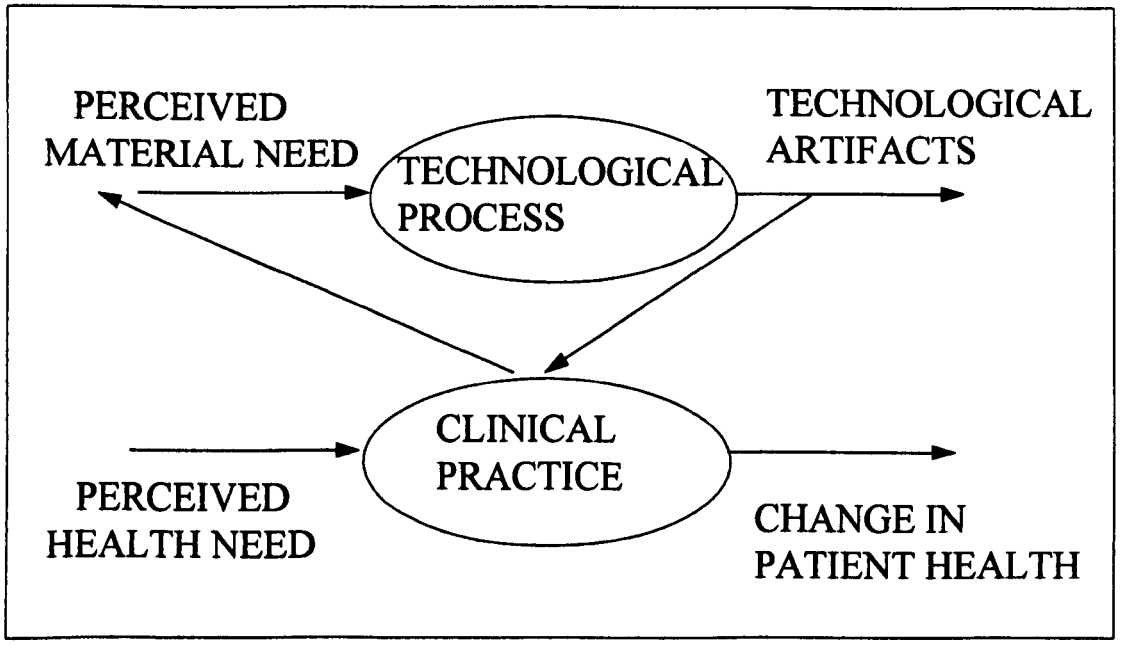


Figure 3.16 Relationship of the technological process and clinical practice

CHAPTER 4

DECISION MAKING AND DECISION SUPPORT

4.1 INTRODUCTION

Chapter three described the ontological and epistemological models to be used in a generic analysis of clinical decision support. This chapter applies these models as the basis for an analysis of decision making and decision support.

To support decision making in an effective manner there first needs to be analysis of what decision making is. Through an analysis and modelling of decision making it is possible to focus on the stages of the process which can be supported and how they can be supported. Without an appreciation of the decision making to be supported there can be no rational attempt at building a decision support system. Thus the first section of this chapter aims to analyse decision making using a series of generic models. At the most generic level this begins with a philosophical analysis applying the ontological and epistemological models described in chapter three. From these, process models are developed and applied to clinical decision making. In the section following the decision making analysis, the potential role of decision support in clinical decision making is investigated through a similar analytical process.

4.2 DECISION MAKING

4.2.1 Ontology of Decision Making

An ontological model of decision making is presented in figure 4.1. The model represents a material problem situation as present in technology, medicine and science. The problem exists in the material reality, and the decision making occurs in the idealist reality. The first stage of the decision making cycle is for the decision maker to perceive the material problem. This perception is dependent on many things, most obviously the perceptive skills of the observer. Moreover, the assessment of the perceived material phenomena as a problem situation will depend on the point of view of the observer. Included in this point of view will be a set of material goals that they are seeking to satisfy. In relation to these goals Daellenbach (1994) defined a material decision problem as the situation where, " a person or a group of individuals would like to achieve one or several goals, or maintain current levels of achievement." Thus a problem situation exists where there is a perception of either goals not satisfied or of the possibility that goals satisfied now may not be in the future. Once the problem has been abstracted from the material domain the process of decision making then begins in the idealist realm. The product of the decision making process is an action; this may be an action to increase the amount of knowledge of the problem, or it may be an action to dynamically impact on the material problem. The action will lead to an outcome which will be perceived as a set further material phenomena. This then leads back into further decision making, and so the cycle repeats itself. These processes are depicted in a generic process model of decision making, figure 4.2.

The ideas impacting upon the decision making process will be influenced by the nature of the idealist reality being considered. A philosophical description of the nature of idealism was given in the previous chapter. The conclusion was that the complexity of idealism can only be explained by the concept of the totality of personality. This concept holds that the nature of idealism is a mixture of rationalism, romanticism and voluntarism. In rationalism reason is the essence, and it is the application of logic which governs all decision making. Romanticism holds that emotion is of the essence, and it is the emotional response to a material problem which governs decision making. Impulsive irrationality is the essence of

voluntarist idealism, where it is simply an individual's will which motivates and shapes their decision making. So, decision making is influenced by a complex mixture of these classifications of idealism. Figure 4.3 illustrates how decision making may be classified using the three natures of idealism. The areas in the figure represent the possible classifications of the nature of decision making. Thus it is possible to apply rationality, romanticism and voluntarism individually in decision making. Moreover, a decision can be characterised as having elements consistent with two of the classifications of idealism. For example voluntarism could define the goal for a rational decision making process. In the drive for continued survival man employs rationalism to solve the problems which conflict with this goal. An emotional response to observed phenomena can combine with rationalism in decision making. For example a response of emotional unhappiness could drive the decision maker to seek a rational solution to achieving a state of happiness. The emotional response to phenomena can also define which of the voluntaristic goals are acted on. For example a fear response could invoke the goal for individual survival. The central portion of figure 4.3 represents the interaction of all three idealistic natures, this could happen through the emotional response to phenomena defining the voluntaristic goals for applying rationalism to satisfying the voluntaristic goals. Thus, all of the combinations of idealist natures can influence each other during decision making, figure 4.4.

Voluntarism, free will, and romanticism, or emotional response, are highly dynamic and can vary between individuals and even for the same individual at different times. Therefore it is not possible to construct detailed generic models of voluntaristic and emotional decision making which can be consistently applied to different instances of their application in decisions. By definition these categories of decision making are not consistently coherent with logic or the available knowledge base. Making decisions in an inconsistent manner does not allow the decision maker to learn about the problem domain, and thus does not logically lead to improved decision making. To build a model of decision making there need to be consistent characteristics of the process which can be abstracted into the model representation. The consistent factors of voluntarism and romanticism are not analysable further than to say they have an affect on decision making. Thus, figures 4.3 and 4.4 represent the extent of the analysis of the affect of voluntarism and romanticism on decision making. Applying these models to decision making shows that rational processes

do take place within a voluntaristic and emotional context. The context of rationalism in decision making is summarised in figure 4.5. Analysing rationalism, consistent application of logical reasoning and available knowledge, in decision making offers the most scope for developing a coherent model of the decision making process. Then through the consistent application of these models to decision making the rational elements of the process can be abstracted and the lessons learnt utilised in future rational decision making. The process models of rational decision making are described in the section 4.2.3.

4.2.2 Epistemology of Decision Making

The epistemology of rational decision making is concerned with the application of knowledge in the cycle of decision making. The nature of the knowledge required in decision making is justified true belief. This implies the knowledge must be believed by the decision maker, in the sense of mentally assenting to the knowledge and acting upon the knowledge. The truth of the belief can be assessed according to many criteria as discussed in the previous chapter. However, the three tests of truth which allow for critical appraisal of belief, and hence rationality of knowledge, are: correspondence; coherence, and pragmatism. In a rational approach to decision making these are the three criteria to be used in testing the truth of the categories of knowledge discussed below.

The scope of knowledge applied in decision making could be any knowledge available to the decision maker. The fundamental elements which must be present for rational decision making are knowledge of material phenomena, conceptual knowledge, and knowledge of the techniques needed to interact with the problem. These different levels of knowledge are depicted in figure 3.6 from the previous chapter. Language can be used to express knowledge at these different levels.

Material phenomena, or state knowledge, can be expressed in the form of propositions, of the form "snow is white." The interpretation of this proposition relies on the application of conceptual knowledge, in the example this includes concepts of white and of snow. Following the conceptual interpretation of a material proposition testing its truth can be done on two levels. Firstly physical verification, applying the correspondence test, can be

sought. Thus if it is observed snow is white then it becomes a justified true belief (knowledge). An alternative test of a proposition is the coherence test. If knowledge already exists that snow is white, then the proposition is accepted as true on the grounds of logical agreement with prior knowledge. If prior knowledge was that snow was black, then there is obviously logical disagreement and further testing of the prior knowledge and the proposition is required. The more correspondence and coherence a proposition has then the greater the certainty in its truth value.

Know how can be expressed in the performance of an action, or as the description of a process. Included in the description is a statement of the goal or purpose of the process, and a series of activities or tasks which describe the process. For example know how of making a snow ball can be expressed in the action itself, or in the description of the process as follows:

GOAL: Make a snow ball

i) Find snow

ii) Pick up snow in hands

iii) Compress snow into a round ball

iv) Release pressure

v) Review results and modify if necessary

In this simplified illustrative example each of the stages of the process will involve the interpretation of the task using conceptual knowledge, and then the application of the interpretation in material action. The truth of know how is ultimately in whether or not the purpose or goal has been satisfied, the pragmatic truth test. The satisfaction of the purpose is dependent on the effectiveness of the process and the material context it is applied to. Therefore if by applying the above set of tasks a snow ball is made then the know how can be said to be pragmatically correct for the snow used. If the main goal is not satisfied then the know how is not pragmatically true in the material context it was applied to, and may need modification. Another truth test which can be applied to know how is other knowledge of how to achieve the goal. Then comparing one process with another to see which produces the most effective results.

The conceptual knowledge which is used to interpret the expression of know how and state knowledge exists in a web of interconnected constructs containing different concepts. Figure 4.6 illustrates the conceptual hierarchy for the concept of snow. Here five concepts have been linked to snow: white; cold; light; solid, and soft. Each of these concepts are part of a deeper construct, for example white is part of the construct defining relative visible colours. The source of the knowledge defining the construct of colours is perception of the material phenomenon of colour. Thus conceptual knowledge of matter can be traced back to its source in the experience of material phenomena. Using all the different levels of knowledge during decision making in a rational and explicit manner allows for the testing and development of a knowledge base.

As illustrated in figure 4.1 the source of problem knowledge which begins the decision making cycle is the observed material phenomena. If there is no knowledge of the material phenomena which constitute the problem there will be no perception of the problem state. The prior know how and conceptual knowledge will be applied to the phenomenal knowledge to form an abstracted view of the problem. Prior knowledge of strategies for solving the problem will then be applied to decide on the course of action to be taken. The prior knowledge available to the decision maker will partially depend on their experience of the problem domain. If the decision maker has a large amount of experience they are assumed to be an expert decision maker, because of their large amount of prior knowledge of the domain.

The validity of the knowledge applied in the decision will be judged by the perceived outcome in the material domain. If the purpose or goal of the decision maker has been satisfied then it can be pragmatically judged that the knowledge applied is valid. The decision evaluation stage is thus dependent on the goals of the decision maker, which are defined during the problem assessment. The validity of the know how and conceptual knowledge are further reinforced by their application to similar future problem scenarios.

4.2.3 Process Models of Decision Making

The ontological model of decision making showed the material problem and the decision maker as two separate entities. Acting between these two entities are the decision maker's perception of material phenomena and the action taken to alter the material phenomena. This leads to the three stage general model of decision making; problem perception; decision making, and action, figure 4.2. This model can be used to describe voluntaristic, emotional and rational decision making; the difference being that it is possible to analyse the rational decision making process in more detail as it is more explicit and includes more consistently applicable concepts.

Rationalism implies consistency according to the concepts of logical reasoning and application of the available knowledge in the reasoning. Rationalism in decision making can be used actively during the decision making process to decide on a course of action, or it can be used to justify a decision made on voluntaristic and/or emotional grounds. In seeking a rational approach to decision making it is important to use rationalism actively in the decision making not as a justification for an emotional or voluntaristic decision. Where the decision has been made on this basis there should be acknowledgement of their influence. It is through the consistent application of logic that a new understanding of the process of decision making, and the knowledge used in it, will be achieved.

Bidgoli (1989) represented the process of rational decision making as a four stage model, figure 4.7. The four stages of the model are: intelligence; design; choice, and implementation. Intelligence gathering includes collecting information on the observed phenomena and assessing the problem. The design phase involves generating alternatives for solving the problem, and evaluating the feasibility of the proposed solutions. The aim of the choice phase is to select the most effective of the alternatives. Finally in Bidgoli's model is the implementation of the chosen solution.

Although Bidgoli's model provides a good basis for building a model of decision making it does have two main shortcomings. The first is the lack of feedback to the intelligence stage from the implementation of the solution. Following implementation further problem

assessment is necessary to ascertain whether the problem has been solved or not. The other necessary stage following the problem reassessment is an evaluation of the previous decision, where the aim of the decision evaluation is to judge the effectiveness and efficiency of the decision making already performed. Without a mechanism for decision evaluation the same inappropriate decisions could be made to solve the problem.

The more complete model of rational decision making is shown in figure 4.8. The rational process has been shown operating in the context of voluntarism and romanticism. Thus even though rationalism is strived for the affects of the other idealist natures cannot be ignored. The defining factor of the core rational decision making process is that it should withstand maximal examination when applying reason and relevant knowledge (Colste, 1992). To withstand this test requires the application of reason and knowledge during the decision making process. Moreover, to aid the examination of the decision, each stage the process should be explicit and transparent. An analysis of reason, or logic, was given in section 3.3.1 of the philosophy chapter. The two core concepts of logic are: deductivism, reasoning from propositions, and inductivism, forming propositions from observations. Inductivism is applied in forming propositions which define the state knowledge, or facts, the form of which is analysed above. Deductivism is used in the reasoning including in the assessment of the problem, and in the application of conceptual knowledge in the process. The relevant knowledge applied during reasoned decision making includes all the categories of knowledge discussed above: state knowledge; know how, and conceptual knowledge. What knowledge within the categories of know how is relevant will be proven by pragmatically testing it in its application.

In figure 4.8 the first stage of the rational decision making process is the problem assessment. The problem assessment will include a definition of the problem in terms of the definition of the problem state A and the long term goal state B. The long term goal state is the state which at the start of the decision making process it is thought should be observed in the material domain. The goal state can be reasoned from conceptual knowledge, know how and philosophical principles, for example ethical codes. Alternatively it could be defined by romantic or voluntaristic ideals. The problem state assessment depends on these goals and the current state knowledge of the material problem

domain, the expression and testing of the state knowledge being an integral part of the explicit state knowledge gathering. Reason is applied to compare the goals and define the problem, obviously if A equals B there is no problem. The definition of the problem will include what is trying to be achieved, e.g. reduce the patient's plasma potassium concentration.

The previous decision analysis follows the problem assessment. The goal of this stage is to judge the effectiveness and efficiency of the decision made in the previous cycle of decision making. Effectiveness of a decision is defined as the goals of the decision being satisfied by the decision making process (Bidgoli, 1989). Efficiency is a measure of the resources used to effectively solve the problem, and can be expressed as a cost (Bidgoli, 1989). Thus efficiency is a function of effectiveness, and with zero effectiveness there is zero efficiency no matter what the costs may be. Effectiveness can be judged by comparing the decision goals of the choices made in the previous cycle with the observed outcomes in the current problem assessment. If the cost of implementing the previous decision can be evaluated this can be used to assess the efficiency of the decision. Thus the effectiveness and efficiency of previous decision making can be used to inform the next cycle. If the decision has been proven to be ineffective when applied to the material problem, this could preclude the option in the next decision cycle. The counterpart of this is where the previous decision is effective which gives scope for improving the efficiency of the next decision.

Using the decision evaluation and problem assessment, options for action are derived from state and prior knowledge for achieving goal state B from the present state A. One source of options is prior knowledge of actions used to solve a similar material problem previously. Another source for possible options is new techniques derived from related problem domains. Each of the options for action generated will have an attached purpose and description of the action. For inclusion as an option the purpose of the option should be logically consistent with the problem definition.

Assuming there are then two or more options some judgement must then be made to choose between them. The criteria for making the choice should be logically derived from

knowledge of the options and the problem context. Once selected the criteria are consistently applied. Possible criteria for selecting options are: resource limitations; knowledge limitations, and predicted effectiveness of the option. If either the resources are not available or the knowledge to use them is unavailable then the option is only an idealistic one, not a pragmatic one. Where resources and know how are not constraints then the option to choose is the one predicted to be the most effective.

The bases for making a rational choice are the reasoned application of knowledge of the problem assessment, knowledge of the previous decision evaluation, and knowledge of the availability of material resources, the aim of the choice being to choose an option which will diminish the problem. Following the choice of action to be taken it will be implemented, depending on the material availability of resources and know how. The action, and the passage of time, will lead to a new state in the problem domain which will require a reappraisal of the problem situation. If the gap between the goal state and the observed state is still unacceptable then a repeat of the cycle may be needed. Thus decision making is an iterative process, where until the pragmatic criteria of goal satisfaction is achieved the decision making cycle will be repeated. Alternatively there may be a need to reappraise the criteria used in the original goals, as by tackling the problem the decision maker will have increased their knowledge of the problem domain and what is pragmatically achievable within the present constraints.

The expression of all the knowledge and reasoning used at each of the stages of the decision making process can aid the analysis of what is to be done and what has been done; providing the opportunity for learning about the structure of the process and the knowledge applied during the decision making.

The first component of the problem assessment is the comparison of the material goal state compared to the observed material state. The first stage in this process is to specify the ideal goals for the domain, and how they are to be assessed. Using the assessment criteria a qualitative or quantitative assessment of the observed phenomena is made and compared to the goal state. Any difference between the goal state and the observed state will constitute a problem of varying magnitude. The difference between the goal state and the

observed state defines the problem to be solved. For example if it is a goal for an individual to attain their ideal body weight, and their observed weight is too high then the problem is how to reduce their weight. The opposite of this being where an individual is below their ideal weight, then the problem is how to increase their weight.

The process of representing the options and arriving at the choice of an option can be represented using a decision tree, figure 4.9. The start point of each tree represents a decision node or root, and the branches represent a decision option. The branches show what possible actions can be taken whilst the structure of a decision tree indicates the order in which the actions are to be chosen. The branches coming from one node of the tree represent mutually exclusive options. The choice between the options is made according to the evaluation of a decision variable(s). Alternatively a decision table can be used, where the upper rows specify variables to be evaluated and the lower rows specify the corresponding action to be taken when the evaluation is satisfied. If it is possible to define all the decision options a decision can be modelled using a tree, or a decision table. Using a decision tree for a limited number of options offers a clear representation of the choices to be made. The knowledge used to make the decisions can be attached to the nodes and applied in practice when using the decision tree.

When specifying the decision tree the knowledge applied at the decision points in the tree can be defined by a set of conditional state knowledge propositions of the form if proposition A is true then choose option 1; the test of the truth of proposition A being the correspondence test, i.e. a material phenomena corresponding to A being observed at time T_1. The options in the tree are defined by know how of what is possible in the context of the problem. If the problem is a common one it may be possible to apply the same decision tree to different instances of the problem.

The actions to be performed are defined by the tree, and the know how required to perform the actions can be attached to each of the options. Thus the implementation of the actions is supported by the application of the tree.

Attached to the options in the decision tree are the goals the decision option is seeking to

satisfy. The evaluation of the decision made is then a pragmatic one, where the outcome state is judged against the goal state, and where the next cycle of decision making is informed by the outcome of the previous decision. Thus if a course of action was taken which did not produce the anticipated results then the option choice can be weighted accordingly in the next decision making cycle. In this way the decision maker "learns from their mistakes and their successes."

4.2.4 Clinical Decision Making

Shortliffe (1987) stated, "Medical practice is medical decision making," thus the process of decision making is fundamental to clinical practice. The cycle of clinical decision making in the ITU setting goes through three phases as described by Friesdorf et al. (1994), figure 4.10. These three phases begin with the gathering of information on the patient's state of health, then an evaluation of their state of health, and depending on the evaluation moving onto treatment. Whilst they are being treated the patient's state of health and treatment are monitored and inform the next evaluation of their state of health. Ontologically the activity of these three stages can be considered to occur as shown in figure 4.11. From figure 4.11 there are three types of matter which are included in the clinical problem. These are: the patient's state of health; the treatment resource being used to control the patient state; and the monitoring resource used to gather information on the patient. In the idealist reality exist the counterpart decision making processes which control the three types of matter. These exist in a hierarchy where the patient state decision making governs the treatment and monitoring decision making. For example if no treatable problems are found with the patient state then further treatment action is unlikely. In figure 4.11 the monitoring and treatment actions act on the material of the clinical problem, and monitoring information is fedback to inform the processes of decision making. The ontological model of clinical ITU decision making leads to the modification of figure 4.10, as the patient state evaluation is controlling both the monitoring and treatment decision making. The extra arrows in figure 4.12 show that it is possible to move from patient evaluation to further monitoring before beginning treatment, and that monitoring of the treatment will inform the treatment decision making cycle.

The process models of decision making developed in the previous section can be applied to each of the three decision making processes identified above, with figure 4.12 defining how the three processes interact. Figure 4.13 shows the three processes of patient state, treatment, and monitoring decision making operating together. The start point is the evaluation of the patient state from the initial perception of their state. Where the decision cycle has already occurred the prior decisions are assessed for their effectiveness. Following this, options for future action will be derived from the results of the initial evaluation and clinical know how of what is appropriate for the patient. Prior clinical knowledge and knowledge of the patient state will then be used to make the choice of action to be taken. Once chosen the actions to be performed will be ordered with the required goals. The actions can be treatment and/or monitoring actions. Each of the actions will have their own decision making cycle to go through.

The treatment decision making begins with an assessment of the present patient treatment, then if the present requirements are not being satisfied options for satisfying the treatment goals are generated. The options at this stage will be determined by clinical goals, resource availability and knowledge of which options are appropriate. Using available clinical knowledge the choice of treatment options will be made, followed by the implementation of the chosen treatment. After implementation the treatment state assessment is repeated and the previous treatment decision is evaluated.

The monitoring activities to be conducted are governed by the patient state evaluation and the treatment decision making. The patient state is assessed on the data gathered during the monitoring activity. Information is also required to assess the state of treatment being delivered to the patient. Thus the monitoring activities and their goals are defined by the two other processes. The cycle for monitoring decision making follows the general cycle discussed above. The variables affecting monitoring decisions will include the availability of resources and the timing of the measurements to be taken. The information generated by the monitoring activity is fedback to assess the patient and treatment state.

The application of knowledge in these three levels of decision making can be characterised by applying the epistemological analysis of decision making to the patient state decision making. To make the evaluation of the patient state knowledge of the observed material

phenomena of the patient state is required. This is interpreted using conceptual knowledge of clinical patient states, and tested by correspondence and coherence. Where the state knowledge is "Potassium is high," this is interpreted as the concentration of the potassium ion in plasma is high. The "web" of conceptual knowledge used to make the assessment on the first layer will have concepts of concentration, potassium, plasma and high. These concepts will then be linked to deeper conceptual knowledge of physiology, pathophysiology and prior clinical experience, figure 4.14. The relationship between these three deeper forms of knowledge is a complex one which is difficult to define. At this stage of the analysis the generic model in figure 4.14 represents the extent of the depth of the modelling of the conceptual knowledge base.

In the decision making process know how and conceptual knowledge are applied to the options for actions and the choice of actions. Know how is then applied to performing the material action. The knowledge application is similar for the treatment and monitoring decision making, although the conceptual knowledge used will be of treatment and monitoring respectively.

The decision making framework described above is a general analysis of clinical decision making in the ITU. How the framework is applied will depend on the decision making being analysed. At the highest level it provides a breakdown of clinical decision making in the ITU. Thus it provides an analytical tool for breaking down the problem into analysable sections. Moreover, through the structuring and expression of decision making required when applying the framework, a greater insight into the decision making process can be achieved. This includes the explicit connection of knowledge to actions giving the opportunity for pragmatic testing of knowledge. Furthermore using the model of decision making to structure clinical decisions offers a framework which can be directly supported by decision support systems.

4.3 DECISION SUPPORT

Shortliffe (1987) defined clinical decision support as any computer program that deals with clinical data or knowledge and which performs one or more of the following tasks:

- serving as a tool for information management;
- helping health care workers to focus attention;
- giving advice in the form of a patient specific consultation.

Bidgoli (1989) defined management decision support as:

A computer based information system consisting of hardware/software and the human element designed to assist the decision maker at any level.

Turbain's (1993) definition of management decision support is as follows:

A decision support system is an interactive, flexible and adaptable CBIS (computer based information system), specially developed for supporting the solution of a particular management problem for improved decision making It utilises data, it provides easy user interface, and it allows for the decision maker's own insights. Decision support also utilises models (either standard and/or custom made), it is built by an iterative process (frequently by end-users), it supports all the phases of decision making, and it includes a knowledge base.

One point all these definitions have in common is that a decision support system is defined as computer based. Although encapsulating decision support onto a computer does allow for testing of the techniques and technology used it does not address fundamental problems of how decisions are made and can be best supported. A decision support system exists as a material entity but it does not have to be in the form of a computer system. Another common point in the above definitions is that a decision support system is built to aid the decision making process, not to replace the decision maker. Therefore, the counterpart of the material decision support system in the idealist reality is the decision maker.

4.3.1 Decision Support Ontology

The place of decision support ontologically is as a material abstraction of the decision making process, figure 4.15. Decision support exists to offer advice to the decision maker.

The functionality of decision support is essentially an epistemological one, offering information to the decision maker which gives them knowledge relevant to solving the material problem. The epistemological function of decision support is discussed in more detail in the following section.

Decision support supplements the decision making options already known in the idealist reality. Its main use being when uncertainty exists in the decision maker's mind, the idealist reality, on what a decision should be or on how to make a decision. Where the decision maker has no uncertainty on the problem assessment or on course of action then they will not require decision support. Therefore, the ideal role for decision support is where it can offer advice to the decision maker who has a high degree of uncertainty on how to reach a decision. This may be due to inexperience of the decision maker, or high complexity of the problem. Both of these factors are relevant to the problems faced in clinical decision making.

4.3.2 Decision Support Epistemology

The epistemological function of decision support is to apply knowledge required in the decision making process. The exact knowledge required will be decision specific, and hence depends on the problem to be solved. However, there are certain epistemological characteristics of the knowledge which are general.

The knowledge needs to be explicitly stated and true. Therefore, the knowledge contained in a decision support system requires testing. The three types of testing of the embedded, or prior, knowledge and the generated knowledge are: coherence testing for logical verification; correspondence testing for observational verification, and pragmatic testing for test of purpose. The coherence test is applied to all types of knowledge providing there is a knowledge base of related propositions available. The correspondence test needs to be applied to all propositions relating to material phenomena. The pragmatic test is applied to any proposition which has a function or relates to an action.

The scope of knowledge of a material decision making problem includes knowledge of the

state of matter, know how and conceptual knowledge. The relation of these three classifications is illustrated in figure 3.6 and discussed in section 3.7. The conceptual knowledge is embedded in the decision support system, and consists of knowledge relating to the decision problem. The conceptual knowledge provides the a priori structure for the application of know how and the interpretation of state knowledge. The state knowledge is time varying and thus will be generated during the operation of the decision support system. The application of the know how depends on the embedded conceptual knowledge, the state knowledge, and the specified pragmatic goals of the application. All the categories of knowledge used in a decision support system need to be logically linked together to aid user understanding of the system, and for internal and external coherence checking of knowledge.

The source of the different categories of knowledge in clinical decision support is primarily observation of clinical phenomena. For the state knowledge this will be time varying. The clinical know how is based on an accumulation of clinical experiences of actions linked to resulting phenomena. The conceptual knowledge will be based on clinical phenomena and phenomena as interpreted by medical science. Therefore, medical science contributes to a clinical knowledge base in decision support at the conceptual level.

4.3.3 Process Models of Decision Support

Ideally decision support should provide an aid to effective rational decision making at all stages of the decision making process, by offering problem sensitive justified advice to the decision maker. How decision support can be used as an aid to all the stages of the rational decision making process is shown in figure 4.16. For the purpose of the illustration decision support has been applied to the problem of clinical treatment decision making. The supported decision maker still goes through the decision making cycle in their mind, and this is supported by the "simulated" decision making cycle in the material reality. Therefore it is vital to have a representation of the decision making process which both the decision maker and the decision support system can apply to the problem. If the whole decision making cycle can be abstracted it is possible to simulate and use the simulation to support the whole process, or just sections of it as required. Advice is then offered to the

decision maker at each stage of the process. For example all the possible options for treating a patient in disease state B. The simulation of the rational decision making process will require abstraction of the knowledge used by decision makers in similar problem scenarios.

Therefore the first stage of decision support is to characterise the material problem which is the subject of the decision making. This includes the goals for the decision and the variables to be used for the assessing the problem and the decision effectiveness. A crucial point here is that "simulated" decision support is problem specific. Therefore for such a decision support system to be useful there needs to be a commonly occurring problem, with consistent characteristics. Characteristics of the problem include the problem goals, the assessment variables, options for action and the criteria for choosing the options. The options for action in the decision support system can be represented using a decision tree. Then by applying abstracted knowledge at each of the nodes the preferred option can be recommended, with the elicited knowledge as justification for the advice. Finally the implementation of the decision can be supported by descriptions of the techniques and tools needed to complete the actions.

Knowledge plays a role in all rational decision making, as illustrated above in the model of clinical decision making. Thus a "simulated" decision support system will require an abstracted knowledge base to inform the simulation, and to justify the advice to the user. By simulating the decision making process in a rational manner it is implied that some form of artificial intelligence (AI) will be required to perform the task. Expert systems, a branch of AI, attempt to mimic human thought in a specific area (Bidgoli, 1989).

The role of "simulated" decision support is to simulate one or more of the stages of decision making and offer reasoned advice to the user on what the outcome of the stage could be. This is a high level modle of decision support; below this level it is possible to support the decision at lower levels. A lower level model of decision support is as a knowledge source to be used during decision making. The form of the knowledge could be state knowledge, know how or conceptual knowledge. The information management tool described by Shortliffe fits into this category of decision support, where an information system is the

source of state knowledge which the decision maker uses to assess the problem. Thus there is not advice on whether or not a problem exists, only access to information for the decision maker to come to their own conclusion.

Information on options for solving the problem could be offered to give the decision maker knowledge of what can be done, or what has been done by others in the past. For example when presented with a patient suffering from renal failure the system could offer the decision maker information on general treatment strategies for managing the problem, without necessarily recommending how to choose between the options or which option to take. Applying Shortliffe's definition this could be considered a system which focuses the decision makers attention on available options. Both the state information and the information on decision options are problem sensitive. Therefore the information offered could be considered to be decision support, and has been considered to be so by Shortliffe.

The highest level knowledge support which could be offered to the decision maker is conceptual knowledge. This could operate like a text book type of reference where the information offered was related to the problem domain, but not specific to the problem. The analogy being that the decision maker looks up the description of concepts for an explanation of their meaning.

The last three categories of supporting the decision maker are perhaps better described by the phrase knowledge support rather than the term decision support. The phrase decision support is reserved to describe systems which actively offer problem sensitive justified advice to the decision maker for any stage of the decision making process (figure 4.16). Thus a decision support system would offer advice on what the problem assessment is, what the options for action are, what the chosen option is and how to complete the chosen option. While a knowledge support system adds to a decision maker's knowledge of the problem and the options for action, it does not simulate the decision making process.

Building a decision support system is essentially a technological problem, where in response to a social need a technological tool or artifact is designed. Therefore, the methodology which gives the structure to designing a decision support system is the

engineering design cycle discussed in the previous chapter. This process can be informed by scientific knowledge as outlined in the previous chapter. The methodology of clinical decision support proposed here is not tied to a particular computing technique. The technique should be defined by the problem, not the problem constrained by the technique to be applied to it. In the past the development of decision support systems has too often been technique driven rather than problem driven (Heathfield and Wyatt, 1993).

The problem domain of medicine is a complex one with a large knowledge base in many different specialisms. The knowledge base is informed by medical science (figure 3.15) ethical codes of practice, and empirical clinical practice. Therefore, in building a knowledge base for clinical decision support there need to be elements of both medical science and clinical experience.

4.4 ONTOLOGY AND EPISTEMOLOGY IN CDS SYSTEM DEVELOPMENT

The reasons for developing the ontological and epistemological models in the thesis are to provide a basis for a coherent analysis of the nature of clinical decision support, and for application to a problem specific clinical decision support system development. The ontological model is fundamental to this approach as it defines the world view taken in all subsequent analysis and development. The primary purpose of the ontological model developed in the thesis is to represent the decision making process, and to show how decision making can be supported by a decision support system, thus providing a basis for analysis which is not centred on the technology used in a decision support system.

The world view expressed in an ontological model provides a basis for including all the entities that are perceived to exist in the realm of CDS. Thus it is the foundation for forming an holistic view of CDS. The form of the model is important as it is the start point for an ontological analysis of a problem scenario. For example basing an ontological model on a monistic materialist view of reality will provide a different model of a problem scenario compared to that based on a dualistic materialist-idealist view.

All entities that are deemed to exist in CDS can be defined within the context of an

ontological model. In addition to defining the existence of entities the model can also be used to represent the relationships between them. Using a dualist ontological model (figure 3.4) all the entities in the problem domain, in both the material and idealist reality, and the relationships between them can be defined. For example in the ontological model of decision making the relationship between the decision maker, in the idealist reality, and the decision problem, in the material reality, is shown in figure 4.1. Then extending the ontological model to include a representation of decision support, figure 4.15, gives a structure within which all of the elements relevant to clinical decision support can be included. Thus the ontological model provides a structure for analysing all the entities in the supported decision making, and avoids focusing solely on the technological tool which is providing the decision support. Ontologically it can be clearly seen that the decision problem and decision maker exist despite of, and independently of, the clinical decision support system, clearly illustrating that the decision support system exists only as a tool in the material domain and exists for the decision maker to use when they need it.

In chapter three the ontological model was also used to analyse the entities involved in the three main disciplines which impact on CDS system development (technology, science, medicine). From the definition of CDS and this analysis of the three main disciplines the production of a CDS system has been characterised as a technological problem. The ontological model of technology, figure 3.10, defined the dual realities involved in the technological process: a problem and artifact in the material reality, and abstractions of the problem and artifact in the mind. The first stage of the technological process is an assessment of the problem to be addressed by the introduction of the technological artifact. The problem to be addressed in CDS has been characterised above as a decision problem. Ontologically the clinical decision problem has been represented by the problem in the material clinical domain and a clinical decision maker in the idealist reality. Therefore, when building a CDS system there needs to be an analysis and modelling of the material clinical problem, followed by an analysis and modelling of the clinical decision making process to be simulated. The modelling of the clinical decision making follows the assessment of the clinical problem, as knowledge gathered during the problem assessment forms an integral part of the modelling of the clinical decision making. The results of these two processes are then used in the CDS tool development. The development of the CDS

tool follows the modelling of the clinical domain and the decision making as the structure of the CDS tool will depend on the output of both the earlier modelling processes. This is particularly true for the model of the decision making process as it is converted into a dynamic decision making model in the decision support system.

The ontological models of the clinical decision support and clinical decision making are used in a manner similar to that described above to structure the next three chapters of the thesis. According to the ontological model of decision making there first needs to be the perception of a material problem. Perception implies representation, therefore the next chapter of the thesis presents the medical knowledge used to represent the material problem. Then from figure 4.1 it can be seen that acting on the material problem there is the clinical decision making process. This process is analysed and represented in the decision model in chapter six. Following the description of the decision model is a description of the prototype CDS tool developed for decision support in the management of CVVHD therapy in the ITU.

Epistemologically the knowledge included in each of the next three chapters can be analysed using the model of the scope of knowledge (figure 3.6). Chapter five begins by building up the conceptual medical knowledge base used to describe the material clinical problem. This conceptual knowledge base is built up on well established common knowledge from medical science of normal kidney function (physiology) and abnormal kidney function (pathophysiology). Following the conceptual knowledge is a systems analysis of the clinical problem and a representation of the know how used to control the patient's failed kidney function. This knowledge is represented by models of the processes of patient management with descriptions of the goals of the therapy processes and the measurements recorded.

Expanding on the conceptual knowledge and know how described in chapter five, the decision making model in chapter six encapsulates elicited clinical knowledge to define decision goals and decision rules for each of the decision nodes in a decision tree. These goals and decision rules all depend on predefined clinical variables. The representation of the clinical knowledge in the decision tree is tested for coherence with knowledge on

patient state and haemodialysis treatment taken from other reference sources. This coherence checking forms the first stage of knowledge base verification, according to the three criteria for philosophically assessing truth as defined in chapter three.

Another criterion for verification of the knowledge base is pragmatism. Producing a dynamic version of the decision making model in a CDS computer based prototype provides an opportunity for the pragmatic verification of the decision making knowledge base. The prototype development described in chapter seven is based on the medical knowledge modelled in the first two stages of the system development. In addition to this, chapter seven also includes technology specific knowledge of system requirements, system design and system coding. There is also some pragmatic validation of the application of this technological knowledge in the form of results from the functional testing of the dynamic operation of each of the decision nodes in the decision model.

To summarise the ontological modelling of this and previous chapters defines the structure for the CDS system development; whilst the epistemological modelling describes the breakdown of the application specific knowledge and the verification tests to be applied to the knowledge described in the subsequent chapters.

4.5 SUMMARY

The ontological and epistemological concepts developed in the previous chapter have been applied in the analysis of decision making and decision support. Based on these concepts models representing the clinical decision making process have been derived, and the role of decision support in this process represented.

The ontological model of the clinical decision making is used in the next two chapters to structure the analysis of the clinical problem of acute renal failure management in the intensive care unit. The analysis is based on relevant conceptual knowledge from medical science, and builds up a representation of the clinical problem of acute renal failure management. The model of the clinical decision making managing the acute renal failure is based on the models of clinical decision making developed in this chapter.

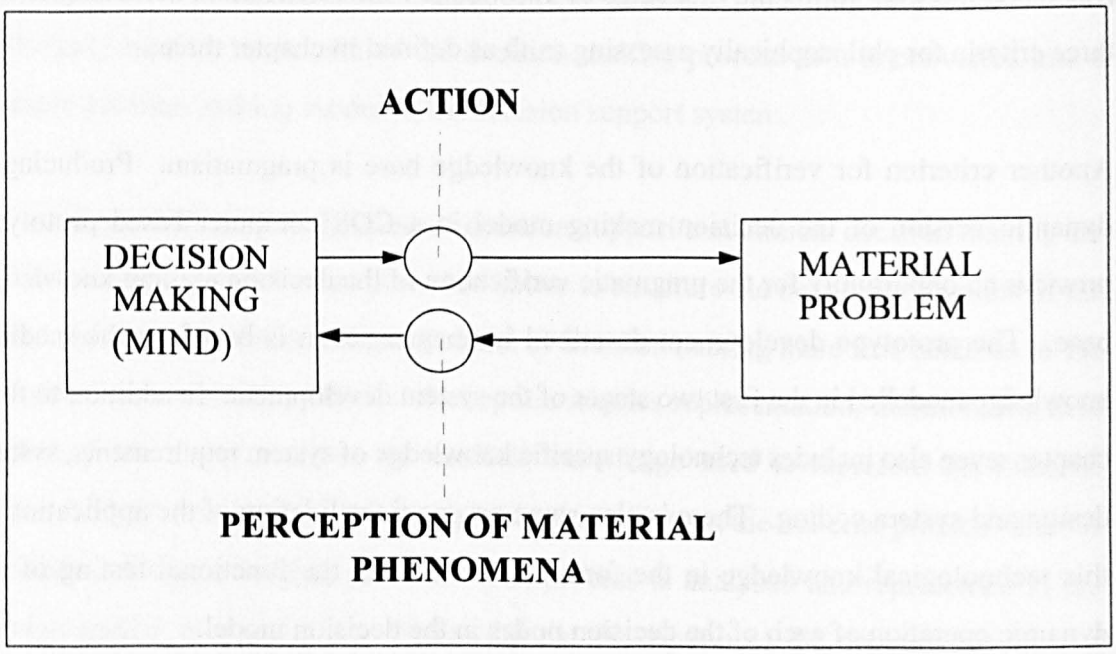


Figure 4.1 Decision making ontology

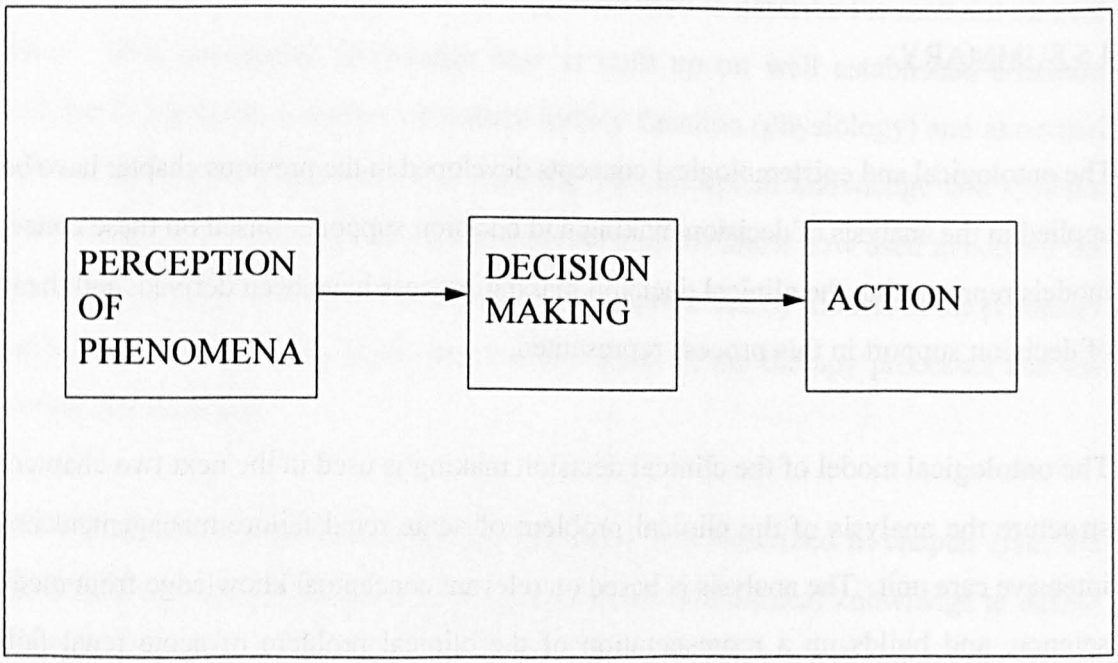


Figure 4.2 Decision making process

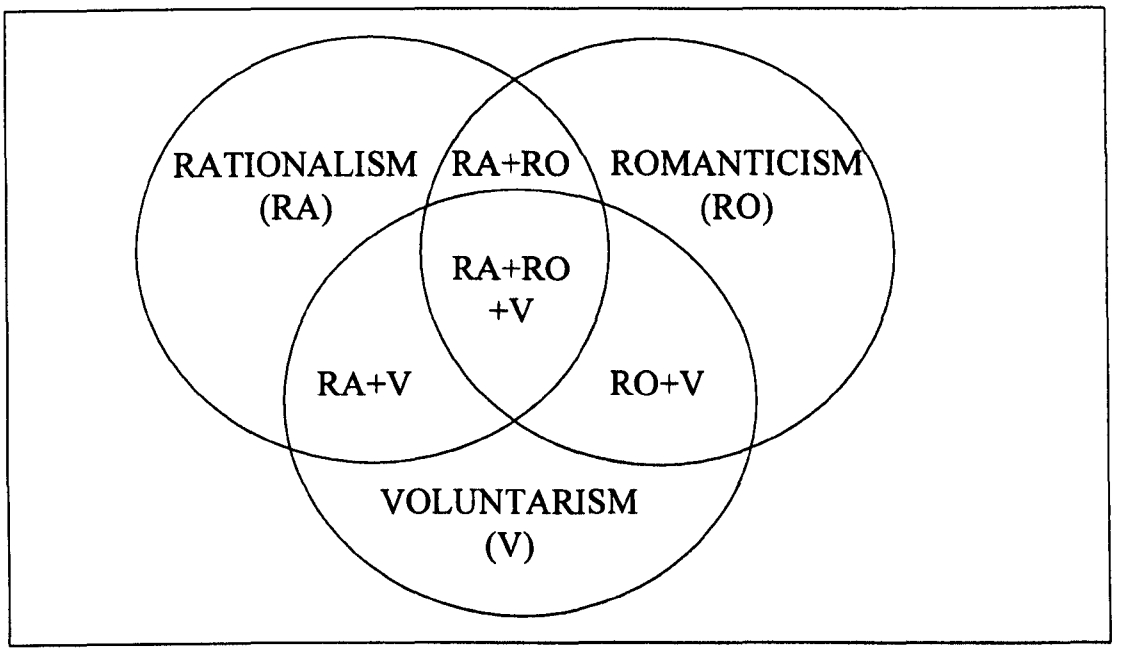


Figure 4.3 Natures of decision making

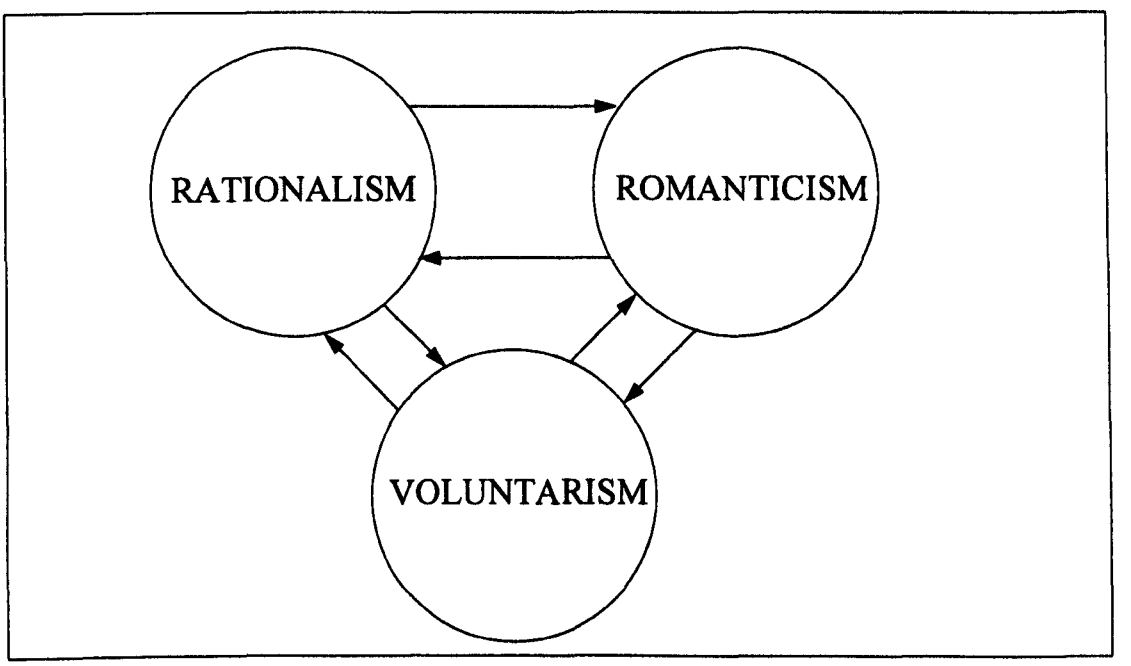


Figure 4.4 Movement between classifications of idealism during decision making

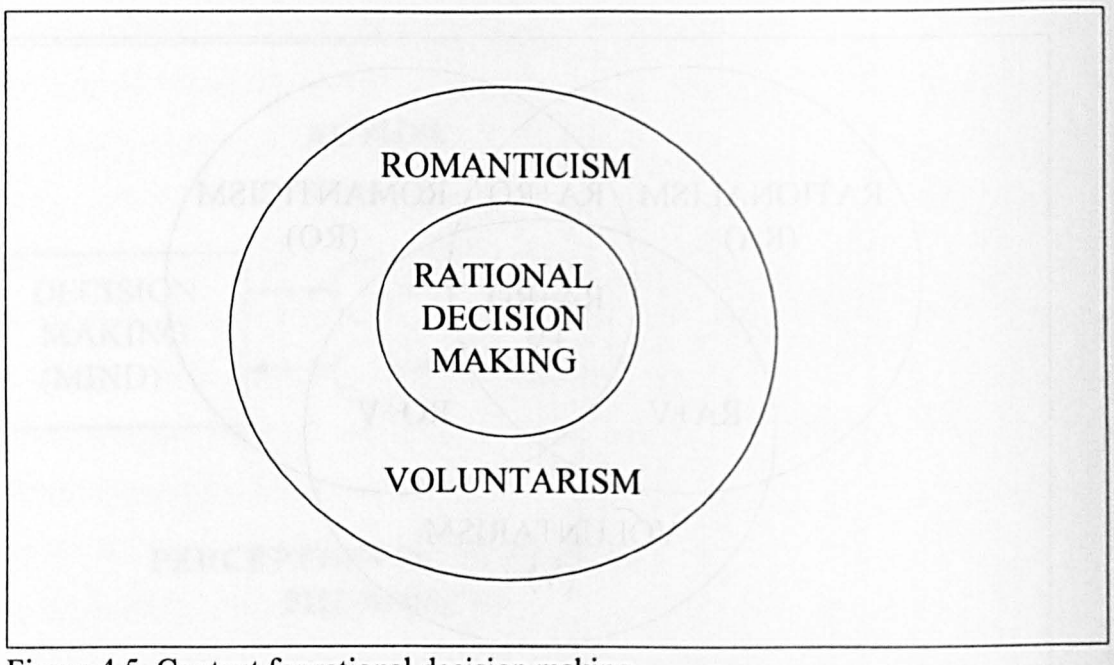


Figure 4.5 Context for rational decision making

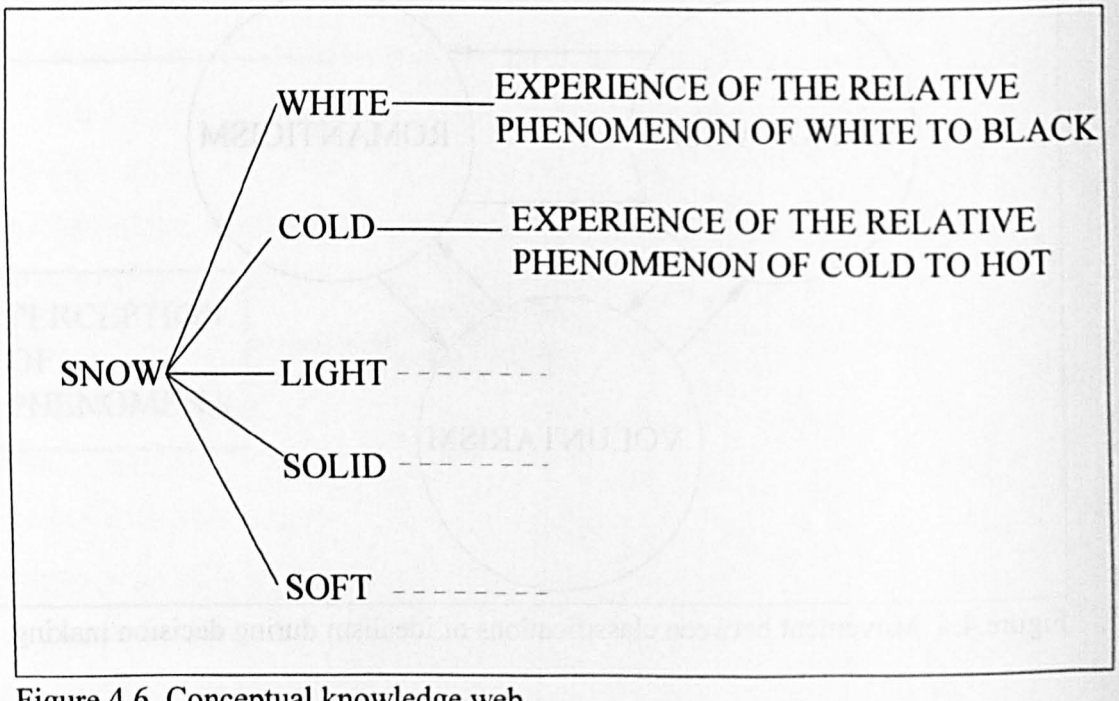


Figure 4.6 Conceptual knowledge web

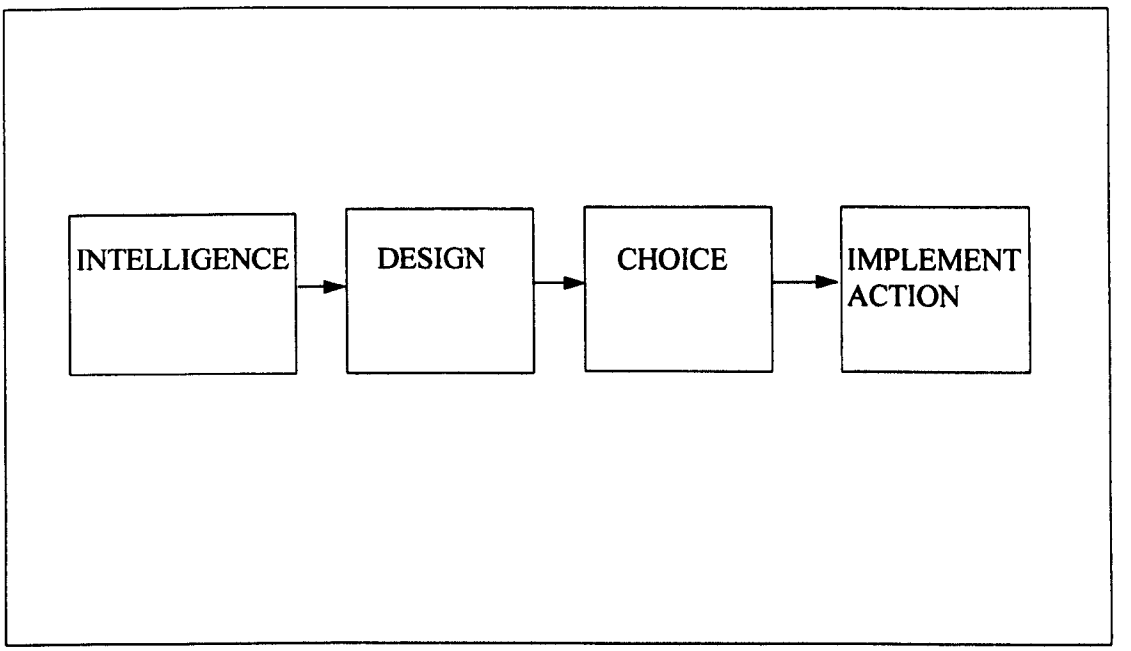


Figure 4.7 Bidgoli's model of decision making

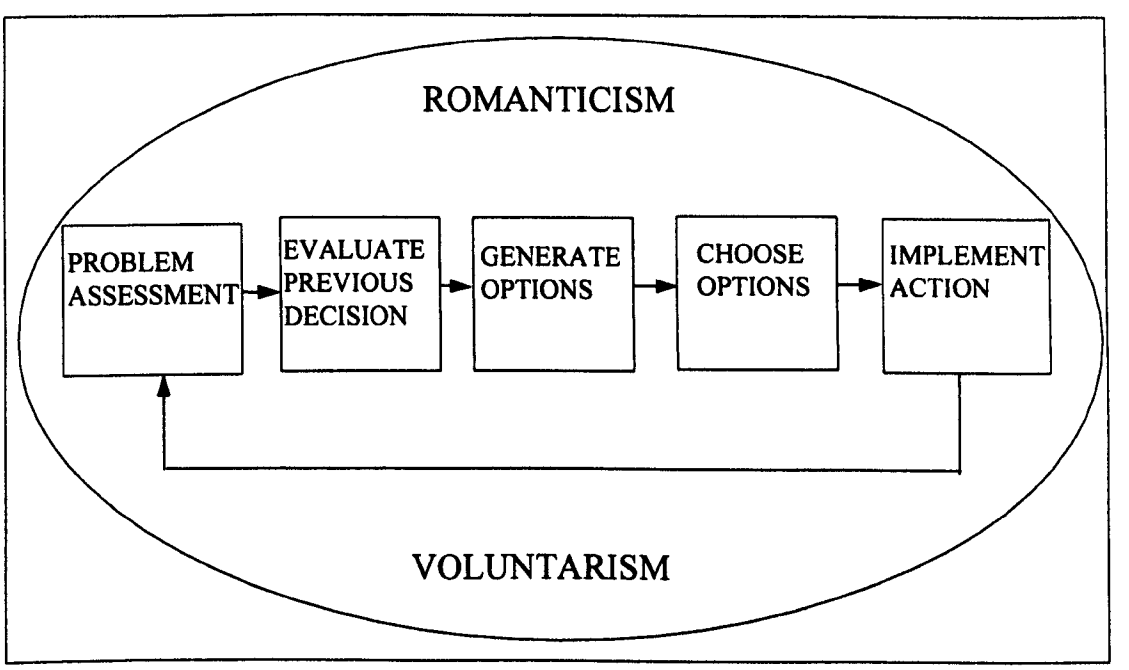


Figure 4.8 Process model of rational decision making

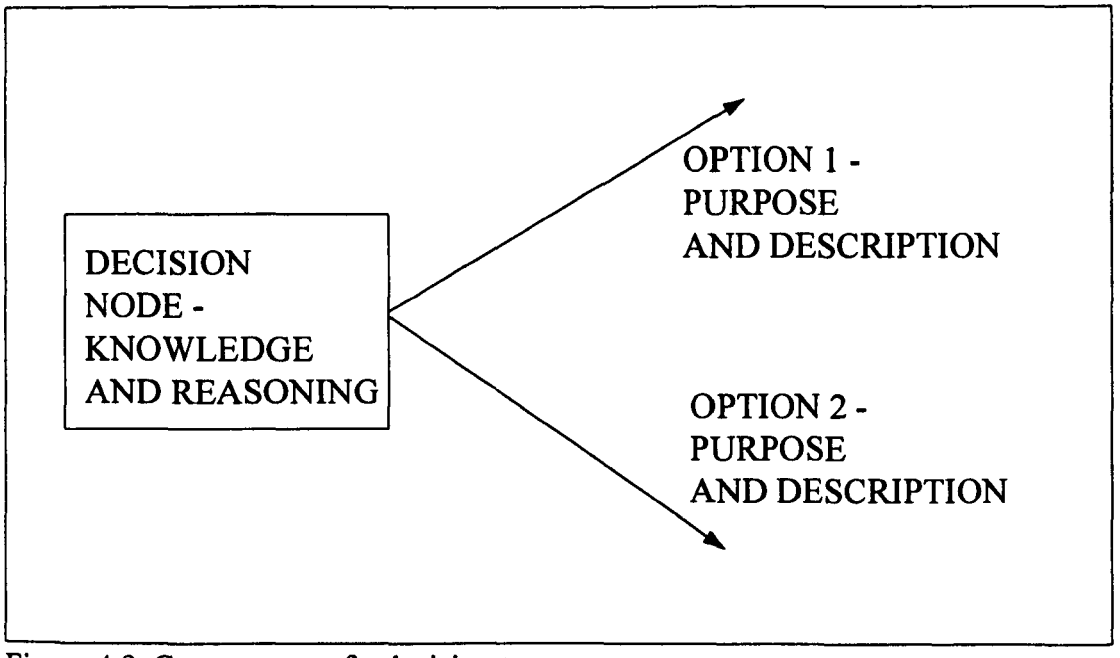


Figure 4.9 Components of a decision tree

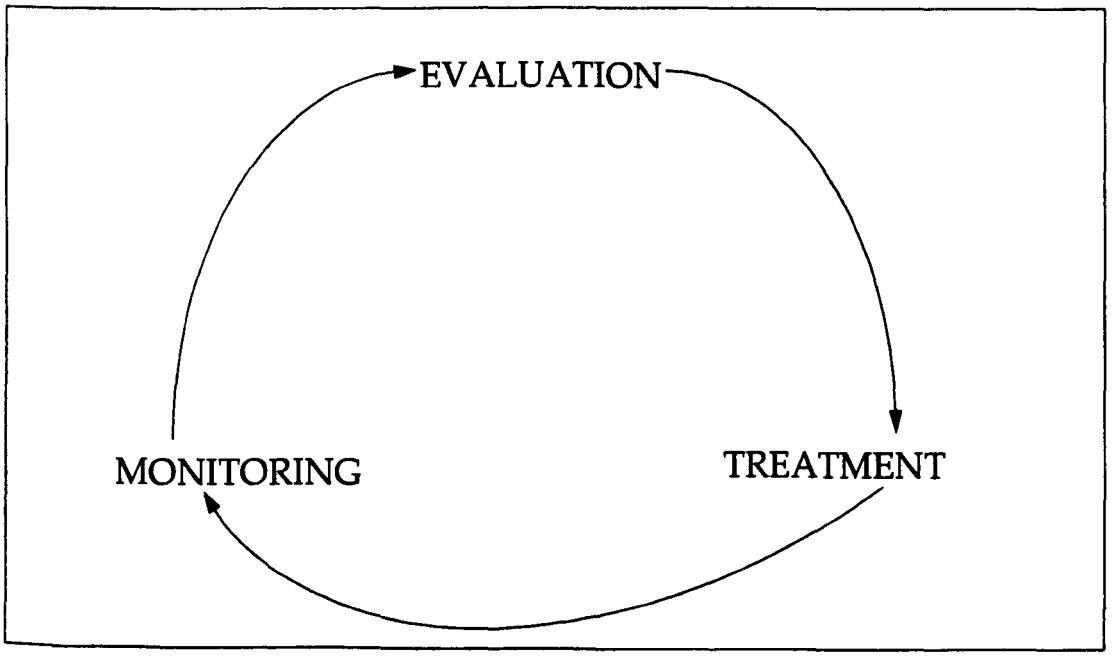


Figure 4.10 Friesdorf's model of the patient care cycle

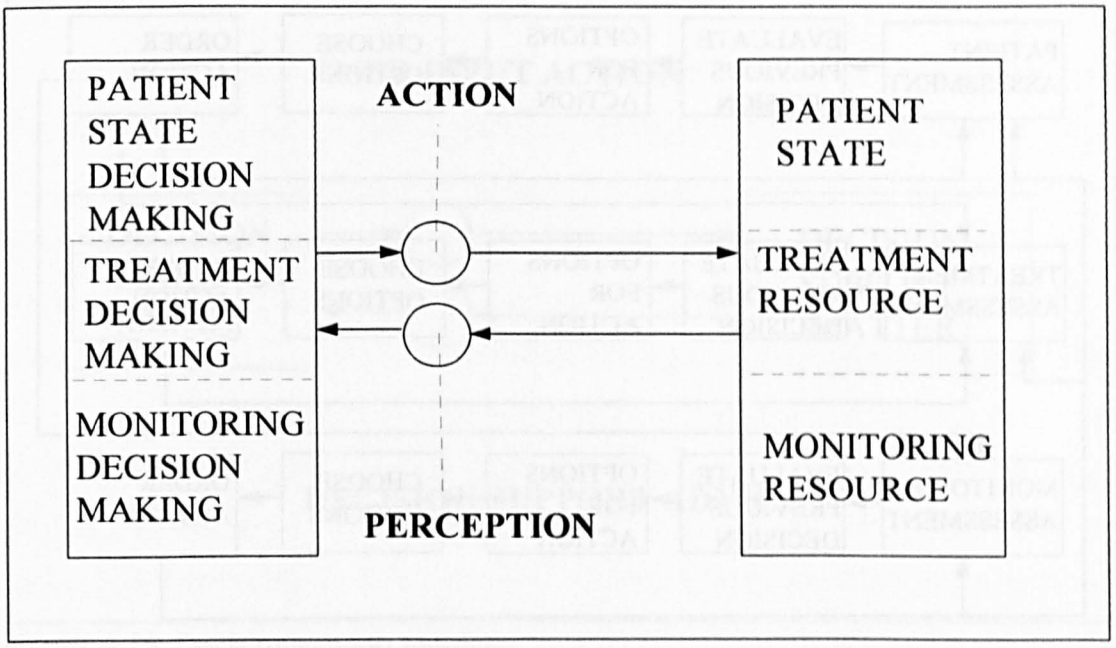


Figure 4.11 Clinical ontology

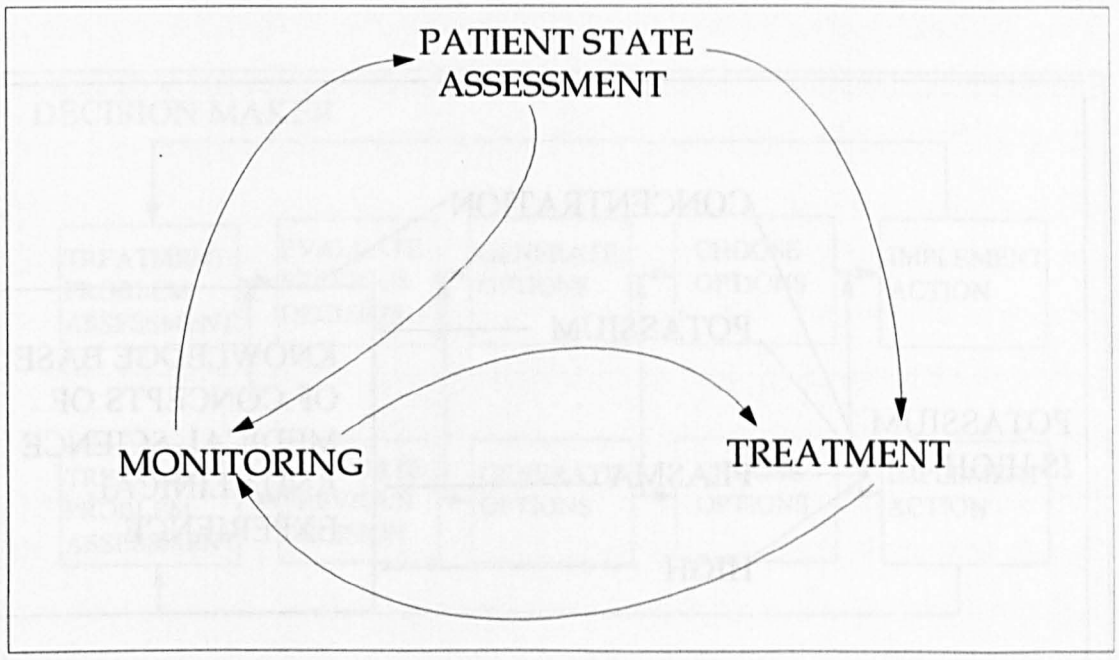


Figure 4.12 Modified model of the patient care cycle

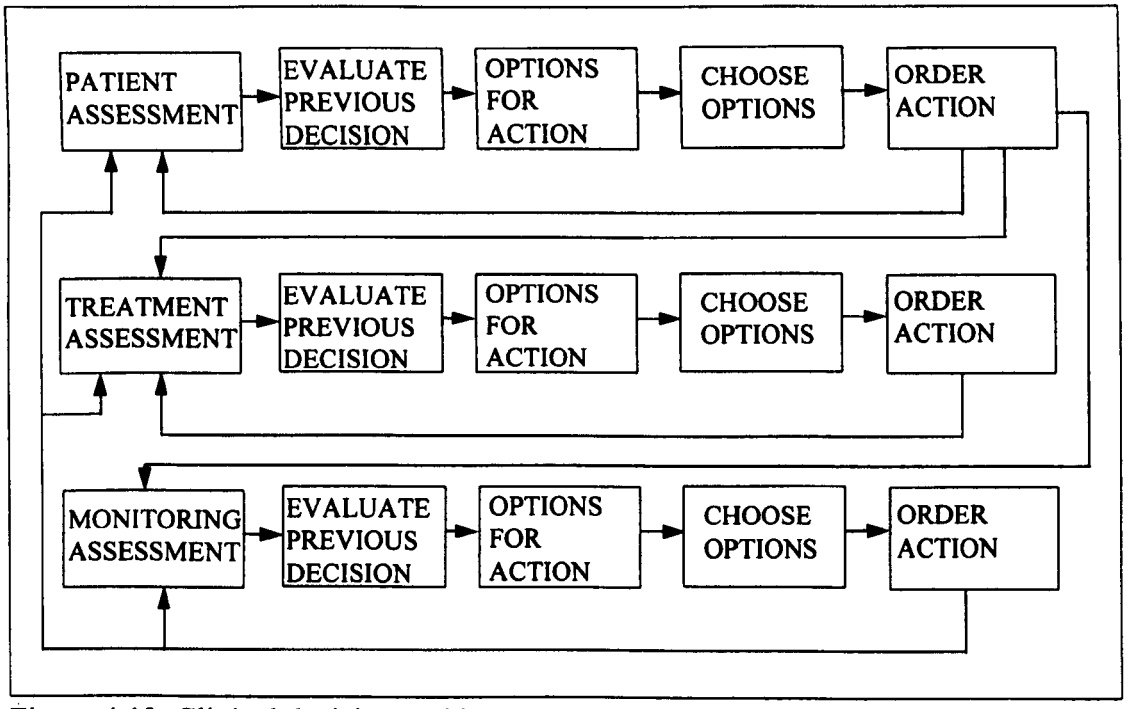


Figure 4.13 Clinical decision making processes

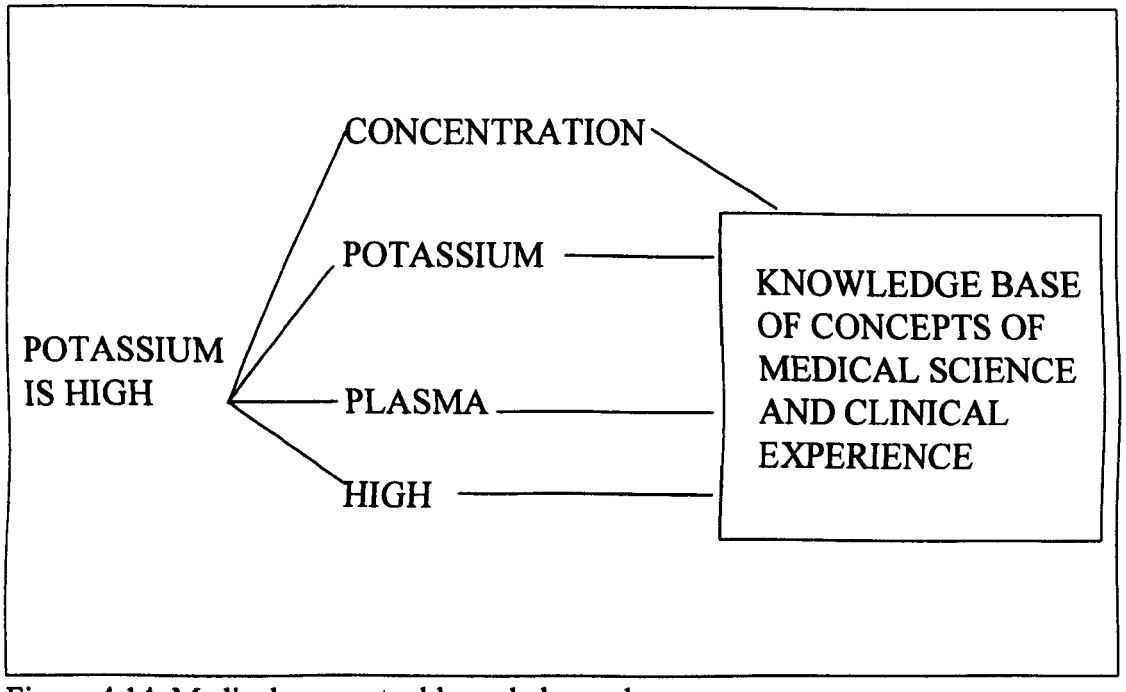


Figure 4.14 Medical conceptual knowledge web

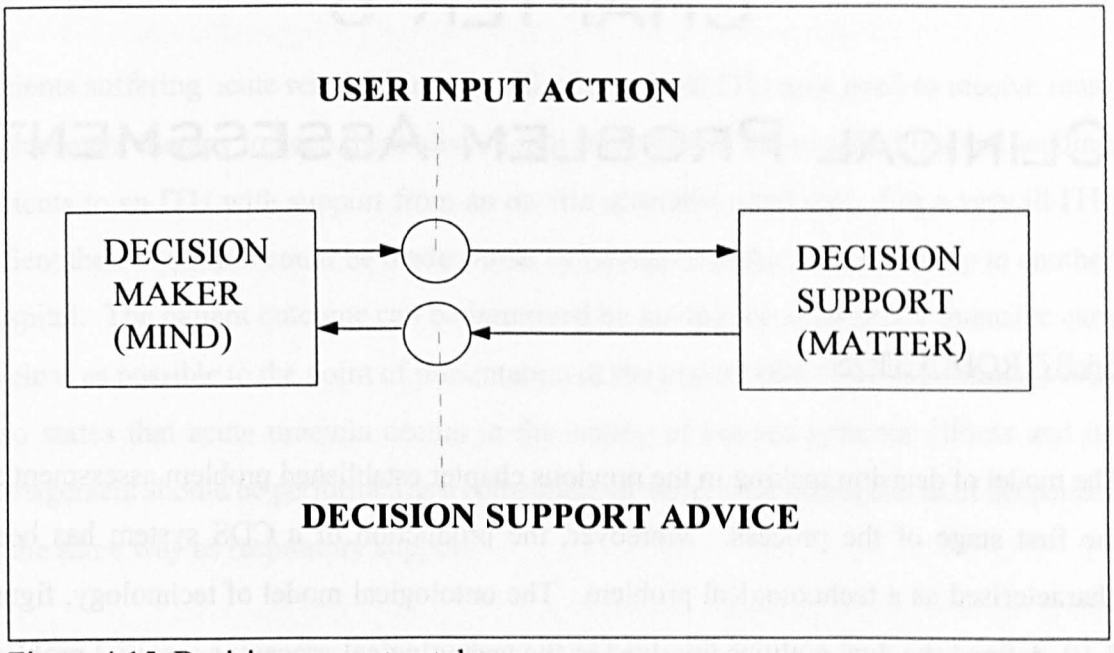


Figure 4.15 Decision support ontology

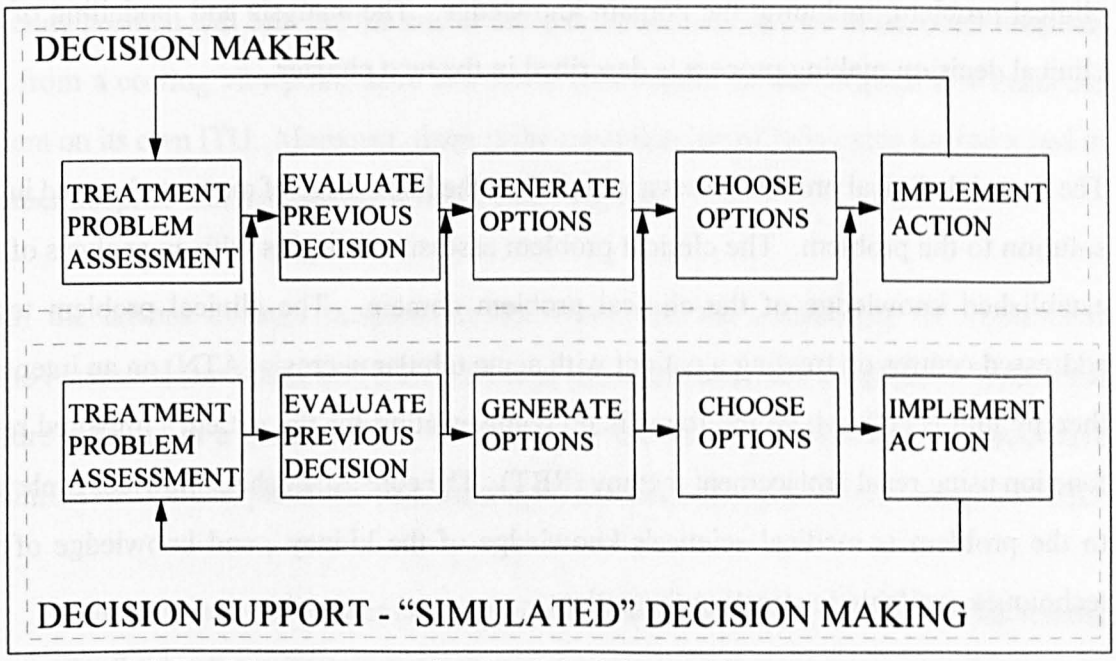


Figure 4.16 Decision support - simulated decision making

CHAPTER 5

CLINICAL PROBLEM ASSESSMENT

5.1 INTRODUCTION

The model of decision making in the previous chapter established problem assessment as the first stage of the process. Moreover, the production of a CDS system has been characterised as a technological problem. The ontological model of technology, figure 3.10, defined the dual realities involved in the technological process: a material problem and artifact in matter, and abstraction of the problem and artifact in the mind. Thus the first stage of the technological process is a representation of the material problem to be solved. Therefore, when building a CDS system there needs to be an analysis and modelling of the material clinical problem, followed by an analysis and modelling of the clinical decision making process to be supported. The aim of this chapter is to present an analysis of the clinical problem, including the domain knowledge. The analysis and modelling of the clinical decision making process is described in the next chapter.

The material clinical problem assessment defines the knowledge of matter to be used in the solution to the problem. The clinical problem assessment begins with an analysis of the established knowledge of the clinical problem domain. The clinical problem to be addressed centres on treating a patient with acute tubular necrosis (ATN) on an intensive therapy unit (ITU), where the focus is on compensating for the patient's impaired renal function using renal replacement therapy (RRT). The core established knowledge relevant to the problem is medical science's knowledge of the kidney , and knowledge of the techniques available for treating the patient.

5.2 CLINICAL PROBLEM ANALYSIS

Patients suffering acute renal failure on a district general ITU may need to receive renal replacement therapy to keep them alive. Until recently this has usually involved sending patients to an ITU with support from an on-site specialist renal unit. For a very ill ITU patient their condition could be made worse by having to make such a journey to another hospital. The patient outcome can be improved by having the appropriate intensive care as close as possible to the point of presentation of the patient (Short, 1993). Short (1993) also states that acute uraemia occurs in the setting of serious systemic illness and its management should be performed as a component of the general management of the patient in the same way as respiratory support.

The current situation in the NHS, where each hospital is a provider in the health care market place, has raised the importance of cost control in each of the hospital trusts. This pressure has been felt particularly by ITU, as high expenditure is needed to keep them operational. If the resources are available to treat the ITU patients in house, then only the marginal cost of their renal replacement treatment will be borne from having to treat their renal failure. However, if the patient has to be referred to another hospital, then the referring hospital will bear the full cost of the patient's intensive care at the other hospital. So, from a costing viewpoint there is a lower cost impact on the hospital if it treats the patient on its own ITU. Moreover, there is the complication of being able to find a bed in another hospital that has specialist nephrology support.

With the advent of trust hospitals in the NHS and the availability of Continuous VenoVenous HaemoDialysis (CVVHD) it is now desirable and possible to treat renal failure patients in a general ITU. Clinicians at the Mayday University Hospital have identified two clinical problems with treating renal failure on a general ITU using CVVHD:

i) A large volume of fluid is exchanged in patients undergoing CVVHD. Maintaining the fluid balance in these patients requires accurate fluid balance calculations. At present there is scope for inconsistencies in the fluid balance calculations. This need was also expressed in Groth and Collinson (1993).

ii) An expert with experience in managing fluid and electrolyte balance will not be available 24 hours a day to offer advice to staff operating the CVVHD.

The initial aim of this chapter is to present the clinical knowledge which defines the concepts used to describe the analysis of the clinical problems above. Familiarity with these concepts is necessary to understand the terms used by, and the problems faced, by the clinicians. The conceptual knowledge represents the prior knowledge used to interpret the observed phenomena and fit the observations into a preconceived construct of ideas. Therefore a CDS system needs to use the same concepts which are used by the clinician. Building on the core conceptual knowledge the second aim of this chapter is to describe the results of the systems analysis of the material clinical problem in the ITU at the Mayday University Hospital. The objective of the systems analysis is to establish a model representing the fluid and biochemical flows into and out of the ARF patient. These two main aims are broken down into a series of objectives:

i) To present the conceptual domain knowledge which describes renal failure in terms of physiology and pathophysiology.

ii) To describe the treatments modalities used for treating renal failure in the ITU.

iii) To describe the clinical problem of managing ARF in the ITU at the Mayday University Hospital.

iv) To give a description of the use of continuous venovenous haemodialysis in the ITU at the Mayday University Hospital.

The knowledge covered in objectives one and two represents the most firmly established conceptual knowledge, and includes the scientific medical knowledge at the foundation of nephrology. This foundation knowledge was used as a basis for understanding the clinical problem and for structuring the systems analysis. Moreover, the scientific basis of the foundation knowledge means it is the most reliable, or truthful, source of knowledge available in the domain.

The problem specific knowledge comes from a systems analysis of the clinical management of CVVHD in the Mayday University Hospital ITU. The concepts used in this analysis are consistent with the those used in the relevant classifications of medical science described below.

5.3 CLINICAL DOMAIN KNOWLEDGE

Domain conceptual knowledge represents the base level of the knowledge required when building a knowledge based decision support system. The domain conceptual knowledge, as in figure 3.6, defines the concepts used to interpret the observed material phenomena and actions. This is particularly applicable to a highly technical field such as medicine which has its own specialised vocabulary. Without a basic conceptual knowledge structure it is not be possible to analyse the clinical problem, or offer a solution, in terms used in the clinical domain. Such a deep level of understanding of the problem is fundamental to building an effective system (Heathfield and Wyatt, 1993). This is because the conceptual knowledge of the domain defines the foundation of the clinical world view. Moreover, the medical science domain knowledge presented here represents the most widely accepted knowledge relevant to the clinical decision making process. Thus, it can be used to judge the coherence and the validity of the more contentious, elicited, clinical knowledge used in the treatment decision making.

Taking scientific knowledge as the start point is assenting to the mechanistic material view of medicine described in chapter 3. One impact of this approach is to reduce the body to a set of interacting systems, for example the heart and lungs. The kidneys are abstracted as one of these interacting systems, and the corresponding medical specialism is nephrology.

The clinical problem domain is essentially that of a nephrologist working in the high dependency environment, making clinical decisions on patient care. Nephrology is the specialism in medicine concerned with the anatomy, physiology and pathology of the kidneys. Therefore, knowledge of kidney physiology and pathophysiology is foundation knowledge for the problem analysis and clinical decision making. Scientific knowledge

of the kidneys in the normal and abnormal state is the most reliable source of domain knowledge available. Therefore using this knowledge as a start point is the best way to begin to understand the problem domain.

5.3.1 The Kidney

This section first gives a description of the concepts used to define the kidney and its renal function, followed by a description of the aspects of the body's physiology affected by the renal function. The knowledge contained in this section forms the foundation of the knowledge used in the problem analysis and the clinical decision making. In particular this section offers an understanding of how the body's systems function normally, and how potentially fatal changes in their function can be compensated for in renal repalcement therapies.

5.3.1.1 Anatomy of the kidney

The two kidneys are situated at the back of the abdomen behind the peritoneum, on either side of the vertebral column. Each adult kidney is approximately 11 cm long, 6 cm wide, 3 cm thick, and weighs approximately 145 g. The kidney produces urine which flows via the ureter into the bladder. This acts as a reservoir for the urine. The arrangement of the kidneys in relation to the bladder, abdominal aorta and inferior vena cava is shown in figure 5.1.

The two main regions of the kidney are the cortex and the medulla, (figure 5.2). The cortex is the outer region of the kidney and is dark in colour due to its highly vascular nature. The medulla is the paler inner region of the kidney, and is divided into a number of renal pyramids. The apex of each pyramid is known as the papilla.

5.3.1.2 Kidney blood supply

The kidneys receive just over 20%, approximately 1.1 l min^{-1}, of the cardiac output (Lote, 1982). In terms of the blood flow per unit tissue mass this is almost equivalent to ten times

the coronary blood flow. Such a high blood flow helps to sustain the plasma filtration rate of approximately 125 ml min^{-1} (20% of renal plasma flow rate) at the glomeruli of the kidney.

Blood is supplied via the renal artery from the abdominal aorta. The blood leaving the kidney drains into the inferior vena cava via the renal vein. The physical layout of the renal artery system is shown in figure 5.3. The renal artery branches out into several interlobar arteries. These feed into the arcuate arteries, which pass along the boundary between the cortex and the medulla. The interlobular arteries come off of the arcuate arteries at 90° flowing towards the outer surface of the kidney. The interlobular arteries divide out into the afferent arterioles. These then flow into the glomerular capillaries of the nephron.

A flow chart representing the flow of fluids through the kidney is shown in figure 5.4. After passing through the Bowman's capsule of the nephron the glomerular capillaries merge and flow into the efferent arteriole. The efferent arteriole is an example of a portal vessel as it carries blood from one capillary network to another. The capillary network that it flows into is the network flowing around the nephrons. There are two classifications of capillary network in the kidney:

i) The peritubular capillaries which surround the cortical elements of the nephron. The efferent arteriole in the outer two thirds of the cortex feed into this type of network.

ii) The vasa recta capillaries; these follow a hairpin course into and out of the medulla, where they flow around the juxtamedullary loops of Henle and the collecting tubules. The efferent arterioles in the inner third of the cortex form some peritubular and some vasa recta capillaries.

The capillaries surrounding the nephron drain into the renal vein via the interlobular, acurate and interlobar veins.

5.3.1.3 Regulation of blood flow through the glomerulus

Over an approximate range of mean perfusion pressures of 90 to 200 mmHg the blood flow into the glomerulus is constant at approximately 1.1 l min^{-1} (figure 5.5); this constant flow is due to the ability of the afferent and efferent arteriole to vasoconstrict.

At a nominal mean arterial pressure of 100 mmHg the afferent and efferent arteriole are unconstricted. If there is an increase in arterial blood pressure the afferent arteriole constricts thus reducing the blood flow to the glomerular capillaries. Upon a fall in blood pressure the efferent arteriole constricts and the afferent arteriole remains relaxed, thereby increasing the blood flow. Therefore, the blood flow through the glomerular capillaries is kept constant over a range of blood pressures.

Below a mean blood pressure of approximately 90 mmHg the glomerular blood flow decreases swiftly, so a low blood pressure causes perfusion problems in the glomerulus. Above 200 mmHg the glomerular blood flow increases, but less rapidly than it decreases below 90 mmHg.

5.3.1.4 Renal function

The kidney plays a central role in the regulation of the cellular environment of the body. The renal function is summarised in figure 5.6. A more detailed description of these functions is given below:

i) The kidney excretes waste products of metabolism by a combination of ultrafiltration and secretion.

ii) The blood pH is regulated by the control of the plasma concentration of free hydrogen ions.

iii) The effective circulating fluid volume is regulated by responding to control signals from the sympathetic nervous system and the hormone control system.

iv) Regulation of plasma osmolarity is achieved through the response of the hypothalamus to changes in the plasma osmolarity.

v) Control of plasma electrolyte levels is effected by the processes of ultrafiltration, secretion and reabsorption. Thus, the kidney exerts indirect control over the level of electrolytes in the other fluid compartments of the body.

vi) Regulation of the red blood cell mass is achieved by the excretion of erythropoietin which acts in the stem cells of the bone marrow, stimulating red blood cell production.

When the kidneys fail it is the loss of these functions which need to be compensated for by treatment. The operation of haemodialysis acts to compensate for the loss of functions (i) to (v). Functions (ii) to (v) will be discussed in more detail in later sections. This section will continue with a description of the operation of the functional units of the kidney.

5.3.1.5 The nephron

The central functional unit of the kidney is the nephron. The kidney produces urine by the interaction of the nephron with the renal capillaries, interstitial fluid space of the kidney, and the collecting tubules (figure 5.7).

Each kidney contains approximately one million nephrons. All nephrons have the following constituents, illustrated in figure 5.8: glomerular capillaries; Bowman's capsule; proximal tubule; the loop of Henle, and the distal tubule. However, there are two different classifications of nephron, figure 5.9: cortical nephrons, and juxtamedullary nephrons. In each kidney approximately 85% (850,000) of the nephrons are cortical nephrons with the remaining 15% (150,000) being juxtamedullary. The cortical nephrons have short loops of Henle and lie almost entirely in the cortex, whilst the juxtamedullary nephrons have long loops of henle which go deep down into the medulla. This physical difference between the nephrons means that their loops of Henle perform differently. However, the other parts of both types of nephron perform the same functions.

5.3.1.6 Nephron function

The glomerular capillaries carry the blood into the blind ended Bowman's capsule. Approximately 11% of the blood volume in the capillaries is filtered into the capsule. Which constituents of blood pass through the glomerular membrane is mainly determined by their molecular weight. Generally filtration of molecules with a molecular weight above 70,000 is insignificant. Blood cells, platelets and plasma proteins have a molecular weight greater than 70,000. Substances with a molecular weight less than 7,000 pass through the glomerular membrane virtually unimpeded. The closer the molecular weight is to 70,000 the smaller the proportion of substance in the filtrate (figure 5.10). So the substances in the filtrate include water, inorganic salts, food substances and waste products such as creatinine.

The rate of flow of filtrate into Bowman's capsule, the Glomerular Filtration Rate (GFR), is typically 180 l day^{-1}. However, the volume of urine per day is of the order of 1.5 l. Therefore, most of the glomerular filtrate is reabsorbed into the blood.

The proximal tubule plays an important role in the reabsorption of fluid. Approximately 70% of the fluid (126 l day^{-1}) in the filtrate is reabsorbed into the peritubular capillaries. The high percentage of fluid reabsorption is mainly due to 70% of the sodium ions being reabsorbed. This sets up an osmotic gradient across the tubule boundary across which water flows.

The proximal tubule also reabsorbs 80% of the potassium ions, 70% of the calcium ions, and 90% of bicarbonate and phosphate ions. In addition, all of the glucose and amino acids are reabsorbed in the proximal tubule.

As indicated above the differences between the cortical and juxtamedullary nephrons are the different lengths of the loop of Henle and the structure of the capillaries around the loops. These differences are the reason why only the juxtamedullary nephrons, 15% of nephrons, play a significant role in concentrating the urine. Concentration of the urine is achieved by the creation of a hyperosmotic environment in the renal medulla.

The creation and maintenance of the hyperosmotic renal medulla can be analysed as shown in figure 5.11. The difference between the factors increasing the osmolarity (system inputs) and factors decreasing the osmolarity (system outputs) determines the osmolarity of the medulla.

The factors increasing the osmolarity of the medulla are:

i) The counter current multiplier effect in the loop of Henle.

ii) The passive diffusion of urea from the collecting tubule into the medulla interstitium and the loop of Henle.

The factors decreasing, or limiting, the osmolarity are:

i) Blood flow through the vasa recta capillaries.

ii) The volume of water entering the medulla.

iii) The diffusion along the length of longitudinally the medulla interstitium.

The counter current multiplier effect in the loop of Henle is illustrated in figure 5.12. The process is driven by the ascending limb, where chloride ions are actively transported into the interstitium and sodium ions passively follow. The ascending limb is relatively impermeable to water when compared to the descending limb. Therefore, more water flows out of the descending limb, up the osmotic gradient created by the movement of sodium ions. So, the osmolarity of the descending limb is higher at the bottom than at the top, whilst the osmolarity of the ascending limb is lowest at the top, figure 5.12.

Half of the peak osmolarity, 1400 mosm l^{-1}, in the renal medulla is due to sodium ions and the remainder is related to the urea concentration. In the presence of anti-diuretic hormone (ADH) the medullary collecting tubule is permeable to urea, thus it escapes into the interstitium of the medulla. From the interstitium it enters the loop of Henle which

increases the osmolarity of the medulla interstitium and the loop of Henle. When ADH is not present then the osmolarity of the medulla is lower as urea is not able to escape into the interstitium.

The vasa recta capillaries have two important characteristics which help to maintain the hyperosmotic environment of the renal medulla. These are:

i) The low blood flow through a hairpin capillary network. They receive 1 to 2%, 11 to 22 ml min^{-1}, of the total renal blood flow.

ii) The counter current exchange in the capillaries of solutes and water maintains the osmolarity of the medulla.

However, some of the solute is removed from the medulla by the vasa recta. If no solute was removed there might be no limit to the counter current multiplication effect in the loop of Henle. Other factors which limit, or decrease, the osmolarity of the interstitium are water entering the interstitium from the collecting tubule and the descending limb., and the diffusion of solutes longitudinally in the interstitium.

The term distal tubule is a purely anatomical description for where the thick ascending limb of the loop of Henle joins the cortical collecting tubules. Functionally it is the same as the thick ascending limb.

The collecting tubules are not strictly speaking part of the nephron, although they do play an important part in their function. Each collecting tubule receives approximately six nephrons in the cortex of the kidney. In the medulla the tubules join together in successive pairings to form a duct of Bellini at the papilla. The collecting tubules are involved in the control of the plasma volume, plasma osmolarity, plasma electrolyte concentrations and the acid base balance.

5.3.1.7 Glomerular filtration rate

Glomerular filtration rate (GFR) is an important parameter of renal function, especially in determining the severity of renal failure in clinical practice. The GFR is the rate at which the kidneys filter plasma and is typically 125 ml l^{-1}.

GFR can be estimated by measuring the plasma clearance rate of a substance that is filtered in the nephron, but not reabsorbed, secreted, synthesised or metabolised. Plasma clearance is only a conceptual measure, as the diffusion of solutes would prevent any volume of plasma from being completely cleared. The concept of plasma clearance assumes that a certain volume of plasma is completely cleared of the solute, and the remainder has the same concentration as when it entered the kidney. Therefore, the clearance is a measure of how effective the kidney is at removing substances from extracellular fluid (ECF). The formula used to calculate the clearance of a substance from plasma is:

$$C_y = \frac{U_y \times V}{P_y} \qquad (5.1)$$

where, C_y = clearance of substance y (ml min^{-1})

U_y = amount of substance y in urine (mg ml^{-1})

V = urine flow (ml min^{-1})

P_y = concentration of substance y in plasma (mg ml^{-1})

If a substance is only filtered in the kidney, then the steady state clearance of the substance will be equal to the steady state GFR. Only the steady state values can be considered as transient changes in GFR cannot be detected by changes in urine concentration.

Clinically GFR, or kidney function, is estimated from the creatinine clearance. Creatinine clearance is used as creatinine is freely filtered and not reabsorbed, synthesised or metabolised by the kidney. Although, creatinine is secreted to some extent in the proximal tubule, this does not detract from its use in giving an indication of GFR.

5.3.1.8 Hormonal control of renal function

There are four main hormones that affect the renal function. Their source and affect on renal function are summarised below:

i) Anti-diuretic hormone (ADH) is excreted from the posterior pituitary gland. ADH increases the permeability of the collecting tubule walls to water and urea, thus promoting water retention.

ii) Aldosterone is secreted from the adrenal cortex. It stimulates the reabsorption of sodium and the secretion of potassium in the collecting tubule.

iii) Atrial natriuretic peptide (ANP) is released from the walls of the cardiac atria. ANP causes increased renal loss of sodium by decreasing reabsorption of sodium.

iv) Parathyroid hormone (PTH) originates from the parathyroid gland. There are two affects on renal function: increased calcium reabsorption in the distal tubule, and decreased phosphate reabsorption in the proximal tubule.

The control processes involving these hormones are described further in later sections.

5.3.2 Kidney Control of Body Physiology

This section aims to give the physiological knowledge of the normally functioning individual, and the role the kidney plays in controlling the body's physiology. The control exerted by the kidney over the body's physiology is described by its renal function. It is these functions which have to be compensated for when the renal function diminishes or ceases. The treatment used for the replacement of renal function is generally haemodialysis. Haemodialysis changes the patient's fluid, electrolyte and acid-base balance, in addition to removing waste catabolites. Thus, an introduction to the physiology of the body's fluids, electrolytes, acid-base balance and metabolic processes is given here.

5.3.2.1 Fluid physiology

Water is the main constituent of the body. Total body water (TBW) varies with age and sex over the range of 45 to 60% of body weight. For an average 70 kg man around 60% of the body weight (42 litres) is water, while for a woman it is approximately 52% of body weight. The total body water is divided into two main compartments:

i) The intracellular fluid (ICF) is all the fluid in the cells of the body, including the blood cells. The ICF compartment contains two thirds of the total body water, 28 litres in the average man.

ii) The extracellular fluid (ECF) is all the other fluid in the body, including the fluid between the cells and the remaining fluid in the vessels of the body. One third of the total body water (14 litres) is in this compartment.

The ECF compartment splits down into the plasma compartment, 9.5% of TBW, and the interstitial fluid, 23.8% of TBW. An illustration of the connection between the different fluid compartments is shown in figure 5.13.

5.3.2.2 Effective circulating volume

The effective circulating volume refers to that part of the body fluid contained within the vascular space which is effectively perfusing the tissues. Effective perfusion involves blood flow through the capillaries as this allows exchange of nutrients, gases and metabolites between tissues and blood. Effective circulating volume is a concept related to blood and ECF volume, but it may vary independently of them.

Changes in effective circulating volume are indirectly detected by stretch receptors: in the renal afferent arteriole; the arterial baroreceptors, and right atrium.

Decreased stretch of the afferent arteriole in the kidneys causes the secretion of renin from cells in the arteriole. Renin acts on the plasma substance angiotensin to form angiotensin

I which is converted angiotensin II in the lungs. Angiotensin II has several actions:

i) Causes aldosterone release from the adrenal cortex

ii) Directly stimulates sodium and water reabsorption in the renal tubule

iii) Acts as a potent vasoconstrictor

iv) Enhances the sensitivity of blood vessels to noradrenaline

v) Stimulates thirst

Figure 5.14 includes an illustration of the renal response to hypotension. The arterial baroreceptors detect changes in arterial blood pressure and by interaction with the sympathetic nervous system bring about rapid changes in cardiac output and peripheral resistance. A fall in blood pressure causes vasoconstriction which shunts blood flow from the skin, gut and kidneys towards the heart, lungs and brain. In addition an increase in the heart beat, tachycardia, is caused by the arterial baroreceptor response to a fall in blood pressure. The vasoconstrictive response can be initiated in seconds and persist for hours. The longer term responses, hours to days, involve the hormonal control system of the body. Over a longer period of time the arterial baroreceptor's activity can influence the release of the anti-diuretic hormone (ADH) from the pituitary gland.

The stretch receptors in the right atrium also influence the release of ADH. A fall in the filling, caused by the blood pressure decreasing, increases the release of ADH. An increase in the filling of the atrium leads to a decrease in ADH release. Atrial natriuretic hormone (ANH) is also released in response to changes in atrial filling. ANH causes increased renal loss of sodium by decreasing the sodium reabsorption, thus it counteracts the action of aldosterone.

5.3.2.3 Osmolarity

The osmolarity of a solution is determined by the number of particles per unit volume of solvent, i.e. the sum of all the solute concentrations in the solution.

Osmolarity is measured in osmoles per litre of water, where the relationship between osmoles and moles is expressed as:

$$\text{osmole} = \text{no. of moles} \times n \tag{5.2}$$

where n= number of particles each mole dissociates into.

For example, the number of osmoles in a solution containing 1 mmole of sodium chloride is 1.75 mosmoles. This is because sodium chloride dissociates into sodium and chloride ions, but the dissociation is only 75% complete. Osmolarity is expressed in osmoles per litre of water, whilst osmolality is expressed in osmoles per kilogram of water. In practice there is very little difference between these two as the density of water is approximately 1 kg l^{-1}.

5.3.2.4 Osmotic pressure

If two solutions of different concentrations (osmolarity) are separated by a semi-permeable membrane, which is permeable to water but not to the solute, then there will be a net movement of water across the membrane. The movement of water generates an osmotic pressure which can raise the level of the more concentrated solution above the level of the less concentrated solution.

It is important to note that an osmotic pressure will only exist if the membrane is impermeable to the solute. In such a solution the solute is called an effective osmole. If the solute can easily cross the membrane it is an ineffective osmole.

5.3.2.5 Plasma osmolarity

Water can rapidly cross the cell membranes between the ICF and the ECF compartments. Therefore, in any given tissue osmotic equilibrium will be reached within seconds of any disturbance of osmolarity, in the ECF or the ICF, of the tissue. However, this localised rapid transfer of water does not mean that complete equilibration occurs between the ECF and the ICF throughout the whole body within this same time period. The reason for this is that fluid normally enters the body through the gut and must then be transported by the blood to all the tissues in the body before complete equilibration occurs. In the normal person it can take as long as 30 minutes to achieve equilibration throughout the body after drinking water. After allowing for such an ingestion time it is reasonable to use the osmolarity of the plasma as a measure of the osmolarity of all the fluid compartments in the body.

The major osmole in plasma is sodium, and for a healthy individual the plasma osmolarity is roughly twice the sodium concentration. This is supported by comparing the normal osmolarity of plasma, which is in the range 280 to 290 mosmol l^{-1}, with the typical sodium concentration in plasma, 142 mmol l^{-1}.

5.3.2.6 Regulation of plasma osmolarity

The ratio of total body water to total body sodium determines the osmolarity of plasma, since sodium is the major osmole in the body. In the body it is the balance between water intake and water loss that determines its osmolarity, rather than changes in the sodium balance. Over a period of time the water intake must balance the loss if the plasma osmolarity is to remain within normal limits.

Osmoreceptors in the hypothalamus sense plasma osmolarity, and regulate thirst and ADH secretion, as shown in figure 5.15. A rise in osmolarity of the plasma stimulates the release of ADH, thereby causing water retention in the kidney and a reduction in osmolarity.

When there is a combination of hypovolaemia and hypo-osmolarity, conflicting signals are

sent to the ADH mechanism in the pituitary gland. In this situation it is the hypovolaemia that takes precedence, and water retention occurs in response to increased ADH secretion. So, the pressure sensors of the body and the osmolarity sensors both operate to help maintain the fluid balance in the body.

5.3.2.7 Electrolyte physiology

An electrolyte is defined as a compound which when in solution dissociates into positively charged cations and negatively charged anions (Eccles, 1993). The body fluids contain a mixture of cations, anions and solutes such as glucose and urea. Despite the complexity of the body fluids, the electrical charges on the cations and ions always balance. In the ICF the major cations are potassium, calcium and magnesium; the major anions are phosphate and negatively charged proteins. Potassium is the most abundant cation in the ICF. The main cation in the ECF is sodium, and the major anions are chloride and bicarbonate.

5.3.2.8 Potassium balance

The majority of the body's potassium is in the ICF compartment, 150 meq l^{-1}, with only a small quantity in the ECF compartment, 4 meq l^{-1}. The large difference in concentrations is maintained by the active pumping of potassium into the cells in exchange for sodium.

Potassium continuously diffuses down a concentration gradient out of the cell. This creates a resting cell membrane potential of -70 to -90 mV (Eccles, 1993). Changes in the ECF concentration change the cell membrane potential, which can lead to decreased excitability of the cells. Therefore, changes in the plasma concentration of potassium cause changes in the activity of excitable tissues such as nerve and cardiac muscle, with symptoms such as muscle weakness and cardiac arhythmias.

Factors influencing the plasma concentration of potassium are illustrated in figure 5.16. There is an intracellular balance between potassium and hydrogen. An increase in the ECF hydrogen ion content, acidaemia, causes more hydrogen to enter the cell and displace the potassium. Thus, acidaemia can be accompanied by hyperkalaemia .

In normal renal function potassium is readily excreted by the kidneys. The potassium balance in the body is regulated by secretion in the collecting tubules. Renal secretion is influenced by two factors:

i) Aldosterone secretion from the adrenal cortex.

ii) Plasma concentration of potassium, and exchange with the ICF compartment.

If renal function is viable, hyperkalaemia is unlikely to develop. However, in renal failure hyperkalaemia can quickly result. Hyperkalaemia can be defined as a plasma concentration greater than the upper laboratory limit; this is typically 5.5 meq l^{-1}. Cardiac abnormalities may be apparent once the plasma concentration exceeds 6 meq l^{-1}, and muscle weakness occurs above 8 meq l^{-1}.

5.3.2.9 Other intracellular cations

Phosphate, calcium, and magnesium are found mainly within bone and the ICF. Despite being small, the ECF concentration of these ions has a marked effect on the excitability of the neuromuscular system. The relative concentrations of the three ions is a balance between intestinal and renal excretion. Absorption and excretion are regulated by the parathyroid hormone (PTH) and the active metabolites of vitamin D.

Within the body phosphate occurs in the form of PO_4. Normally the majority of phosphate, 85%, is in the bone, with approximately 14.0% in the intracellular compartment, and only 0.02% in plasma. The normal balance of phosphate, or homeostasis, is determined by the absorption of phosphate across the intestine and renal excretion of phosphate. The kidneys are the main regulator of plasma phosphate concentration. The renal threshold for phosphate excretion is close to the normal plasma concentration, and in normal conditions any increase in phosphate concentration is rapidly followed by an urinary excretion. Thus for a patient suffering kidney failure their plasma phosphate levels will rise.

Hyperphosphataemia can be defined as plasma phosphate concentrations above 1.35

mmol/l (Willatts, 1987). Acute hyperphosphataemia can cause hypocalcaemia by reducing the availability of ionised calcium in plasma. Hypocalcaemia is only a risk with acute hyperphosphataemia as parathyroid hormone secretion restores plasma [Ca^{++}] in chronic hyperphosphataemia.

Ninety-nine per cent of calcium is found in bone, 0.9% is in the intracellular compartment and approximately 0.1% is in extracellular fluid. Only half of the plasma concentration of calcium exists as physiologically active free calcium, [Ca^{++}], ions. The remainder is bound to proteins or other anions. The availability of calcium ions is reduced by the presence of bicarbonate and phosphate, and increased by the presence of free hydrogen ions. For the normal adult the excretion of calcium from the kidneys balances the absorption across the intestine. Plasma calcium ion concentration is regulated by parathyroid hormone secretion which controls renal, intestinal and bone mechanisms.

Hypocalcaemia occurs when the total plasma Ca is less than 2.20 mmol/l. This can be caused by renal failure and be a life threatening emergency as the increased excitability of the neuromuscular system can lead to tetanic seizures and respiratory arrest. In milder cases there may be parasthesias and hyperreflexia. Hypocalcaemia predisposes to cardiac arrhythmia.

Magnesium is found mainly in bones and the intracellular compartment. Less than 1% is found in the extracellular compartment. Free magnesium ions in plasma influence neuromuscular excitability. Hypermagnesaemia, above 0.9 mmol/l, can occur during renal failure, and it depresses the activity of cardiac and skeletal muscle.

5.3.2.10 Acid-base physiology

An acid is a substance that can donate hydrogen ions, protons, and a base is an acceptor of hydrogen ions. The regulation of the concentration of hydrogen ions within and around the cells is vital for survival. All of the proteins of the body are influenced by hydrogen ion concentration and the rate of any enzymatic reaction can be disrupted by changes in the hydrogen ion concentration. Furthermore, the plasma concentration of hydrogen ions

affects the distribution and state of ionisation of electrolytes such as potassium and calcium. Therefore, disturbances in hydrogen ion concentration can cause serious electrolyte disorders.

The pH of the body can be expressed in terms of blood concentration of the free hydrogen ions, the normal body pH being around 7.4:

$$pH = \log \frac{1}{[H^+]} \tag{5.3}$$

Note that pH measures only the concentration of free hydrogen ions and buffered ions are not included. Buffering of the hydrogen ions effectively stabilises the concentration of free ions, and the buffer systems in the body play an extremely important role in controlling the free ion concentration around the cells.

The main source of hydrogen ions is the body's metabolism. There are two types of acid generated by the metabolism:

i) Carbonic acid. The carbon dioxide from the metabolising tissues is hydrated in the red blood cells to form carbonic acid (H_2CO_3). This carbonic acid then dissociates into hydrogen and bicarbonate ions.

ii) Non-carbonic acids (H^+A^-) are also produced from the cellular metabolism. Examples of these are mineral acids, such as sulphuric acid, and organic acids, for example lactic acid.

The hydration of carbon dioxide is described by the following chemical equation:

$$CO_2 + H_2O \rightleftharpoons H_2CO_3 \rightleftharpoons H^+ + HCO_3^- \tag{5.4}$$

The daily production of carbonic acid is in the region of 11 eq and the daily production of non-carbonic acids is in the range 50 to 100 meq. There is only approximately 40 nanoeq l^{-1} of free hydrogen ions in the blood. Therefore, most of the hydrogen ions produced in the body are buffered by a base.

The carbonic and the non-carbonic acids are buffered on different buffers and excreted by different mechanisms. The hydrogen ions from the carbonic acid are buffered in the blood cells by haemoglobin. In the lungs the hydrogen ions are liberated by the oxygenation of the haemoglobin. The freed hydrogen ions combine with bicarbonate ions and form carbon dioxide as shown in the above chemical equation, and the carbon dioxide is discharged from the lungs upon expiration.

The non-carbonic acids do not have a gaseous form, therefore their excretion involves the kidneys. These acids are buffered on the bicarbonate ions in the interstitial fluid. As shown in the chemical equation below the bicarbonate is consumed during the buffering process.

$$H^+A^- + Na^+HCO_3^- \rightleftharpoons Na^+A^- + CO_2 + H_2O \qquad (5.5)$$

The carbon dioxide generated on the neutralisation of the acid is lost via the lungs. The sodium salt is transported in the blood and filtered by kidneys into the renal tubule, figure 5.17. The acid (HA) is effectively regenerated in the renal tubule, where the hydrogen ions are buffered on urinary buffers. Whilst the acid is excreted, the bicarbonate ions are reabsorbed into the blood, as are the sodium ions.

5.3.2.11 Maintenance of blood pH

There are several different buffer systems in the body. In such a mixture if the pH of one buffer system is fixed, or controlled, all the other buffer systems in the body will equilibrate around this pH. The controlled buffer system in the body is the carbonic acid-bicarbonate system, which responds to changes in the blood pH.

The pH of a buffer system is determined by the relative concentrations of the anion and the weak acid. In the carbonic acid-bicarbonate system the concentration of the carbonic acid is directly proportional to the partial pressure of carbon dioxide. The equation describing the relationship between the pH and the relative concentrations is the Henderson-Hasselbach equation:

$$pH = pK + \log \frac{[HCO_3]}{pCO_2 \times 0.03} \qquad (5.6)$$

where, pK = constant = 6.1 for the carbonic acid-bicarbonate system.

In this equation the bicarbonate plasma concentration is controlled by the renal system and the partial pressure of the carbon dioxide is controlled by the respiratory system.

5.3.2.12 Disturbances in acid-base balance

Acid-base balance can best be described by plotting a graph of bicarbonate concentration against blood pH (figure 5.18). Also plotted on this graph is the contour representing a pCO_2 of 40 mmHg, the normal level, and the body buffer line. The body buffer line describes the variation of bicarbonate with pH for whole blood, where the buffering action is mainly due to haemoglobin. The graph illustrates the following definitions of acid-base disturbances:

i) Respiratory acidosis is any point on the body buffer line where the pH is lower than 7.4 and the pCO_2 is greater than 40 mmHg.

ii) Respiratory alkalosis is any point on the body buffer line where the pH is higher than 7.4 and the pCO_2 is less than 40 mmHg.

iii) Metabolic acidosis is any point on the 40 mmHg contour where the pH is less than 7.4, and the bicarbonate concentration is less than 24 meq l^{-1} (24 mmol/l).

iv) Metabolic alkalosis is any point on the 40 mmHg contour where the pH is greater than 7.4 and the bicarbonate concentration is greater than 24 meq l^{-1}.

Points on the graph not on the lines described above represent a combination of acid-base disturbances. For example, point P on the graph represents a combination of respiratory acidosis and metabolic acidosis. Note that the pH can still be 7.4 despite there being an acid-base disturbance. The pH level of the blood is defined by the terms acidaemia, an arterial blood pH less than 7.4, and alkalaemia is a pH greater than 7.4.

In acute renal failure the most common disturbance in acid-base is metabolic acidosis, and as mentioned above this disturbance is often associated with hyperkalaemia.

5.3.2.13 Measurements of acid base balance

An arterial blood sample is used to measure pH, $PaCO_2$, HCO_3 and base excess. Normal values for each of these are in the range: for pH 7.36 to 7.44; $PaCO_2$ 35 to 42 mmHg; HCO_3 22 to 28 mmol/l, and base excess is -2.3 to +2.3 mmol/l (Willatts, 1987). Base excess is the base concentration of whole blood measured by titration against a strong acid to pH 7.40 at a $PaCO_2$ of 40 mmHg at 37°C. For negative values (base deficit) titration is performed against a strong base. It is an attempt to quantify the excess or deficit compared to normal of bicarbonate in the blood. Thus a positive base excess is equivalent to having an extra bicarbonate buffering capacity available, as in alkalosis, and a negative value is equivalent to not having enough bicarbonate buffer, as in acidosis.

In renal failure the kidney is unable to excrete excess hydrogen ions, thus metabolic acidosis occurs. The excess hydrogen ions are buffered on bicarbonate, causing the bicarbonate concentration to fall. Typical values indicating metabolic acidosis are: pH less than 7.36; $PaCO_2$ less than 35 mmHg, and HCO_3 less than 18 mmol/l (Willatts, 1987). This bicarbonate concentration represents a base excess of -6 mmol/l, taking the reference bicarbonate concentration to be 24 mmol/l.

5.3.2.14 Metabolic processes and uraemic toxicity

Metabolism is the sum of physical and chemical processes which control the internal environment of the body. The two constituents of metabolism are anabolism and catabolism. Catabolism relates to destructive chemical transformations by which energy is made available for the uses of the organism, whilst anabolism is the building of more complex chemicals in the body from simpler ingredients. It is the destructive catabolic process which result in the waste products which are secreted by the kidney, the theory being that some of these catabolites are poisonous to the body and so if not excreted their affects could be fatal.

Uraemic toxins produced in the body during uraemia have effects in the body similar to systemic poisoning (Vanholder et al., 1989). However, knowledge of exactly what these toxins are is not complete. So, two nitrogenous marker substances are taken as an indication of the levels of these toxins in the body and how well the kidneys are removing the toxins. These two substances are urea, from catabolism in the liver, and creatinine, from catabolism in the muscle tissue. The plasma concentration of both of these substances is measured to monitor the renal function of the patient during treatment. Moreover, the clearance rate of creatinine is used to calculate the glomerular filtration rate.

5.3.3 Pathophysiology of Acute Renal Failure

Patients suffering from acute renal failure (ARF) on an ITU will have at least one other organ in failure, such as the liver or lungs, which may even be the cause of the ARF. Patients with isolated ARF will ordinarily receive treatment in a renal unit. The mortality of patients in ARF, receiving renal replacement therapy, on an ITU is approximately 75% to 80%, mainly due to their underlying condition.

A broad definition of ARF is the abrupt cessation of renal function. It is perhaps more relevant to consider the pathophysiology of the condition. Generally the pathophysiology of ARF is classified into one of the following three categories: pre-renal; intra-renal, or Parenchymal, and post renal.

Post-renal ARF includes those conditions caused by an obstruction in the flow of the urine. The obstruction may result in anuria (<100ml/day urine), however this will not always be the case. Treatment of post-renal failure involves the location of the obstruction and its removal, possibly by ultrasonography.

Pre-renal ARF is the reversible disturbance of renal blood flow in response to fluid or haemodynamic derangements. It is most frequently caused by relative or absolute volume depletion resulting in a decrease in renal blood flow. The decreased renal blood flow will cause a fall in the glomerular hydrostatic pressure and thus the glomerular filtration rate decreases. A lower glomerular filtration rate means patients will often be oliguric (urine volume >100ml/day, but, <500ml/day). Early correction of the hypovolaemia by administration of colloid or crystalloid fluids quickly reverses the pre-renal failure. Treatment should be administered as early as possible to prevent the progression of pre-renal into intra-renal failure.

Intra-renal ARF is characterised by cell damage and tubular dysfunction in the nephrons. In hospitalised patients in whom reversible pre-renal and post-renal failure have been excluded, ARF is usually due to acute tubular necrosis (Schrier et al., 1990). Acute tubular necrosis (ATN) may be induced by renal ischaemia, such as prolonged pre-renal failure, or by toxic injury to the nephrons. Causes of toxic ATN are nephrotoxic drugs, or toxic microbial products, or inflammatory mediators in the circulation, or a combination of the preceding factors. Inflammatory mediators may be produced during septicaemia, septic shock or multi system organ failure (MSOF). Ischaemic ATN usually results in oliguria whilst toxic ATN can produce either oliguria or polyuria (urine >400ml/day). ATN is not immediately reversible on removal of the insult, but is normally a self limiting pathological process rarely persisting for more than four weeks. During the `self healing' process some form of renal replacement therapy, such as haemodialysis, to take over the excretory function of the kidneys is required.

5.3.4 Renal Replacement Therapy for Acute Renal Failure

Acute tubular necrosis (ATN) requires renal replacement therapy. Renal replacement

includes intermittent haemodialysis, where the patient receives treatment for approximately 4 hours every other day, or equivalent. The treatment operates at high flow rates, rapidly altering biochemical concentrations and fluid balance. The problem for the ITU patient is that these rapid changes cause large cardiovascular changes which put a large strain on their cardiovascular system. Thus, continuous renal replacement procedures are preferred to the intermittent process. Two of the continuous therapies used in the ITU are continuous haemofiltration and continuous haemodialysis. The vascular access for these can be either via an artery or a vein, with the return being into a vein. The vascular access is used to define the treatment, thus there is continuous aterio-venous haemodialysis and continuous veno-venous haemodialysis, a difference between the two being that veno-venous therapy requires a blood pump. Otherwise the function and operation of the two continuous therapies is similar. Descriptions of continuous veno-venous haemodialysis (CVVHD) and continuous veno-venous haemofiltration will be used as a basis for describing renal replacement in the ITU.

Continuous venovenous haemodialysis (CVVHD) is a renal replacement therapy where blood is pumped from the patient's venous system and returned to the venous system. A schematic representation of the procedure is given in figure 5.19. The treatment is administered continuously over a 24 hour period, providing there are no reasons for stoppages. The aims of dialysis are to remove unwanted solutes and excess fluid from the patient. Haemodialysis relies on two principles for the removal of solutes and fluid from the blood:

i) Diffusion, or conduction across the semi-permeable membrane. This relies on the concentration of a solute being higher on one side of the membrane than the other. The solutes to which the membrane is permeable will flow to the side of the membrane with the lower concentration.

ii) Ultrafiltration of water and convection of solutes across the semi-permeable membrane. Convection relies on there being a pressure difference across the membrane, the trans-membrane pressure (TMP). The pressure gradient will force water through the membrane and the water will drag through the solutes with it.

The TMP has a hydrostatic and an osmotic component.

These two processes mean that dialysis is an effective way of removing solutes and fluids. Haemofiltration relies solely on ultrafiltration which means it is not as effective at removing solutes from the blood. Haemofiltration may be used if the patient is in a severely fluid overloaded state and a lot of water has to be removed quickly. The process involves the filtration of the blood and the replacement of lost fluid into the blood, figure 5.20. A description of the application of both of these therapies in given in the systems analysis of the clinical problem below.

5.4 SYSTEMS ANALYSIS OF THE CLINICAL PROBLEM

The Mayday University Hospital is a district general hospital in the Croydon area, south of London. The hospital does not have its own specialist renal unit, therefore in the past it has had to send ARF patients requiring dialysis to St Helier Hospital, where there is a renal unit to support the ITU. To overcome this problem Dr S Morgan set up the operation of the CVVHD service at the Mayday, thus reducing the likelihood of having to transfer acutely ill patients. The problems of fluid data management and lack of constantly available expertise have been identified as two potential areas requiring support.

5.4.1 Intensive Therapy Unit

The Intensive Therapy Unit (ITU) is concerned with treating patients suffering acute failure of vital functions, whose underlying condition is potentially curable. When treating these patients the driving goals of the ITU are to support their failing vital functions and to prevent the development of further failures in vital functions. Vital functions include the renal system, central nervous system, respiration, cardiovascular functions, gastrointestinal function, endocrine system together with humoral and immune function. The two main classifications of ITU are:

i) A general ITU caring for a wide variety of patients, including those with a life threatening medical illness, multiple trauma following an emergency, in recovery

following major surgery, and those receiving treatment that requires intensive monitoring.

ii) A specialised ITU where a specific pathology is treated, for example a Coronary Care Unit (CCU), paediatric ITU, or neurological ITU.

The ITU at the Mayday University Hospital falls into the category of general ITU.

The nature of the patient conditions mean that the ITU has a high resource requirement. In terms of staffing the ratio of nurses to patient for the most severely ill patients is one to one. Even for the less ill patients the ratio is still normally one nurse to two patients. In addition to this, depending the size of the unit, a team of physicians led by a consultant will be required. The patients require intensive use of monitoring equipment whilst on the unit. So, there is a need for a lot of capital intensive monitoring equipment in an ITU. This high resource requirement makes treatment of ITU patients expensive, Gilbertson et al. (1991) calculated the average cost of treating a patient on the ITU for one day at £757. For dialysed patients suffering acute respiratory and renal failure this cost rose to £938 per day.

5.4.2 Patient Profile

The patient group for this project are ITU patients with two or more compromised organ functions, where the kidney is one of the organs in failure, and the patient is normally on a respirator. In addition to this, the renal function of the patient will be in ATN and require renal replacement therapy on the ITU. Only the adult ITU is being considered so the patient will be of adult proportions. Approximately thirty such patients a year are treated on the ITU at the Mayday University Hospital. Nationally the number is of the order of 50 patients per million population (Renal Association, 1991), in total approximately 2,900 patients per year.

5.4.3 Analysis of Patient Management in the Mayday ITU

The renal function essentially controls the fluid and biochemical balances of the body.

Therefore, the clinical problem is essentially one of controlling the fluid and biochemical inputs and outputs from the patient. The purpose of this section is to provide a systems analysis of the problem of managing the whole of the patient's fluids and biochemistry, with the intention of defining the material clinical problem by representing and analysing all of the flow elements affecting the patient. Thus the context of the operation of the renal replacement therapy will be defined.

A flow diagram representing a patient receiving renal replacement therapy in the ITU is shown in figure 5.21. Between each of the boxes in the diagram flows a volume of fluid and a quantity of biochemical substances. Each of the flows represents a factor which can potentially change the patients fluid balance and their biochemistry. A detailed description of the components of this flow analysis is given below.

5.4.3.1 Phases of treatment

The principal goal of the management of ATN is to sustain the life of the patient until they no longer need to receive dialysis therapy on the ITU. Achieving this goal is a two phase process; a resuscitation phase, followed by a recovery phase. The two most immediate threats to the life of the patient from ATN are fluid overload, leading to pulmonary oedema, and hyperkalaemia, leading to cardiac arrest. Therefore, the patient must first be supported through a resuscitation phase where the following two goals must be satisfied: removal of excess fluid from the patient ,and removal of excess potassium from the patient's serum.

After the resuscitation goals have been satisfied the patient goes into the "recovery" phase, where the goals are:

i) To maintain the patient in a state of fluid balance;

ii) To maintain the serum potassium levels around the optimum level;

iii) To treat any other electrolyte imbalances, particularly phosphate;

iv) To treat the acid-base imbalances, as acidosis is often associated with ATN,

v) To reduce the levels of urea and creatinine in the serum.

The main renal replacement therapies used to treat ATN at the Mayday ITU are continuous haemodialysis or haemofiltration.

5.4.3.2 Continuous venovenous haemodialysis

A schematic of the set up Continuous VenoVenous Haemodialysis (CVVHD) shown in figure 5.19. The equipment used in this set up on the ITU at the Mayday University Hospital is:

i) A Gambro BMM 10-1 blood monitor, which pumps the blood around the blood circuit and displays the blood flow rate and venous line pressure.

ii) A flat plate polyacrylonitrile (AN69-Biospal) dialyser where the dialysis occurs.

iii) A Gemini infusion pump, which controls the flow of the dialysate and displays the rate of infusion of the.

iv) The dialysate used is 5 litre bags of haemofiltration fluid.

v) The anticoagulant used in the circuit is heparin, or sometimes prostacyclin.

Figure 5.19 can be considered as two circuits: the blood circuit and the dialysate circuit. Firstly consider the blood circuit:

- Access to the patient's blood supply will be into a major vein, the subclavian, femoral or internal jugular, via a double lumen dialysis catheter.

- The saline solution, mixed with heparin, is used to prime the extracorporeal blood

circuit and to administer extra fluid to the patient when required.

- The blood pump takes blood out of the patient's vein at approximately 100ml min^{-1}. The rate of blood flow through the pump is indicated on a blood flow meter.

- The heparin pump delivers anticoagulant to the blood before it goes through the dialyser. The reasons for using the anticoagulant is to prolong the useful life of the filter and to prevent coagulation in the extracorporeal blood circuit.

- The dialyser consists of a semi-permeable membrane: on one side of the membrane flows the blood and on the other the dialysate. The blood flows through the dialyser in a counter current direction to the dialysate. This prevents undesired diffusion of solutes back into the blood. In the filter waste products and plasma water are removed from the blood. Solutes can also flow from the dialysate into the blood. This is used for the treatment of acidosis where acetate, lactate or bicarbonate diffuse from the dialysate into the blood.

- The bubble trap is there to prevent air getting into the patient's blood supply.

- The venous pressure sensor indicates the pressure in the return, or venous, line of the blood circuit.

Now consider the dialysate circuit:

- The Dialysate is delivered from two 5 litre bags of fluid. These bags are suspended above the infusion pump.

- The Gemini infusion pump is used to administer the dialysate at the prescribed rate. The rate of dialysate flow will vary between 1 to 2 litres per hour.

- The heater is used to heat up the dialysate to 37 degrees celsius, thus reducing the temperature gradient over the filter membrane.

- The dialysate travels along its own path through the filter in a counter current direction.

- The dialysate is collected in a waste bag and once an hour the volume is measured in a measuring cylinder. The waste bag is moved between the height of the dialyser and the floor to alter the TMP, thus altering the volume of fluid removed from the blood.

It is normal working practice to change the dialyser once every 72 hours. Although, to monitor filter performance comparisons of the concentrations urea and creatinine in the waste dialysate against the plasma values are made twice a day. When the filter is operating at full efficiency the ratios of concentrations should be 1:1. A ratio of 0.75:1 indicates that the dialyser should be changed as it is no longer removing sufficient solutes.

The states, or stages that define the operation of haemodialysis are:

i) The set-up state - this includes positioning all the equipment and priming the blood and dialysate circuits before connecting to the patient.

ii) The transient state- where the dialysate and blood pump speeds are changed one or more times in two hours.

iii) The steady state - where the dialysate and blood pump speeds are constant for two or more hours.

iv) An alarm state - where an alarm on the blood pump or the infusion pump is activated.

v) The shut-down state - where the patient is removed from the dialysis equipment.

Hourly charting of the following measurements is carried out by the nurse:

- blood flow rate;
- venous blood pressure;
- dialysate infusion flow rate;
- quantity of anticoagulant delivered;
- volume of saline introduced, and
- the volume of waste dialysate collected.

From figure 5.20 it can be seen that the set up for CVVHF is similar to CVVHD. The main differences are:

- Only ultrafiltration is taking place in the filter. Therefore, CVVHF is used primarily to remove excess fluid from the patient. It does not remove solutes from the blood as well as CVVHD, neither can it be used to treat acidosis in the same way as CVVHD.
- Substitution haemofiltration fluid is delivered directly into the blood circuit. It can be introduced into the blood circuit before or after the filter.

The equipment used in CVVHF is the same as that used in CVVHD, the difference is in how the components are connected. The stages of the haemofiltration process are the same as those for CVVHD. The hourly measurements are the same apart from:

- Substitution flow rate is measured instead of dialysate infusion flow rate,
- The volume of waste measured should be recorded as ultrafiltrate.

By allowing the removal of fluid from the patient, dialysis and filtration enable the administration of other fluid therapies such as nutritional, drug and colloid transfusions. The detailed knowledge used to make the treatment prescription decisions for the steady state treatment operation is given in chapter 6.

5.4.3.3 Nutrition

The nutrition is delivered in liquid form via a naso-gastric tube (enteral feeding) or directly into the patients blood supply (total parenteral nutrition) . Which method is used will depend on whether the patient's gut function is viable. The desired nutritional levels for the patient's feed are:

i) A high calorie content

ii) A protein content commensurate with the patient's metabolic state

iii) High amounts of essential and non-essential amino acids

iv) Additional electrolytes and trace elements, for example zinc, required by the patient

The goals of nutritional therapy are:

i) To minimise fluid and electrolyte imbalances

ii) To maintain adequate nutrition - typically, patients will receive 2000 calories a day

iii) To maintain an anabolic state - tissue catabolism develops rapidly during ATN, resulting in raised plasma urea levels, acidosis and hyperkalemia. Therefore, proper balanced nutritional management is essential.

iv) To minimise uraemic toxicity

Measurements to be recorded:

i) The volume of fluid used to administer the nutrition, to be taken hourly by the ITU nurse

ii) The prescribed nutrition

iii) The nutritional intake of the patient (FEED IN - FEED OUT)

5.4.3.4 Drug infusion

This consists of various infusions of different drugs delivered in infusion fluid. Continuous infusions are delivered by a pump or on a drip basis, whilst bolus injections are delivered by syringe. The goals of drug therapy include:

i) The treatment of sepsis. This is one of the most important reasons for administering drugs during CVVHD. Sepsis is one of the prime medical causes of ATN, and can be caused by infection around the venous access. Thus sepsis is one of the prime causes of death in ATN.

ii) To raise the patient's blood pressure using inotropes

iii) To treat acidosis using bicarbonate

A complication for ATN patients is that drugs are normally eliminated from the body via the kidneys. However, a patient with severely compromised renal function will rely on the CVVHD for the disposal of the drugs from their body. Thus the interaction between the drug and the dialyser membrane is vitally important when considering the drug prescription. The actual effectiveness of the drug needs to be monitored closely as the drug is administered to the patient. The measurements to be recorded are:

i) Volume of fluid used to deliver the drugs. For continuously delivered drugs this

will be an hourly nursing measurement, whilst for bolus injections the volume will be recorded when the drug is injected.

ii) The amount of the drug prescribed by the doctor.

iii) The type and quantity of drug actually delivered.

From the hourly measurements cumulative totals will be worked out for the 24 hour period. A comparison of the amount actually delivered against the amount prescribed needs to be assessed and adjusted for.

5.4.3.5 Colloids

These are the replacement blood products delivered to the patient, such as blood cells, plasma and platelets. The goals of administering colloids are:

i) To keep the patient's haemoglobin and platelets at the correct level

ii) To replace lost plasma

There is an important balance in the coagulation of the blood for patients receiving CVVHD. Low coagulation is needed in the CVVHD circuit, but the patient's clotting capability cannot be removed completely. This is particularly critical where patients have suffered haemorrhaging. The measurements to be recorded are:

i) The volume of fluid administered per hour

ii) Blood products prescribed

iii) Blood products delivered

5.4.3.5 Blood out

The main reasons for significant blood removal or loss are:

i) Blood drains and fistulas from the patient

ii) Patient haemorrhaging

Measurements taken on the blood removed from the patient are:

i) Clotting times of the patient's blood

ii) The volume of blood loss from the drains, fistulas and haemorrhaging

iii) The laboratory variables, normally measured twice a day, relevant to the renal function of the patient include the following :

(a) Blood pH
(b) Base Excess
(c) Plasma creatinine levels
(d) Plasma potassium levels
(e) Plasma phosphate levels
(f) Blood urea nitrogen (BUN)

5.4.3.6 Urine

This is fluid passed from the patient's kidneys. The purpose of collecting urine is to use the measurements to define the patient's renal function. The prime measurement is that of the volume of urine passed per hour. From daily analysis of the urine the following concentrations can be obtained: creatinine; urea; potassium, and sodium.

5.4.3.7 Gastric output

This refers to all fluid output from the stomach, including naso-gastric aspirated fluid. The volume of fluid from the stomach is measured in terms of volume of output per hour.

5.4.3.8 Insensible water and sensible sweat loss

Insensible water loss and sensible sweat loss are two separate processes. Insensible loss is the passive diffusion of water from the lungs and the skin. Sweating is an active physiological processes where water and solutes are lost from the skin. In practice on the ITU the insensible losses are estimated to be 500ml per day. The sweat losses are estimated to be 500ml per day for every degree rise in patient temperature. Doubt over the validity of these estimates was expressed by the clinicians at the Mayday University Hospital. Therefore, the reasonableness of these estimates and the possibility of using a quantitative model to calculate an individual's insensible losses is assessed in the next section.

5.5 ESTIMATING INSENSIBLE AND SWEAT LOSSES

The two processes of insensible and sensible sweat loss from the body are separate. The insensible loss involves only a passive physical process, while sensible losses are the result of an active physiological process.

5.5.1 Insensible Loss

Insensible loss from the body is the continuous passive diffusion of water from the body (Brebner et al., 1956). The insensible water loss contains essentially no electrolytes (Wilson, 1992). The two components of insensible water loss are :

i) The Respiratory Water Loss (RWL).
This is water which is lost from the body upon the expiration of humidified air from the lungs. The addition of water vapour to the inspired air takes place in the respiratory system.

ii) The Transepidermal Water Loss (TEWL).

This is the passive diffusion of water through the skin. It has been shown that TEWL occurs even in the absence of sweat glands (Brebner et al., 1956; Cox, 1987), therefore sweat glands are not involved in TEWL.

5.5.2 Sensible Sweating

Sensible sweating is the active loss of water and electrolytes through the skin. Sweating occurs as a result of a thermoregulatory or an emotional response of the brain. There are two types of sweat glands (Epstein and Sohar, 1985) : The apocrine glands which are involved in heat and emotionally induced sweating, and the eccrine glands, which form the majority of the sweat glands, are involved only in the thermoregulatory process. The reported electrolyte content of sweat varies over a range of values. A range of values suggested by Wilson (1992) is: Sodium 40-50, Potassium 5-10, and Chloride 45-50 mEq l^{-1}.

5.5.3 Techniques Used to Estimate Insensible loss

From a review of articles on the subject, it is clearly common practice to use the same estimate of insensible losses for every patient. However, there have been some attempts to construct quantitative models. A recent attempt to build a detailed quantitative model of the total insensible losses, was that of Ultman (1987). As in the definition of insensible losses the model has two main components, the RWL and the TEWL. Models of these two components of the insensible loss were reviewed separately.

5.5.3.1 Respiratory water loss

The principle of respiratory water loss (RWL) is that unsaturated air enters the lungs and during exchange of gases in the alveoli it becomes saturated with water vapour (Ferrus et al, 1980). By this process the expired gas has a higher water vapour content than the inspired air. The limit of RWL occurs when the inspired air is already saturated, then there is no net increase of water vapour in the alveoli, so RWL is zero. It is generally accepted

that alveolar gas is fully saturated and at the core body temperature (Reithner, 1981). However, several authors (Ferrus et al., 1980; Newburgh and Johnston, 1942; McCutchan and Taylor, 1951) have shown that the expired gas at the mouth or nose is not saturated. The two quantitative models presented below take account of the unsaturated nature of the expired air.

(1) Quantitative Models

(a) Ultman (1987) and McCutchan & Taylor (1951)

Ultman states that the net rate of RWL is a product of the mass flow of air per hour, m_a, with the difference between the expired, Y_e, and ambient inspired absolute humidity, Y_i.

$$\text{RWL per hour} = m_a (Y_e - Y_i) \quad (5.7)$$

For definitions of the terms in this expression see appendix B. McCutchan and Taylor (1951) performed an experiment on five healthy males and found that the change in the absolute humidity from inspired to expired air was :-

$$Y_e - Y_i = 0.02645 + 0.0000361t_i - 0.798Y_i \quad (5.8)$$

where t_i = temperature in fahrenheit of inspired air

Y_i = absolute humidity of the inspired air

Y_e = absolute humidity of expired air

Equation 5.8 shows that as the inspired absolute humidity rises the RWL goes down, and the inspired air temperature has a relatively small influence on RWL. Expressing equation 5.8 using temperature in degrees celsius, T_i

$$Y_e - Y_i = 0.02761 + 0.0000650T_i - 0.798Y_i \quad (5.9)$$

Combining the McCutchan and Taylor equation with the expression for m_s in appendix B, equation B1.3:

$$RWL = (f_{RR} \times V_T \times 72{,}240)(0.02761 + 0.0000650T_i - 0.798Y_i) \quad (5.10)$$

Appendix B shows how absolute humidity can be expressed in terms of relative humidity, equation B5.3, which is a more common measure of humidity. Thus, equation 3.4 can be expressed as:

$$RWL = (72{,}240\, f_{RR}V_T)(0.02761 + 0.0000650T_i - \frac{0.496RH_i \times p_{vp}}{100P_T - RH_i x p_{vp}}) \quad (5.11)$$

Assuming the environment of an ITU in northern Europe is constant, and using figures suggested by Cox (1987) of room temperature around 24°C and relative humidity of 40%, then

$$\text{RWL per unit volume} = (72{,}240 f_{RR}V_T)0.023 \quad (5.12)$$

$$= 1683 f_{RR}V_T \text{ g h}^{-1} \text{ m}^{-3}$$

Wilson (1992) and Cooney (1976) state that for a standard man, the typical minute volume ($f_{RR}V_T$) is approximately 0.006 m^3 min^{-1}. So, at a room temperature of 24°C and a relative humidity of 40% and for a 'standard man' weighing approximately 70 kg:

$$RWL = 10.10 \text{ g h}^{-1}$$

Obviously this figure for RWL is only valid for the conditions stated above, but changes in conditions can be accommodated by the model.

(b) Ferrus et al. (1984)

The other main body of work in the area of RWL has been conducted by Ferrus et al. (1984). They performed 345 experimental runs on seven (two female and five male) healthy subjects. The aim of the Ferrus study was to derive an expression for the mass of water vapour expired per litre of BTPS ventilation. The first correlation Ferrus produced by multiple linear regression analysis showed that:

$$MV_E = 28.70 - 0.27f_{RR} + 0.22T_i + \frac{0.14RHp_{vp}}{100} \quad (5.13)$$

where MV_E = mass of water vapour expired per litre of ventilation (mg dm^{-3})

f_{RR} = respiratory rate or frequency (min^{-1})

T_i = inspired air temperature (°C)

RH_i = relative humidity of the inspired air

p_{vp} = the vapour pressure of water at T_i (Torr=mmHg)

In a similar manner to the above, this expression shows that the expired gas water content is partly determined by the inspired gas temperature and the humidity of the ambient air. It also shows that the quantity of water vapour expired is partly determined by the respiratory rate. Ferrus suggested this dependency may be due to a 'time dead space', which can be thought of as the time taken for water to diffuse into the inspired air in the mouth and the tracheobronchial tree. Two different time dependent mechanisms were put forward that may account for this phenomenon:

i) Diffusion of water vapour from the wet surface into the gas phase, and/or

ii) Water supply from underlying tissues & salivary glands to the wet surface.

This theory was supported when four of the subjects held a five second apnoea at the end of inspiration and a large increase in the mass of expired water vapour was observed.

Considering the theory of the time dead space, Ferrus also showed a strong positive correlation between MV_E and the respiratory period (T_R). That is the longer the respiratory period, the more time is available for the process of water exchange in the respiratory system and the more saturated the expired air will become. Replacing f_{RR} by T_R results in the following equation

$$MV_E = 20.9 + 0.87T_R + 0.22T_i + 0.14p_i \quad (5.14)$$

where T_R = respiratory period (s)
T_i = inspired air temperature (°C)
p_i = inspired partial water pressure (Torr)

The third and final correlation performed by Ferrus, replaced the respiratory rate and the tidal volume with the minute volume. By this correlation the following expression was derived:

$$MV_E = 24.27 - 0.09V_m + 0.22T_i + 0.27p_i \quad (5.15)$$

where V_m = minute volume (dm^3)
T_i = inspired air temperature (°C)
p_i = partial pressure of inspired water vapour (mmHg)

However, the coefficient for the minute volume represents a variation of 0.9 mg for every 10 dm^3 min^{-1} variation in minute volume. Thus, in practice the dependency on minute volume can be neglected.

Equation 5.15 does not take account of the effect of varying the respiratory period, therefore using equation 5.14 or 5.15 is preferable. In practice the respiratory rate is probably more commonly measured, so the equation 5.14 is likely to be the most practical equation to use.

The expression using MV_E to calculate the RWL is :-

$$RWL = (\text{Volume respiration per hour})(MV_E - MV_I)\ mg\ h^{-1} \quad (5.16)$$

where MV_E = mass of water vapour per volume of expired gases (mg dm^{-3})

MV_I = mass of water vapour per volume of inspired gases (mg dm^{-3})

From the expressions given in appendix B:

$$RWL = (60 \times V_T \times f_{RR})(28.70 - 0.27f_{RR} + 0.22T_i + \frac{(100P_T - RHp_{vp})(0.14RHp_{vp}) - 0.749RHp_{vp})}{100 (P_T100 - RHp_{vp})} \quad (5.17)$$

where RWL= Respiratory Water Loss (mg h^{-1})

V_T = tidal volume (dm^3)

f_{RR}= respiratory rate (min^{-1})

T_i = inspired air temperature (°C)

P_T = total ambient pressure (mmHg)

RH = ambient relative humidity

p_{vp}= water vapour pressure at T_i (mmHg)

For the typical conditions used previously, where the minute volume is 6 l min^{-1}, the respiratory rate is 12, the ambient temperature is 24°C, the ambient total pressure is 760 mmHg and the relative humidity is 40.

$$RWL = 11{,}515\ mg\ h^{-1} = 11.51\ g\ h^{-1}$$

(2) Estimates of RWL

All the estimates of RWL listed here are based on the assumption that the expired air is saturated.

(a) Cox (1987)

From the assumption given above, Cox states that a theoretical loss via the lungs is 28 g m^{-3} of expired air. For the standard man this implies a RWL of 10.1 g h^{-1}. This value was for an approximate room temperature of 24°C and a relative humidity of 40%.

(b) Cooney (1976)

States that the RWL for the standard man in normal conditions is 350 ml per day (15 g h^{-1})

(c) Newburgh and Johnston (1942)

At a temperature of 24°C and a relative humidity of 50% Newburgh measured an average RWL of 25.1 g m^{-3}. For a standard man this equates to a loss of 9.1 g h^{-1}.

(d) Reithner (1981)

Reithner's paper was concerned with the effect of fever on the RWL. For a patient with a temperature of 37°C, and a surface area of 1.75 m^2 the water loss is stated to the 390 g day^{-1} (16.25 g h^{-1}). For a patient with a temperature of 39°C this was found to rise to 500 g day^{-1}. This represents an approximate increase of 5 g h^{-1} for the 2°C rise in temperature.

(e) Wilson (1992)

Wilson states that for an average sized 70 kg man the insensible water loss from the lungs is approximately 700 ml day^{-1} (29.2 g h^{-1}).

5.5.3.2 Summary of respiratory water loss for a standard man

For a standard man (68 kg, BSA = 1.8m^2, Cooney, 1976) in conditions approximating to a room temperature of 24°C and a relative humidity of 40% the values of RWL obtained are listed in Table 5.1 (overleaf).

The quantitative methods used offer far more flexibility when calculating RWL. They can take into account the effect of variations in ambient conditions and patient variables. If the variables used by the model are constant, for example ambient temperature, then the constant can be used to simplify the model.

Identifier	Source	RWL ($g\ h^{-1}$)	RWL ($ml\ day^{-1}$)
1	McCutchan & Taylor (1951)	10.1	242.2
2	Ferrus et al (1984)	11.5	276.0
3	Cox (1987)	10.1	242.4
4	Cooney (1976)	15.0	360.0
5	Newburgh and Johnston (1942)	9.1	218.4
6	Reithner (1981)	16.3	391.2
7	Wilson (1992)	29.2	700.8
Average		14.5	348.0

Table 5.1 Summary of respiratory water losses

5.5.3.4 Transepidermal water loss

(1) Quantitative Model

The stratum corneum performs the main barrier function in the skin. The passive diffusion of water through the stratum corneum can be modeled by applying Fick's law of diffusion (Michniak-Mikolajczak and Barry 1988), as shown in appendix C, C1.4:

$$TEWL = \frac{M_w D_w (p_{vp}(T_p) - p_s)}{RT_a l} \qquad (5.18)$$

where M_w = molecular weight of water ($g\ mol^{-1}$)

D_w = diffusivity of water through the stratum corneum ($m^2\ h^{-1}$)

R = universal gas constant (m^3 kPa/kmol °K)

T_a = ambient temperature (°C)

l = thickness of stratum corneum (m)

$p_{vp}(T_p)$= water vapour pressure at perfusion temperature (kPa)

p_s = partial pressure of water at the skin surface (kPa)

The diffusivity of water D_w, through the stratum corneum can vary by 20 to 30 times between its dry state and its fully hydrated state. Moreover, the stratum corneum exhibits regional differences in thickness over the body. It is as thick as several hundred micrometers on the soles of the feet and the palms of the hand, whilst the average thickness over the body is approximately ten micrometers. Due to these variations in parameters the coefficient of the partial pressure difference is replaced by the mass transfer coefficient k. This coefficient is then determined from experimental measurements and will vary between individuals, and with temperature.

The subcutaneous temperature and the partial pressure at the skin surface are unknowns. Ultman (1987) assumed the subcutaneous temperature was equivalent to the skin temperature, and that the partial pressure of water vapour at the skin was equivalent to the ambient partial pressure. Combining these facts with the expression relating partial pressure and relative humidity the following expression is derived:

$$TEWL = k \left(p_{vp}(T_s) - \frac{p_{vp}(T_a) \times RH_a}{100} \right) \qquad (5.19)$$

where $p_{vp}(T_s)$ = vapour pressure at skin temperature (KPa)

$p_{vp}(T_a)$ = vapour pressure at ambient temperature (KPa)

RH_a = ambient relative humidity

k = mass transfer coefficient

The mass transfer coefficient has been shown to vary with temperature. From the results quoted by Grice et al (1971) Ultman showed that the mass transfer coefficient's dependency on skin temperature could be expressed by :-

$$k = k_o \exp [9.119 - 2809/(273 + T_s)] \qquad (5.20)$$

The constant k_o will vary with each individual. If k is equal to 1.5 the curve representing TEWL over the skin temperature (T_s) range 25 to 40°C is approximately in the middle of the range of values reported by Grice. However, the values of TEWL were only measured on the forearm by Grice, so her results do not represent the TEWL for the whole body. Lamke et al. (1977) performed a correlation between the average TEWL from the forearm, chest and abdomen and the TEWL for the whole body. The values of TEWL at the forearm, chest and abdomen were shown by Lamke to be equivalent at different skin temperatures, so the correlation can be applied to the model derived from Grice's work. The equation representing the correlation is (Lamke et al., 1977):

$$\text{Total TEWL} = 1.05(\text{Local TEWL}) + 3 \qquad (5.21)$$
$$= TEWL_T$$

where TEWL is expressed in g m^{-2} h^{-1}

So, the expression for TEWL can be approximated to:

$$TEWL_T = 1.6 \left(p_{vp}(T_s) - \frac{p_{vp}(T_a)RH}{100} \right) + 3 \qquad (5.22)$$

Applying equation 5.22 to a skin temperature of 33°C in an ambient temperature of 24°C and a relative humidity of 40%:

$$TEWL_T = 9.1 \text{ g } m^{-2} h^{-1}$$

To calculate the total TEWL per hour this would then have to be multiplied by the body surface area of the patient. The body surface area can be calculated using the DuBois method, provided the patient's weight and height are known. The formula proposed by Dubois is given in appendix C, C2.2. For the standard man with a body surface area of approximately 1.8 m^2 (Cooney, 1976):

$$TEWL_T = 16.38 \text{ g } h^{-1}$$

(2) Estimates of TEWL

(a) Cox (1987)

Cox stated that the insensible loss through the skin per day is approximately 250 ml m^{-2}.

(b) Wilson (1992)

Estimated the insensible loss through the skin to be approximately 170 ml m^{-2} per day.

(c) Cooney (1976)

The insensible losses through the skin were stated to be 195 ml m^{-2} per day.

(d) Lamke et al. (1977)

Lamke et al., measured the insensible losses for three ambient temperatures of 22°C, 27°C and 30°C. The average insensible skin losses at these temperatures were 218 ml m^{-2} day^{-1}, 301 ml m^{-2} day^{-1} and 397 ml m^{-2} day^{-1} respectively.

(e) Rosenburg et al. (1962)

Rosenburg quoted the results of his own study and of a number of previous studies for the loss of water vapour through non-sweating skin (Table 5.2).

Identifier	Source	Insensible loss (g m^{-2} h^{-1})
1	Felsher (1944)	13
2	Burch & Winsor (1944)	50
3	Blank (1953)	2
4	Mall (1956)	5
5	Monash & Blank (1958)	60
6	Rosenburg et al. (1962)	2

Table 5.2 Quoted estimates of transepidermal water loss

5.5.3.5 Summary of transepidermal water loss

Table 5.3 summarises the insensible skin losses from the quantitative model and the other estimates quoted.

I.D.	Source	TEWL (g m^{-2} per day)	TEWL (ml day^{-1})
1	Quantitative model (Ultman, 1987)	218	392.4
2	Cox (1987)	250	450.0
3	Wilson (1992)	170	306.0
4	Cooney (1976)	195	351
5	Lamkeet al. (1977) (at T_a=22°C)	218	392.4
6	Rosenberg et al. (1962)	48	86.4
7	Felsher (1944)	312	561.6
8	Burch & Winsor (1944)	1200	2160
9	Blank (1953)	48	86.4
10	Mall (1956)	120	216
11	Monash & Blank (1962)	1440	2592
Avg		384.6	690

Table 5.3 Summary table for transepidermal water losses

The results of the studies reported in 1962 and prior years have a very wide range of values. On the assumption that experimental and measurement techniques are more accurate in the later studies, the early results will not be compared with the result from the quantitative model.

So, considering only the values number 1 to 5 the quantitative model has produced a result in good agreement with the estimates. The quantitative model has the advantage of taking into account ambient conditions and the patient's skin temperature. It should be noted that the skin temperature should be taken from the volar surface of the forearm, as this was the point used by Grice to relate the local TEWL to skin temperature.

5.5.4 Accounting for Sweat Losses

The literature search to date has mainly produced studies that give estimates of sensible sweat losses. Moreover, the complexity of the process of sweating makes it difficult to apply general rules to it. In particular, Epstein and Sohar (1985) states that in a healthy individual the heat centre in the brain has a set point of 37°C and directs the heat dissipating mechanism to conserve this temperature; whilst in disease, endotoxins are released into the blood which affect the set-point causing it to rise to 40°C or higher.

(a) Lamke et al. (1980)

Lamke found that visible sweating was only observed in patients with a core temperature higher than 39.5°C. On average patients with an elevated temperature sweated for approximately 5 hours a day, and the losses through the skin due to this were approximately 375 ml m^{-2} day^{-1}. So, for a person with a body surface area (BSA) of 1.8m^2 this represents an additional loss of 675 ml per day.

For a guideline Lamke suggests that in an ambient temperature of 22-25°C a patient with highly elevated temperature will need an extra water supply of at least 500 ml a day to compensate for the loss due to sweating.

(b) Reithner (1981)

For a patient in high fever, the loss due to sweating can be in the region of 500 - 1,000 ml per day.

(c) Wilson (1992)

Two possible methods are suggested:

(i) Allow for 500 ml per day of increased sensible sweating per 1°C of fever, or

(ii) Allow: - 500 ml per day for mild sweating
- 1000 ml per day for moderate sweating
- 1500 ml per day for severe sweating

Whether method a, b, or c is used to estimate losses due to sensible sweating requires experienced judgement.

5.5.5 Techniques for Measuring Evaporation From the Skin

The two techniques that were found to have been used to measure evaporation from the skin are: the ventilated chamber method, and the evaporimeter. Both of these methods are described in Scott et al. (1982).

5.5.6 Conclusion on Insensible Water and Sweat Losses

Insensible losses occur independently from sensible sweating losses. Insensible losses occur by the passive diffusion of water in the respiratory system and through the skin. Sensible sweating involves the active response of the brain to thermoregulatory or emotional signals. Further, sweating occurs through the apocrine and eccrine sweat glands, and electrolytes are excreted with the water lost.

The insensible respiratory water loss (RWL), and the insensible transepidermal water loss (TEWL) can be considered separately. Quantitative models for both these losses have been developed. Two models for the RWL were developed, and are expressed below in their fullest form:

(1) Model based on McCutchan & Taylor (1951)

$$RWL = (60xf_{RR}xV_Txd_A)(0.02761+0.0000650T_i-0.798Y_i) \quad (5.23)$$

where RWL = Respiratory water loss (g h^{-1} m^{-3})

f_{RR} = Respiratory rate (min^{-1})

V_T = Tidal volume (m^3)

d_A = Density of dry air at the ambient conditions (g m^{-3})

T_i = Temperature of inspired air (°C)

Y_i = Absolute humidity of the inspired air

(2) Model based on Ferrus et al. (1984)

$$RWL = (60xV_Txf_{RR})(28.70-0.27f_{RR}+0.22T_i+0.14p_i-d_AY_i) \quad (5.24)$$

where RWL = Respiratory water loss (mg h^{-1})

V_T = Tidal volume (dm^3)

f_{RR} = Respiratory rate (min^{-1})

T_i = Inspired air temperature (°C)

p_i = Partial pressure of inspired air (mmHg)

d_A = Density of dry air in ambient conditions (mg dm^{-3})

Y_i = Absolute humidity of inspired air

The quantitative model for TEWL can be expressed as:

$$TEWL = 1.05k (p_{vp}(T_s) - \frac{p_{vp}(T_a)xRH_a}{100}) + 3 \quad (5.25)$$

where TEWL = Transepidermal water loss g m^{-3} h^{-1}

$p_{vp}(T_s)$ = the water vapour pressure at skin temperature (kPa)

$p_{vp}(T_a)$ = the water vapour pressure at the ambient temperature (kPa)

RH_a = ambient relative humidity

k = mass transfer coefficient (g m^{-2} h^{-1} kPa^{-1})

The mass transfer coefficient was found to vary with skin temperature as follows:

$$k = k_o \exp\left[9.119 - \frac{2809}{273+T_s}\right] \qquad (5.26)$$

where T_s = skin temperature (°C)

k_o = pre-exponential constant (g m^{-2} h^{-1} kPa^{-1})

The pre-exponential coefficient, k_o, will vary between individuals. With k_o set at 1.5 the calculated local TEWL values were in the middle of the range of results presented by Grice et al. (1971). So when using the model an average, or initial value, of 1.5 could be used for k_o.

For a standard 68kg man the respiratory water loss estimates in table 5.1 varied from 218 ml/day to 700 ml/day, with an average of 348 ml/day. From table 5.3 the range of published estimates for TEWL was 86 ml/day to 2,592 ml/day, average 690 ml/day. This large variation in TEWL estimates could be due to measurement of sweat loss being included in the water volume measurement, and poor measurement or experimental techniques. Indeed Lamke et al. (1977) showed that variation in water loss from different parts of the body and the measurement technique used can alter the environment over the skin. The values from the studies prior to 1963 were based on measurements taken when there were no visible signs of sweating. However, the very high variations in these estimates suggest that there has been some error in their measurement. Disregarding these earlier estimates in table 5.3 leaves a range of 306 to 450 ml/day for a standard man, with an average of 378 ml/day. Therefore the average estimate of the total insensible loss for a standard man in typical room conditions is 726 ml/day. The range of estimates is from 524 ml/day minimum to 1,150 ml/day maximum.

Other authors have also published estimates for the total insensible losses for a patient. Cox (1987) suggested using an estimate of 10 ml per day per kg body weight. For a 68 kg man this equates to a loss of 680 ml/day. Eccles (1993) suggested allowing for a total insensible loss of 1400 ml/day, and Willats (1987) suggested 816 ml/kg per day. Wilson

(1992) suggested a range of total insensible losses from 600 ml/day to 1200 ml/day.

Therefore, the range of estimates for the total insensible loss vary from 524 to 1400 ml/day. In the case where the lower estimate is used in fluid balance calculations, but the patient is losing the maximum amount estimated this could be leading to a systematic 900 ml daily error in fluid balance calculations. Such an error in the estimate of insensible losses will cause problems in keeping the patient in fluid balance causing them to be consistently under hydrated. The practice on the ITU at the Mayday is to allow 500 ml/day for a typical 70 kg male patient, which is at the lower end of the range of published estimates. With the consideration of the possible miscalculation of insensible losses this suggests that further investigation into the estimation of these losses is warranted.

On the ITU there will be many variables which will affect the actual fluid balance. From the models of transepidermal insensible loss the ambient temperature, ambient humidity and the patient's skin temperature will all affect the loss. The insensible respiratory water losses will depend on how the patient's respiration is being controlled. The majority of ATN ITU patient's are ventilated and thus the humidity of the inspired air is artificially controlled. Where the humidity of the inspired air is raised the respiratory water loss will be reduced, as is shown by equations 5.23 and 5.24. The theoretical limit being where the inspired air is fully saturated with water, and no water is lost through respiration. Moreover, the patient's respiratory rate and tidal volume will affect their respiratory water loss. Therefore there are many variables which can change the insensible losses. The quantitative models described above do allow variations to be included in the estimate, thus they offer the opportunity for producing more accurate patient and ambient sensitive estimates. However, the models have not been evaluated in the estimation of insensible losses for critically ill patients in the ITU. Therefore before the implementation of the models detailed studies of their accuracy would be required. This would require prospective clinical testing to gather the required data to prove the models. How the insensible losses are to be estimated in the computer based fluid charting system will be discussed in chapter 7.

No detailed quantitative model representing sensible sweating losses has been found to

date. Accounting for sweat losses seems to rely mainly on using approximate estimates. Lamke et al. (1980) reported that patients in fever on average will sweat for 5 hours a day and lose approximately 375 ml m^{-2} per day of sweat. An alternative approach suggested by Wilson (1992) was to allow for 500ml of increased sensible sweating for every 1°C of fever.

5.6 SUMMARY

This chapter has analysed the clinical problem that the proposed CDS system is to support. Knowledge of the material clinical domain is founded in the concepts of medical science. Therefore, an analysis of the material problem of acute renal failure in the ITU is built on knowledge of kidney physiology, pathophysiology and the kidney's control of the body's physiology. Using these concepts of medical science as a basis a model of the fluid and biochemical flows for a patient receiving CVVHD treatment on the ITU has been constructed. This is used as the basis for defining the monitoring of the patients fluid volumes and biochemistry. Furthermore, the model is also the foundation for the development of a fluid charting system, described in chapter 7.

From the systems analysis for a patient suffering from ATN, the main treatment which acts to compensate for the loss of their renal function is the CVVHD. Therefore the treatment decision making governing the patients CVVHD treatment is the controlling factor in compensating for ATN. Hence the analysis of the decision making in the next chapter will focus on the problem of modelling the decision making controlling a patient's CVVHD treatment.

Figure 5.1 The two kidneys in relation to the bladder and major blood vessels (Lote, 1982)

Figure 5.2 Longitudinal section of the kidney showing the major regions (Lote, 1982)

Figure 5.3 Renal blood supply (Lote, 1982)

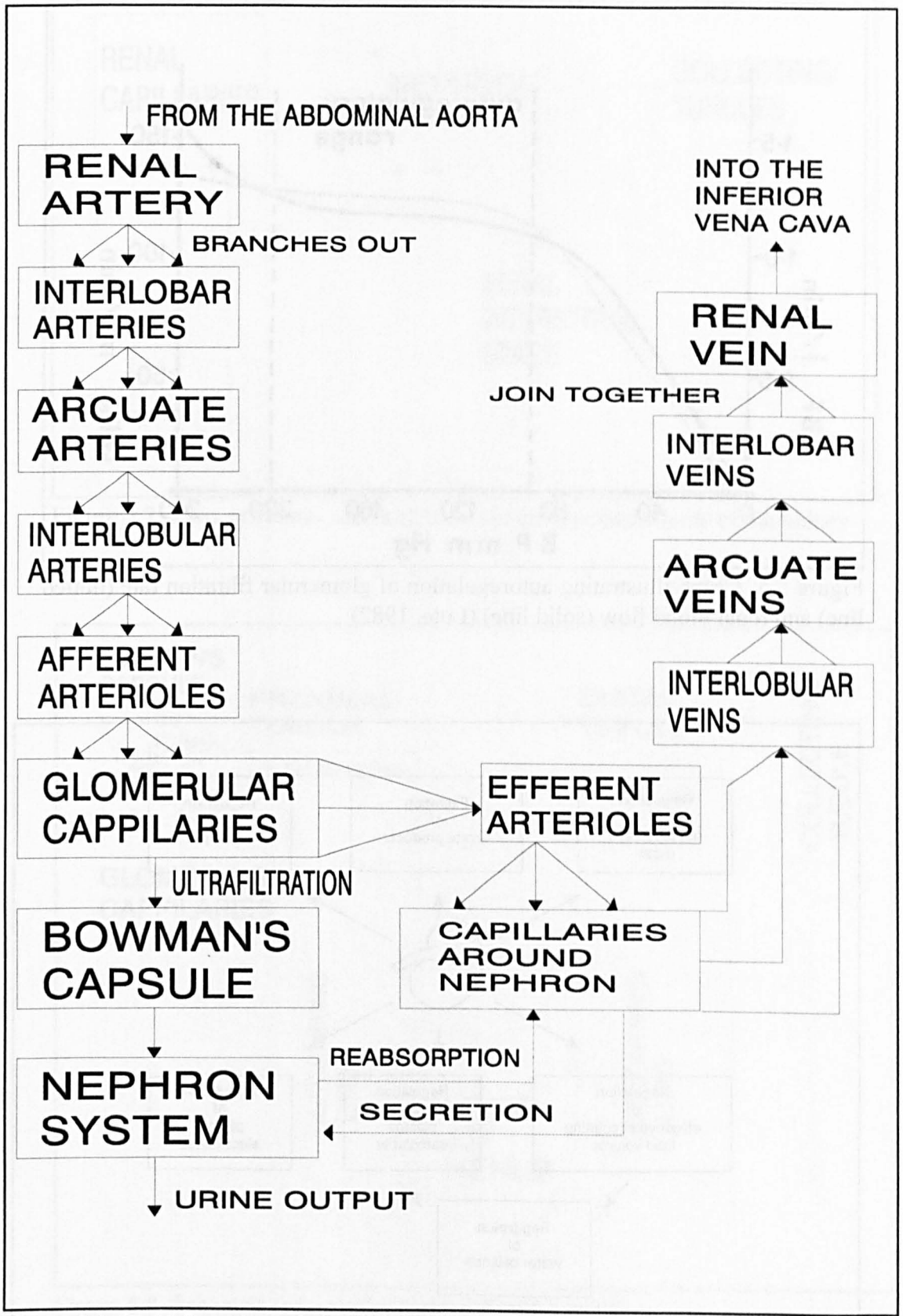


Figure 5.4 Fluid flow through the kidney

Figure 5.5 Graph illustrating autoregulation of glomerular filtration rate (dotted line) and renal blood flow (solid line) (Lote, 1982)

Figure 5.6 Kidney Functions (Eccles, 1993)

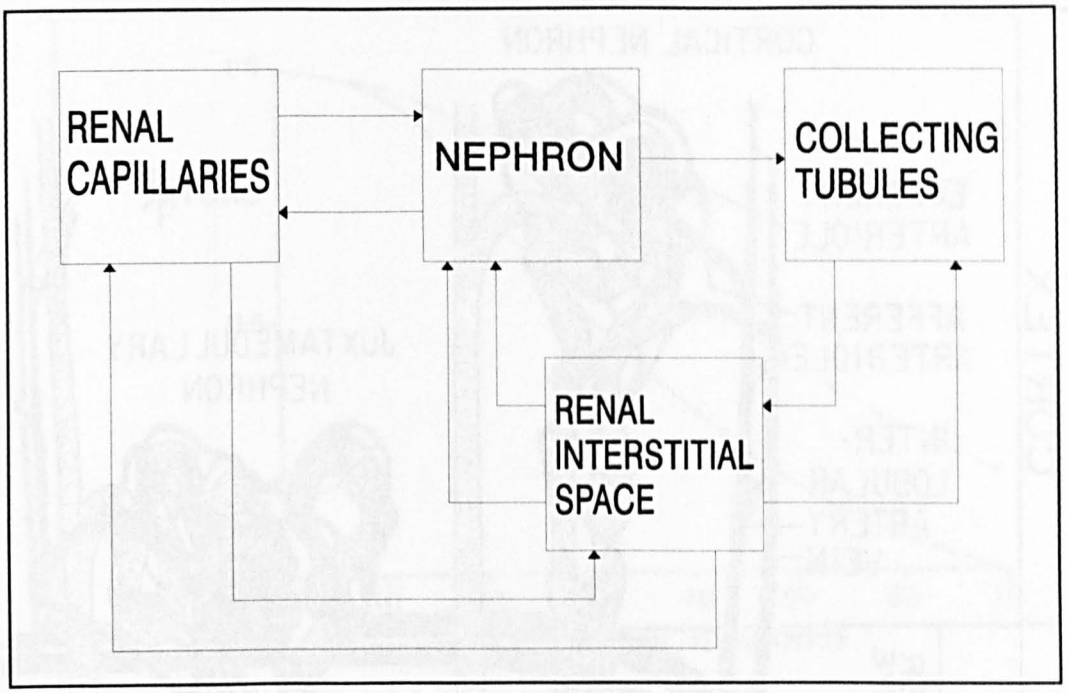


Figure 5.7 Flow of solutes and fluid between the functional units of the kidney

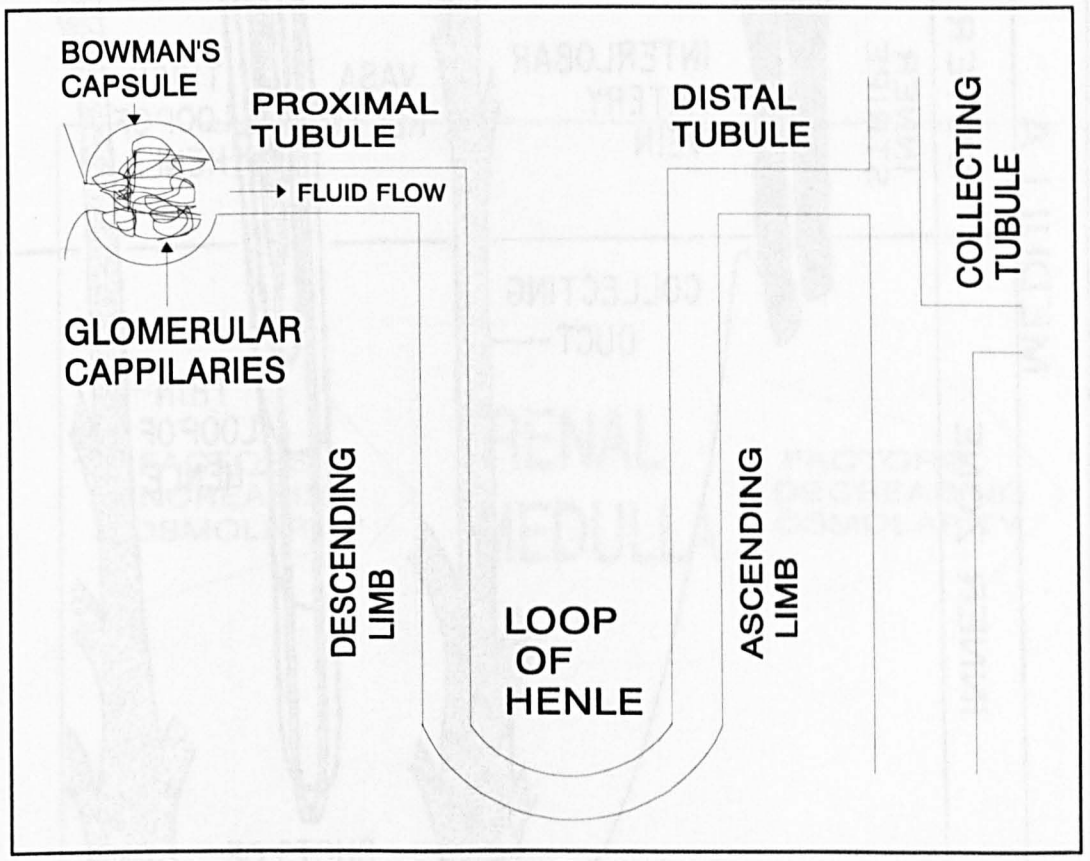


Figure 5.8 Schematic of a nephron and collecting tubule

Figure 5.9 Cortical and juxtamedullary nephron (Lote, 1982)

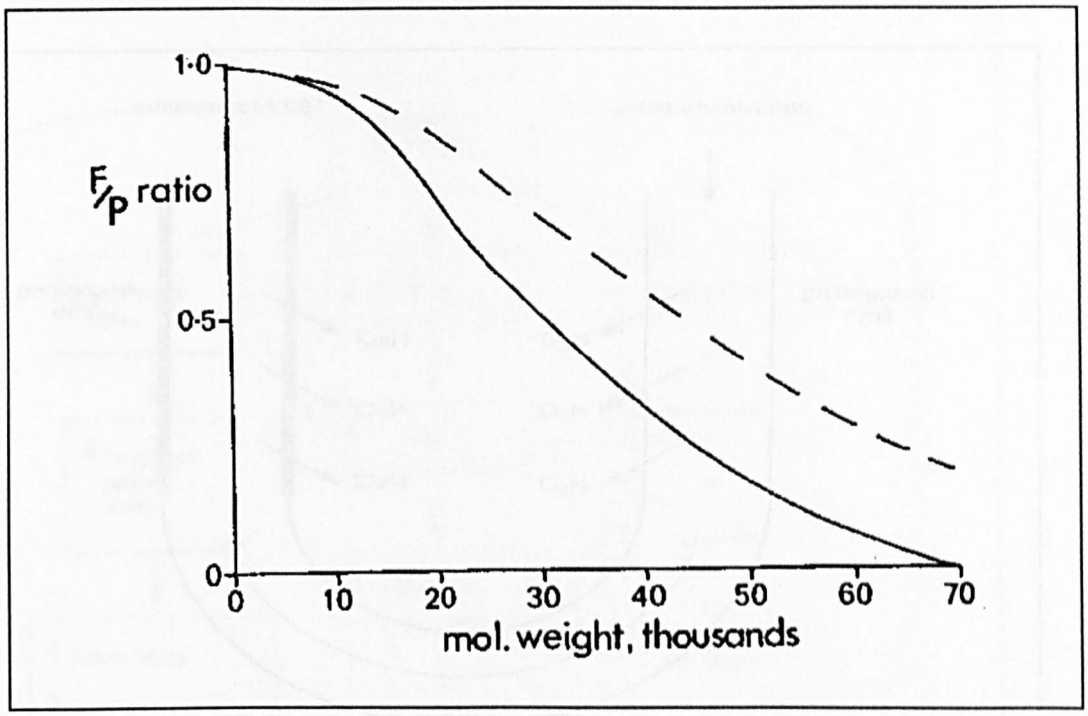


Figure 5.10 Graph describing the variation in the glomerular filtrate to plasma concentration ratio for various molecular weights (Lote, 1982)

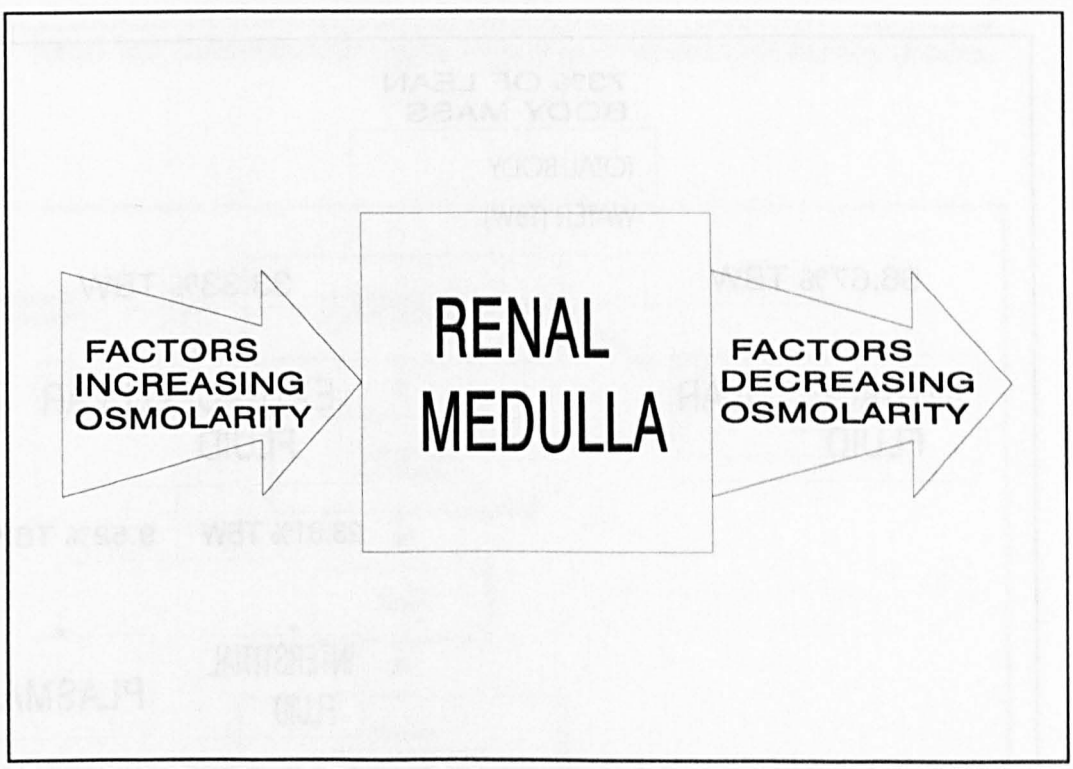


Figure 5.11 Renal medulla osmolarity

Figure 5.12 Countercurrent multiplier (Eccles, 1993)

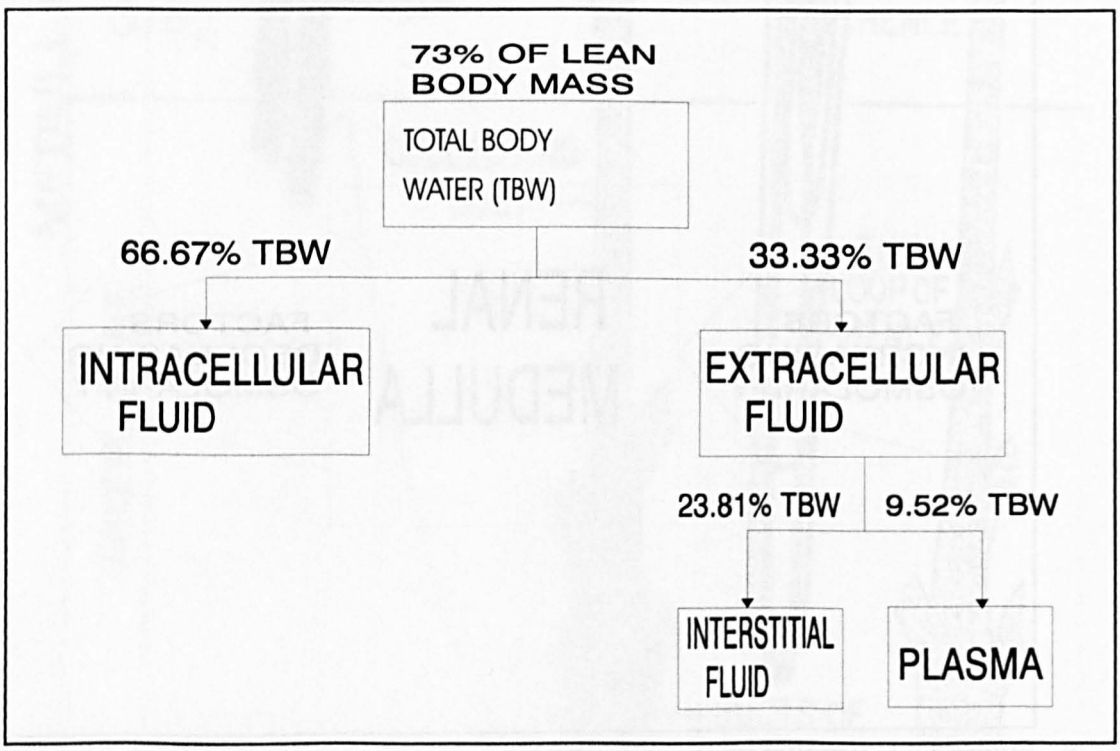


Figure 5.13 Body fluid compartments

Figure 5.14 Renal and cardiovascular response to hypovolaemia/hypotension (Eccles, 1993)

Figure 5.15 Regulation of plasma osmolarity (Eccles, 1993)

Figure 5.16 Factors influencing extracellular potassium concentration (Eccles, 1993)

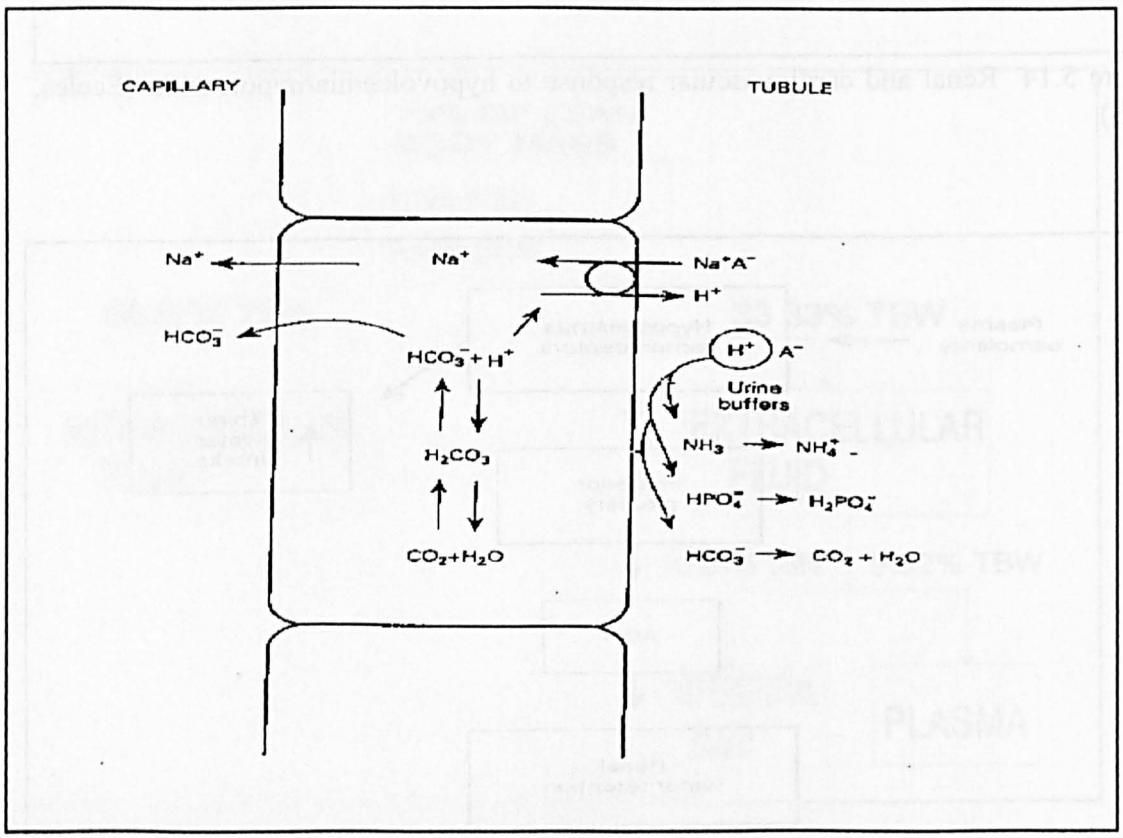


Figure 5.17 Renal excretion of non-carbonic acid

Figure 5.18 Acid-base disturbances defined on the bicarbonate v pH graph (Eccles, 1993)

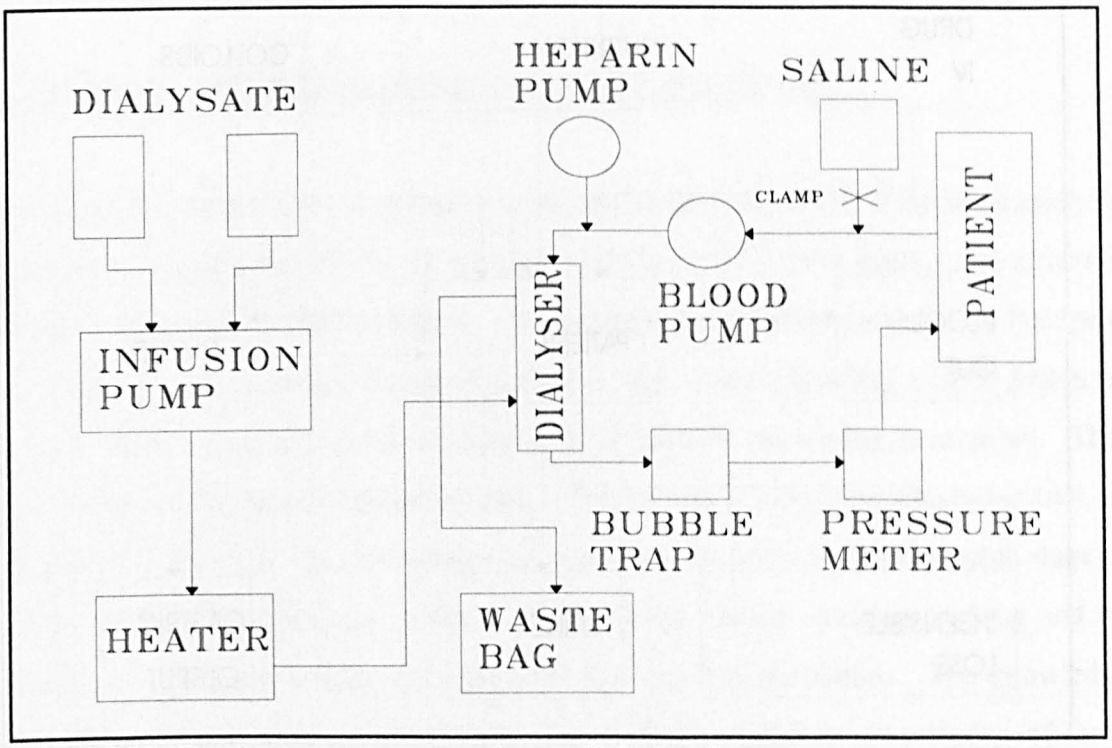


Figure 5.19 Continuous venovenous haemodialysis schematic

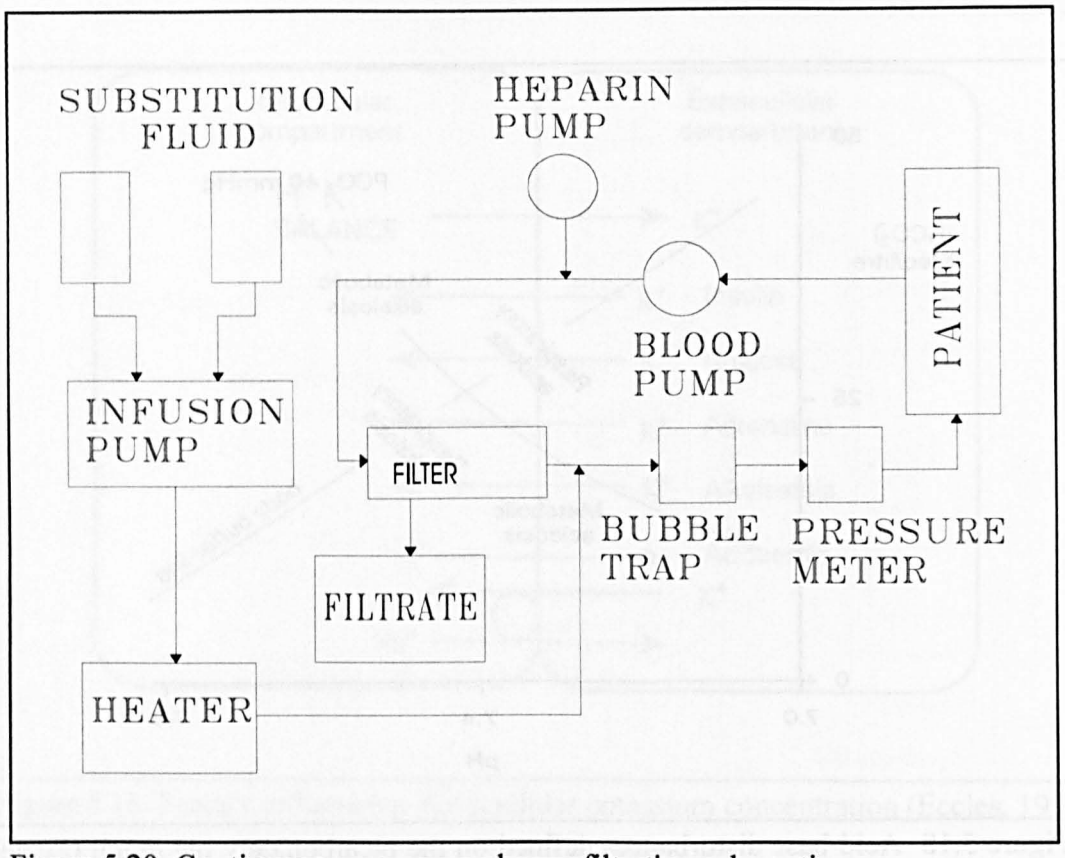


Figure 5.20 Continuous venovenous haemofiltration schematic

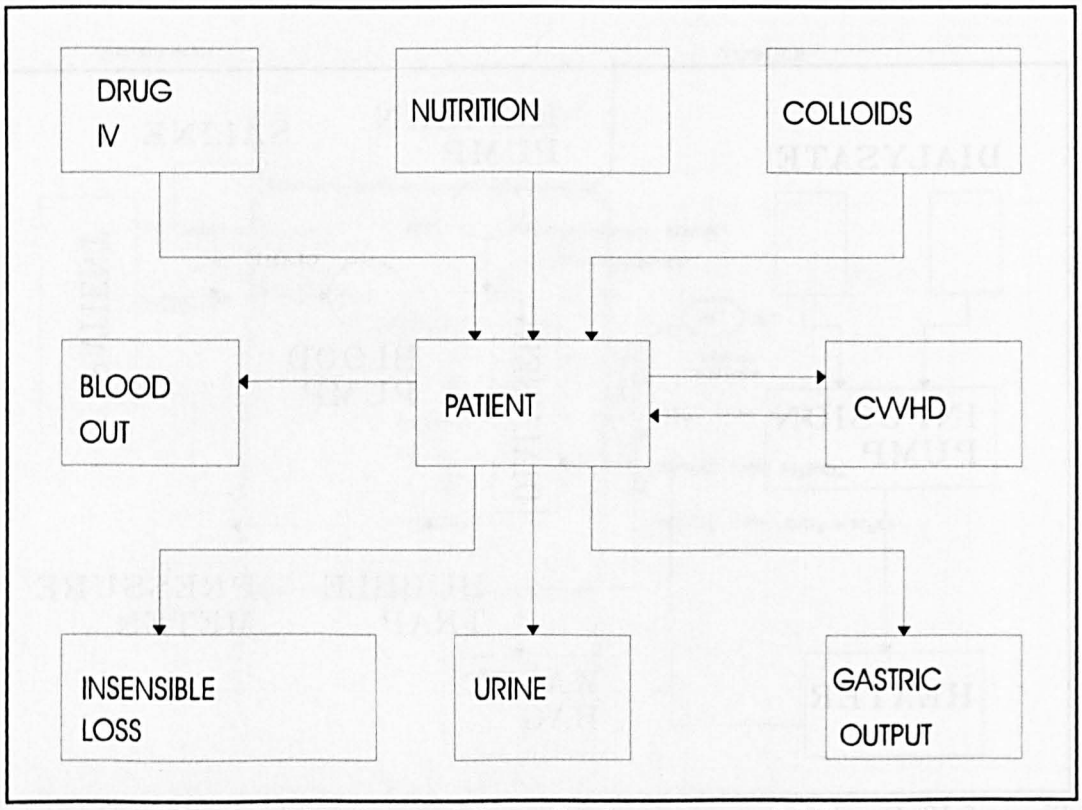


Figure 5.21 Fluid and biochemical flows for the acute renal failure patient

CHAPTER 6

DECISION MAKING FOR HAEMODIALYSIS MANAGEMENT

6.1 INTRODUCTION

It was established in the previous chapter that the decision making managing an ITU patient's loss of renal function controls their continuous venovenous haemodialysis (CVVHD) treatment. The aims of this chapter are: to present a model of the clinical decision making used to control a patient's CVVHD treatment, and to specify the clinical knowledge elicited for use in the CVVHD treatment advice. The model of the CVVHD decision making is based on the models of decision making developed in chapter 4.

6.2 CLINICAL DECISION MAKING CONTROLLING CVVHD

The controlling factor in the treatment of acute tubular necrosis (ATN) is the haemodialysis treatment. Therefore to effectively manage ATN in the ITU there needs to be effective management of the CVVHD treatment. The decision making which controls this treatment can be informed by a clinical decision support system. Before building a CDS system an analysis of the clinical decision making and the clinical knowledge is required. This requirement is clear when considering that a CDS system is a decision simulation tool, as depicted in figure 4.16. As a simulation tool it mirrors the decision maker at each stage of the decision making process. Thus, a model of the clinical decision making and an abstraction of the knowledge are central to this decision simulation. The knowledge elicited on the management of patients represents the expressed knowledge of Dr S Morgan, the ITU consultant who is a nephrology specialist.

The three main stages of the clinical decision making cycle in the ITU are patient state evaluation, monitoring and treatment (figure 4.12). The derivation and explanation of this three tier process model of decision making are given in chapter 4. The process begins with the collection of data from patient monitoring; this includes the fluid and biochemical data in addition to other clinical signs. From these data an initial evaluation of the patient state is made. The evaluation is carried out by the classification of the patient data into categories, for example low, normal and high. Individual classifications can then be grouped to form higher level classifications or diagnosis. Depending on the evaluation of the patient and prior decisions where made, options for action will be generated. The actions could be further monitoring and/or treatment. Choice of an action then follows and this is then ordered in the implementation stage. This usually leads to a treatment action being set up, which begins with an assessment of what is required and what is presently being done for the patient. The treatment decision cycle is then similar to the patient evaluation. The monitoring decision making begins in a similar way, although much of the monitoring action is at present standard and routine. From the monitoring the whole process then repeats itself. A decision tree can be used to represent the options for action in each of the decision loops.

The analysis of the decision making views the process in reverse. For controlling a treatment the first stage is to define the treatment options which are implementable. These then need to be put into a structured format. A decision tree has been used to structure the model of the decision making controlling CVVHD. For each of the decision nodes a set of conditional propositions for making the decision are attached. Goals are attached to each of the options in the tree to enable testing of pragmatic effectiveness of the decision in the subsequent cycles of decision making. The conditional propositions depend on the assessment of the material problem presenting to the decision maker. The material clinical problem has been analysed above as the clinical state of the patient and of their treatment. These assessments of state depend on the variables recorded during the monitoring stage. So, the material state assessment required is defined by the treatment decisions and the patient state assessment. The variables monitored on the ITU at the Mayday are defined in the systems analysis above and by the patient state assessment below.

The decision tree with the goals and conditions for the treatment choices is described below. Derived from the conditions for the treatment decisions is the required patient state assessment to choose which options to implement.

6.3 PROTOCOL FOR CVVHD TREATMENT DECISION MAKING

The protocol described in this section was elicited from a series of structured interviews with Dr Steven Morgan, at the Mayday ITU. The structure of the protocol is defined by the analysis of decision making given above. The protocol includes treatment goals and the conditional propositions attached to the nodes of the decision tree in figure 6.1. The nodes and the branches of the decision tree have been defined according to the set of decision options which exist for operating CVVHD. These have been split into levels denoting the sequence of decisions which must be active before proceeding deeper into the decision making. Thus level A decisions must be active before proceeding to level B. The status of the options recommended represent the decision state at that point in time. Thus the decision state is dynamic.

6.3.1 Actions, Goals and Conditions for the Knowledge Based Decision Making

DECISION NUMBER: A1

DECISION DESCRIPTION: TO BEGIN RRT OR NOT?

HOW ACTION IS CHOSEN: **IF** any of the T1 conditions are satisfied **AND** none of the T2 conditions are satisfied then begin treatment **ELSE** do not begin RRT

ACTION T1: BEGIN RRT TREATMENT ON PATIENT

GOAL(S) OF ADMINISTERING TREATMENT:

IN GENERAL TERMS:

To prevent the patient's death from the metabolic affects of acute renal failure; these being fluid overload (leading to pulmonary oedema), acidosis, uraemia and hyperkalaemia.

MORE PRECISELY:

A) To keep the patient in the state of fluid balance prescribed by the physician for each 24 hour period, where the RRT fluid balance is the balancing figure in the total patient fluid balance equation.

B) To reach a base excess level of ≥ -10 mmol/l within 6 hours of beginning RRT, and then to maintain this level.

C) To reach a urea concentration less than 30 mmol/l AND a creatinine concentration of less than 350 μmol/l within 2 days of beginning RRT, and then to maintain them through out the treatment period.

D) To reach a plasma potassium concentration in the range 3.5 to 4.5 mmol/l within 6 hours of beginning RRT, and then to maintain this level.

E) To reach a plasma phosphate concentration in the range 0.8 to 2.0 mmol/l within 2 days of beginning RRT, and then to maintain this level.

CONDITIONS FOR BEGINNING RRT:-

CONDITIONS BASED ON ABSOLUTE REFERENCES FOR BEGINNING RRT

1) If the urea level is high, > 30 mmol/l **AND** the creatinine is high, > 150 μmol/l **AND** the patient is not dehydrated **AND** the intravascular filling is adequate then start RRT.

2) If the potassium concentration is > 6.5 mmol/l despite the patient receiving insulin and dextrose to reduce the concentration and any treatment aimed at correcting acidosis has not been effective then begin RRT.

CONDITIONS BASED ON RATE OF CHANGE MEASUREMENTS

1) Rate of change in the concentration of urea is ≥ 10 mmol/l per day **AND** rate of change in the concentration of creatinine is ≥ 100 μmol/l per day for the previous two days then begin RRT treatment.

OR

2) Rate of change in potassium has been ≥ 0.5 mmol/l per day for the previous six hours.

OR

3) The patient is overhydrated, or there is evidence of pulmonary oedema, and the patient has been oliguric (urine volume ≤ 500 ml/day) for the previous two days.

ACTION T2: DO NOT BEGIN RRT

GOAL(S) FOR NOT STARTING RRT

IN GENERAL TERMS:

To allow the kidneys of the patient to remain self supporting for the next 12 hour prescription period, **AND** not to degrade the patient's state i.e. not to increase the patient's chances of dying.

MORE PRECISELY:

A) Without the aid of RRT to allow the patient's kidneys to maintain the fluid balance as prescribed by the physician, and adequate plasma concentrations of: base excess > -10 mmol/l , urea < 30 mmol/l, creatinine < 350 μmol/l, phosphate in the range 0.8 to 2 mmol/l, and potassium in the range 3.5 mmol/l to 4.5 mmol/l.

B) Not to cause a further drop in the blood pressure when the patient is critically hypotensive (systolic blood pressure below 70 mmHg).

CONDITIONS FOR NOT STARTING RRT

1) If the patient is in a state of hypotension which has not responded to any intervention such as drug therapy (refractory hypotension).

OR

2) If the patient is suffering a massive uncontrollable bleed.

DECISION NUMBER: A2

DECISION DESCRIPTION: TO CONTINUE WITH RRT OR NOT?

HOW ACTION IS CHOSEN: **IF** any of the T1 conditions are satisfied **AND** none of the T2 conditions are satisfied then continue treatment **ELSE** do not continue RRT

ACTION T1: CONTINUE WITH RRT

GOAL(S) OF ADMINISTERING TREATMENT:

IN GENERAL TERMS:

To prevent the patient's death from the metabolic affects of acute renal failure; these being fluid overload (leading to pulmonary oedema), acidosis, uraemia and hyperkalaemia.

MORE PRECISELY:

A) To keep the patient in the state of fluid balance prescribed by the physician for each 24 hour period, where the RRT fluid balance is the balancing figure in the total patient fluid balance equation.

B) To reach a base excess level of ≥ -10 mmol/l within 6 hours of beginning RRT, and then to maintain this level.

C) To reach a urea concentration less than 30 mmol/l AND a creatinine concentration in less than 350 μmol/l within 2 days of beginning RRT, and then to maintain them through out the treatment period.

D) To reach a plasma potassium concentration in the range 3.5 to 4.5 mmol/l within 6 hours of beginning RRT, and then to maintain this level.

E) To reach a plasma phosphate concentration in the range 0.8 to 2.0 mmol/l within 2 days of beginning RRT, and then to maintain this level.

CONDITIONS FOR CONTINUING RRT:

1) The plasma creatinine concentration is still above 150 μmol/l.

AND

2) The daily urine output of less than 500ml/day for the previous two days.

ACTION T2: DO NOT CONTINUE RRT

GOAL(S) FOR NOT CONTINUING

IN GENERAL TERMS:

To allow the kidneys of the patient to remain self supporting for the next 12 hour prescription period, or not to degrade the patient's state i.e. not to increase the patient's chances of dying.

MORE PRECISELY:

A) Without the aid of RRT to allow the patient's kidneys to maintain the fluid balance as prescribed by the physician, and adequate plasma concentrations of: base excess > -10 mmol/l , urea < 30 mmol/l, creatinine < 350 μmol/l, phosphate in the range 0.8 to 2 mmol/l, and potassium in the range 3.5 mmol/l to 4.5 mmol/l.

B) Not to cause a further drop in the blood pressure when the patient is critically hypotensive (systolic blood pressure below 70 mmHg).

CONDITIONS FOR NOT CONTINUING WITH RRT

1) If the patient is in a state of hypotension which has not responded to any intervention such as drug therapy (refractory hypotension).

OR

2) If the patient is suffering a massive uncontrollable bleed.

OR

3) The patient's renal function is recovering, defined as urine volume > 1 l/day and a fall in creatinine for the previous two days of 50 μmol/l per day from a two day

steady state range of values. A steady state range of values for creatinine is defined as a single value +/- 20 μmol/l.

OR

4) If the patient suffers a cardiac arrest.

OR

5) If the urine volume has been in the range 500 ml to 1000 ml and the potassium concentration is in the safe range 3.5 to 4.5 mmol/l and the acid-base balance of the patient is safe, pH > 7.2 and base excess > -10 mmol/l and there has been a fall from a steady state value of creatinine of 50 μmol/l per day for the previous two days.

DECISION NUMBER: B1

DECISION DESCRIPTION: TO USE CVVHD TREATMENT AS THE SOLE MODE OF RRT OR TO USE ANOTHER MODALITY?

HOW ACTION IS CHOSEN: **IF** any of the T1 conditions are satisfied **AND** none of the T2 conditions are satisfied then use CVVHD as the sole RRT **ELSE** use another treatment regime

ACTION T1: USE CVVHD TREATMENT FOR PATIENT

GOAL(S) OF ADMINISTERING TREATMENT:

IN GENERAL TERMS:

To prevent the patient's death from the metabolic affects of acute renal failure. These being

fluid overload (leading to pulmonary oedema), acidosis, uraemia and hyperkalaemia.

MORE PRECISELY:

A) To keep the patient in the state of fluid balance prescribed by the physician for each 24 hour period. Where the CVVHD fluid balance is the balancing figure in the total patient fluid balance equation.

B) To reach a base excess level of ≥ -10 mmol/l within 6 hours of beginning CVVHD treatment, and then to maintain this level.

C) To reach a urea concentration less than 30 mmol/l AND a creatinine concentration of less than 350 μmol/l within 2 days of beginning CVVHD treatment, and then to maintain them through out the treatment period.

D) To reach a plasma potassium concentration in the range 3.5 to 4.5 mmol/l within 6 hours of beginning CVVHD treatment, and then to maintain this level.

E) To reach a plasma phosphate concentration in the range 0.8 to 2.0 mmol/l within 2 days of beginning CVVHD treatment, and then to maintain this level.

CONDITIONS FOR USING CVVHD TREATMENT:

1) The conditions for starting, or continuing, with CVVHD are the same as for general RRT, i.e. use CVVHD unless there are indicators for not using CVVHD.

ACTION T2: USE ALTERNATIVE RRT REGIME

GOAL(S) FOR USING AN ALTERNATIVE RRT REGIME

IN GENERAL TERMS:

To more effectively treat the patient by using an alternative RRT treatment regime.

MORE PRECISELY:

A) To use an alternative RRT treatment regime, involving the use of intermittent haemodialysis (IHD), or Peritoneal haemodialysis.

CONDITIONS FOR USING AN ALTERNATIVE RRT

1) If patient is ITU independent (i.e. they no longer require the level of care provide by the ITU), then consider treating renal failure with IHD.

2) If despite a filter change 24 hours previously, and its effective subsequent operation, the rate of change in the concentration of urea is ≥ 10 mmol/l per day **and** rate of change in the concentration of creatinine is ≥ 100 μmol/l per day for the previous day AND CVVHD has been administered for at least 2 days then either: 1) Stop CVVHD at the end of the next prescription period and begin Intermittent Haemodialysis treatment; or 2) Run CVVHD and IHD together. The decision making model for these decisions is beyond the scope of this decision model.

3) The patient is suffering from suspected lactic acidosis, this will initially observed as a falling pH and base excess despite the patient having received CVVHD treatment for 12 or more hours, (base excess ≤ -10 mmol/l and lactate plasma concentration ≥ 5 meq/l and pH ≤ 7.2) then discontinue CVVHD immediately and begin IHD (go to the IHD decision support module in the Patient Management System).

4) If the patient cannot tolerate prostacyclin and the use of heparin will or does cause bleeding problems then discontinue with CVVHD. The intolerance of prostacyclin will be indicated by a fall in the patient's blood pressure (hypotension) and a

slowing of the heart rate (bradycardia).

DECISION NUMBER: C1

DECISION DESCRIPTION: TO ADD POTASSIUM TO THE DIALYSATE SOLUTION OR NOT?

HOW ACTION IS CHOSEN: **IF** any of the T1 conditions are satisfied **AND** none of the T2 conditions are satisfied then add 3 mmol/l to the dialysate **ELSE** do not add any potassium to the dialysate.

ACTION T1: DO ADD POTASSIUM TO THE DIALYSATE

GOAL(S) OF ADDING POTASSIUM TO THE DIALYSATE:

IN GENERAL TERMS:

To prevent the plasma concentration of potassium becoming critically low (hypokalaemia).

MORE PRECISELY:

A) To achieve a potassium concentration in the range 3.5 mmol/l to 4.5 mmol/l within six hours of starting to add potassium to the dialysate.

CONDITIONS FOR ADDING POTASSIUM:

1) The plasma concentration is in the range 3.0 to 3.5 mmol/l.

2) If a bolus of potassium was given to the patient 1 hour previously and the potassium concentration is now in the range 3.0 to 4.0 mmol/l then add potassium to the dialysate.

ACTION T2: DO NOT ADD POTASSIUM TO THE DIALYSATE

GOALS FOR NOT ADDING POTASSIUM

IN GENERAL TERMS:

To allow for other injections of potassium, to prevent the patient becoming hyperkalaemic; not to elevate the potassium concentration above the target range.

MORE PRECISELY:

A) To allow the patient to maintain a potassium concentration in the range 3.5 to 4.5 mmol/l within 6 hours of the addition of the potassium to the dialysate.

CONDITIONS FOR NOT ADDING POTASSIUM TO DIALYSATE

1) If the patient's potassium concentration is less than 3 mmol/l then do not add potassium to the dialysate and give a bolus of potassium chloride.

OR

2) If the patient's potassium concentration is greater than 4.5 mmol/l do not add any potassium to dialysate.

DECISION NUMBER: C2

DECISION DESCRIPTION: TO USE A 2 LITRE PER HOUR OR 1 LITRE PER HOUR DIALYSATE INFUSION RATE?

HOW ACTION IS CHOSEN: **IF** any of the T1 conditions are satisfied then use a 2 l/hour infusion rate **OR** if the T2 conditions are satisfied use a 1 l/hour infusion rate

ACTION T1: USE A 2 LITRE PER HOUR DIALYSATE INFUSION RATE

GOAL(S) OF USING A 2 LITRE PER HOUR DIALYSATE INFUSION RATE:

IN GENERAL TERMS:

To sufficiently remove excess potassium, phosphate, uraemic catabolites (urea and creatinine taken to be indicators of their removal) and to introduce additional buffer into the patient.

MORE PRECISELY:

A) To achieve, within 6 hours of an alteration in the rate of infusion and then maintain, a potassium concentration in the range 3.5 mmol/l to 4.5 mmol/l.

B) To achieve, within 2 days of an alteration in the rate of infusion and then maintain, a urea concentration less than 30 mmol/l and creatinine less than 350 μmol/l.

C) To achieve, within 6 hours of an alteration in the rate of infusion and then maintain, a base excess above -10 mmol/l.

D) To achieve, within 2 days of an alteration in the rate of infusion and then maintain, a phosphate concentration in the range 0.8 mmol/l to 2 mmol/l.

CONDITIONS FOR USING A 2 LITRE PER HOUR DIALYSATE INFUSION

1) Depends on when the treatment began. If the treatment has begun within the last two days then go to condition 1A. If treatment was begun more than 2 days ago then go to condition 1B.

TREATMENT STARTED IN THE PREVIOUS TWO DAYS

1A) If the treatment began in the previous two days then always use a 2 l/h dialysate infusion rate.

TREATMENT STARTED MORE THAN TWO DAYS AGO

1B) If the potassium concentration is > 4.5 mmol/l

2B) If the plasma concentration of phosphate is > 2 mmol/l

3B) If the plasma base excess is < -10 mmol/l.

4B) If the creatinine concentration is > 350 μmol/l

5B) If the urea concentration is > 30 mmol/l

ACTION T2: USE A 1 LITRE PER HOUR DIALYSATE INFUSION RATE

GOALS FOR USING A 1 LITRE PER HOUR DIALYSATE INFUSION RATE

IN GENERAL TERMS:

To sufficiently remove excess potassium, phosphate, uraemic catabolites (urea and creatinine taken to be indicators of their removal) and to introduce additional buffer into the patient. Whilst ensuring that the patient does not become over dialysed, removing too much potassium or phosphate from the patient.

MORE PRECISELY:

A) To achieve, within 6 hours of an alteration in the rate of infusion and then maintain, a potassium concentration in the range 3.5 mmol/l to 4.5 mmol/l.

B) To achieve, within 2 days of an alteration in the rate of infusion and then maintain,

a urea concentration less than 30 mmol/l and creatinine less than 350 μmol/l.

C) To achieve, within 6 hours of an alteration in the rate of infusion and then maintain, a base excess above -10 mmol/l.

D) To achieve, within 2 days of an alteration in the rate of infusion and then maintain, a phosphate concentration in the range 0.8 mmol/l to 2 mmol/l.

CONDITIONS FOR USING A DIALYSATE INFUSION OF 1 LITRE PER HOUR

1) Depends on when the treatment began. If the treatment has just begun then got condition 1A if treatment was begun more than 2 days ago then go to condition 1B.

TREATMENT STARTED IN THE PREVIOUS TWO DAYS

1A) If treatment began in the previous two days then do not use a 1 l/h dialysate infusion rate.

TREATMENT STARTED MORE THAN TWO DAYS AGO

1B) If the potassium concentration is < 4.5 mmol/l and > 3.5 mmol/l

2B) If the plasma concentration of phosphate is < 2 mmol/l and > 0.8 mmol/l

3B) If the plasma base excess is > -10 mmol/l.

4B) If the creatinine concentration is < 350 μmol/l

5B) If the urea concentration is < 30 mmol/l

DECISION NUMBER: C3

DECISION DESCRIPTION: WHETHER TO USE HEPARIN AS THE ANTICOAGULANT INFUSION IN THE BLOOD CIRCUIT OR NOT?

HOW ACTION IS CHOSEN: **IF** any of the T1 conditions are satisfied then use a heparin infusion **OR** if the T2 conditions are satisfied then use an alternative anti-coagulant regime.

ACTION T1: USE HEPARIN AS THE ANTI-COAGULANT INFUSION

GOALS FOR USING HEPARIN AS THE ANTI-COAGULANT INFUSION

IN GENERAL TERMS:

To prevent the extracorporeal blood circuit becoming clotted without endangering the life of the patient.

MORE PRECISELY:

A) To prevent the blood circuit clotting for at least 48 hours without requiring a change of filter.

B) Not to degrade the patient's clotting capability, to keep the patient's PTT less than twice the normal value.

C) Not to cause the patient to lose more blood from their vessels.

CONDITIONS FOR USING HEPARIN FOR THE ANTI-COAGULANT INFUSION

1) The patient has not received any surgery in the previous 24 hours

AND

2) The patient is haemostatically stable, i.e. not bleeding.

ACTION T2: DO NOT USE HEPARIN FOR THE ANTI-COAGULANT INFUSION

GOAL(S) OF USING AN ALTERNATIVE ANTI-COAGULANT REGIME:

IN GENERAL TERMS:

To prevent the extracorporeal blood circuit becoming clotted for patient's who are at a high risk of bleeding.

MORE PRECISELY:

A) To prevent the blood circuit clotting for at least 48 hours without requiring a change of filter.

CONDITIONS FOR USING AN ALTERNATIVE ANTI-COAGULANT REGIME

1) The patient has undergone surgery within the previous 24 hours, then if the patient can tolerate prostacyclin use it for the infusion.

2) There is evidence the patient is suffering continuing controlled blood loss.

3) The patient is suffering from ARDS (adult respiratory distress syndrome), also known as shocked lung.

DECISION NUMBER: C4

DECISION DESCRIPTION: WHETHER TO CHANGE THE FILTER OR NOT ?

HOW ACTION IS CHOSEN: **IF** any of the T1 conditions are satisfied then change the filter **OR** if the T2 conditions are satisfied then do not change the filter.

ACTION T1: CHANGE THE FILTER

GOAL(S) OF CHANGING THE FILTER

IN GENERAL TERMS:

To improve the ultrafiltrate volume, to improve the clearance of uraemic catabolites, to not increase the chances of patient infection, to prevent the loss of the patient's blood due to a ruptured filter, and to prevent the filter from becoming clotted.

MORE PRECISELY:

A) To increase the ultrafiltrate volume above 100 ml/hour and up to as high as around 1,000 ml/hour.

B) To attempt to keep the rate of rise in creatinine less than 100 μmol/l per day and the rate of rise of urea less than 10 mmol/l per day.

C) To reduce the risk of infection from the extracorporeal circuit.

D) To prevent interference with the patient's blood flow.

CONDITIONS FOR CHANGING THE FILTER

1) The ultrafiltrate volume is less than 100 ml/hour for the previous two hours.

2) Blood is observed in the dialysate circuit.

3) The blood flow stops.

4) If urea concentration is rising at a rate of 10 mmol/l day and creatinine is rising at a rate of 100 μmol/l per day for 2 days or more.

5) If the filter was last changed more than 72 hours ago. (The filter must be changed before it has been used for 72 hours as this presents a risk of infection to the patient.)

ACTION T2: DO NOT CHANGE THE FILTER

GOALS FOR NOT CHANGING THE FILTER

IN GENERAL TERMS:

To allow for the continuous dialysis of the patient and the goals for the treatment are being satisfied.

MORE PRECISELY:

A) The goals for the treatment stated under the decisions number A1 are being satisfied.

B) For the patient to continuously receive dialysis for a continuous 24 hour period.

CONDITIONS FOR NOT CHANGING THE FILTER

1) All of the goals stated for decision A1 and A2 are being satisfied.

2) The filter was changed ≤ 72 hours previously.

DECISION NUMBER: D1

DECISION DESCRIPTION: TO ADD POTASSIUM TO THE REPLACEMENT FLUID SOLUTION OR NOT?

HOW ACTION IS CHOSEN: **IF** any of the T1 conditions are satisfied **AND** none of the T2 conditions are satisfied then add 3 mmol/l to the replacement fluid **ELSE** do not add any potassium to the replacement fluid.

ACTION T1: DO ADD POTASSIUM TO THE REPLACEMENT FLUID

GOAL(S) OF ADDING POTASSIUM TO THE REPLACEMENT FLUID:

IN GENERAL TERMS:

To prevent the plasma concentration of potassium becoming critically low (hypokalaemia).

MORE PRECISELY:

A) To keep the patient's potassium concentration in the range 3.5 mmol/l to 4.5 mmol/l within 6 hours of beginning the addition to the replacement fluid.

CONDITIONS FOR ADDING POTASSIUM:

1) The plasma concentration is in the range 3.0 to 3.5 mmol/l.

AND

2) The addition of potassium to the dialysate solution began more than 6 hours ago.

ACTION T2: DO NOT ADD POTASSIUM TO THE REPLACEMENT FLUID

GOALS FOR NOT ADDING POTASSIUM

IN GENERAL TERMS:

To allow for other injections of potassium, to prevent the patient becoming hyperkalaemic; not to elevate the potassium concentration above the target range.

MORE PRECISELY:

1) To allow the patient to maintain a potassium concentration in the range 3.5 to 4.5 mmol/l within 6 hours of the addition of the potassium to the replacement fluid.

CONDITIONS FOR NOT ADDING POTASSIUM TO REPLACEMENT FLUID

1) If the patient's potassium concentration is less than 3 mmol/l then give a bolus of potassium chloride.

OR

2) If the patient's potassium concentration is greater than 3.5 mmol/l do not add any potassium to replacement fluid.

OR

3) Potassium was added to the dialysate less than 6 hours ago.

DECISION NUMBER: D2

DECISION DESCRIPTION: VOLUME OF INFUSION TO BE USED FOR HEPARIN INFUSION?

HOW ACTION IS CHOSEN: The CVVHD protocol states that a standard mix is 5000 units of heparin per litre of saline, i.e. a concentration of 5000 units/litre. Therefore, the infusion volume depends on the dose prescribed by the physician.

ACTION : FIXING OF THE ISOTONIC FLUID VOLUME TO INFUSE THE HEPARIN

GOAL(S) USING A VOLUME OF FLUID TO INFUSE THE HEPARIN:

IN GENERAL TERMS:

To dilute the heparin sufficiently that the dosage can be accurately administered using the anti-coagulation pump on the dialysis equipment.

MORE PRECISELY:

A) To ensure the heparin dose calculated using the protocol below is delivered in the prescribed time.

PROTOCOL FOR CALCULATING THE HEPARIN DOSE

FOR PTT < TWICE NORMAL

infusion dose = 10 u/kg per hour delivered in a volume of 5u/ml.

bolus dose = 20 u/kg delivered in a bolus volume of 30 ml

FOR PTT >= TWICE NORMAL

infusion dose = 5 u/kg per hour delivered in a volume of 5u/ml.

bolus dose = 10 u/kg delivered in a bolus volume of 30 ml or 50 ml

DECISION NUMBER: D3

DECISION DESCRIPTION: VOLUME OF INFUSION TO BE USED FOR PROSTACYCLIN INFUSION?

HOW ACTION IS CHOSEN: Dependent on the dose of prostacyclin required in the infusion, the patient's body weight and the concentration of the stock solution to set the infusion rate.

ACTION : FIXING OF THE VOLUME TO INFUSE THE PROSTACYCLIN

GOAL(S) USING A VOLUME OF FLUID TO INFUSE THE PROSTACYCLIN:

IN GENERAL TERMS:

To dilute the prostacyclin sufficiently that the dosage can be accurately administered using the anti-coagulation pump on the dialysis equipment.

MORE PRECISELY:

A) To ensure the prostacyclin dose calculated using the protocol is delivered in the prescribed time.

PROTOCOL FOR CALCULATING THE PROSTACYCLIN DOSE

infusion dose = a trial dose of 5 ng/kg per min is given for 20 minutes. If the patient is prostacyclin tolerant then continue to administer this dose of 300 ng/kg per hour.

infusion rate = (dose * body weight)/conc of stock solution

DECISION NUMBER: E1

DECISION DESCRIPTION: VOLUME OF REPLACEMENT FLUID?

HOW ACTION IS CHOSEN: Dependent on the volume of all other infusions given to the patient (the final balancing figure).

ACTION : FIXING OF THE ISOTONIC FLUID VOLUME DELIVERED IN THE DIALYSATE CIRCUIT

GOAL(S) USING REPLACEMENT FLUID:

IN GENERAL TERMS:

To balance out the patient's fluid volume.

MORE PRECISELY:

A) To adhere to the 24 hour fluid prescription for the patient.

PROTOCOL FOR CALCULATING THE REPLACEMENT FLUID VOLUME

replacement fluid volume = planned fluid input volume - ultrafiltrate volume +/- target fluid balance

6.4 PROBLEM STATE ASSESSMENT FOR CVVHD TREATMENT PROTOCOL

The material problem assessment in a clinical setting relies on establishing the material state of the patient and of their treatment, through the implementing of monitoring decisions. Which treatment and patient state assessments are required in the specified protocol have been defined above. These are condition sensitive propositions describing the observed state of patient and treatment. By comparing the data set defined by the systems analysis above with the one defined by the patient and treatment state decision variables below, it can be seen there are differences between the two. The proposed decision support system is to solely support the above protocol and thus the data set required is the one below. How the two data sets are to be used in the system design will be considered in the next system design chapter.

6.4.1 Patient State Assessment

For the patient state assessment the monitored variables are classified into ranges before being used by the clinician in the decision making process. A possible framework for performing this classification is specified below.

Applying the *a priori* concept of space and time, the assessment of state relates to a particular patient at a particular time. There will be a series of assessments made in a chronological sequence. The relation between a series of assessments is assessed to identify trends in changes in the patient state. Thus, two classifications of state assessment will be used in the system:

i) STATIC PATIENT STATE ASSESSMENT:

A single patient state assessment either derived, or user entered, representing the patient state at a single point in time and not related to any prior state assessment. Where quantitative variables need to be classified into ranges the clinical classification of single data measurements are put into one of five classes, in a similar way to the assessments performed in the TANIT project (Uppsala University, 1993). The following qualitative

scale is proposed for this classification:

a) CRITICALLY HIGH - indicating that some intervention must be made to reduce the reading.

b) HIGH - indicating that the reading is above the target range and should perhaps be monitored more closely to ensure it does not become critical.

c) IN TARGET RANGE - the measurement is within an acceptable range

d) LOW - indicating that the reading is below the target range and should perhaps be monitored more closely to ensure it does not become critical.

e) CRITICALLY LOW - indicating that some intervention must be made to increase the reading.

ii) DYNAMIC STATE ASSESSMENT:

Two or more measurements on the patient, used to calculate and then classify the rate of change of the variable. The rate of change will be classified into one of the following five states:

a) RISING RAPIDLY/ACUTELY - the rate of increase of the variable could be life threatening.

b) RISING - the value is rising more quickly than the acceptable limits

c) STABLE - the rate of change is within acceptable limits.

d) FALLING - the value is decreasing more quickly than the acceptable limits

e) RAPIDLY FALLING, OR ACUTELY FALLING - the rate of decrease of the

variable could be life threatening.

6.4.2 Patient States to be Assessed

The CVVHD treatment decisions rely on the following categories of patient states:

- fluid state
- acid-base state
- electrolyte state
- state of catabolites
- urine volume
- cardiovascular state
- haemostasis
- ITU dependency
- anticoagulant tolerance
- respiratory state
- body mass

A description of how these states of the patient are assessed is given below.

6.4.2.1 Fluid state

STATIC STATE ASSESSMENT

i) Absolute volume assessment defined as either:

(a) Overhydrated, total body fluid volume overload. (High)

(b) Uvoleamic, total body fluid volume normal. (Target)

(c) Dehydrated, total body fluid volume deficit. (Low)

ii) The prescribed volume figure for fluid balance for the current 24 hour period.

iii) The intravascular filling is adequate.

iv) Evidence of pulmonary oedema.

DYNAMIC STATE ASSESSMENT

i) Fluid volume balance for the previous 24 hours

ii) Accumulated fluid balance in the current treatment period.

iii) The remaining fluid to be lost or gained in the current treatment period.

6.4.2.2 Electrolyte state

STATIC STATE ASSESSMENT

Plasma concentration of:

i) Potassium:

(a) >= 6.5 mmol/l (CRITICALLY HIGH)

(b) > 4.5 mmol/l and < 6.5 mmol/l (HIGH)

(c) >= 3.5 to <= 4.5 mmol/l (TARGET)

(d) > 3.0 to < 3.5 mmol/l (LOW)

(e) <= 3 mmol/l (CRITICALLY LOW)

I) Phosphate

(a) > 2.0 mmol/l (HIGH)

(b) <= 0.8 to >= 2.0 mmol/l (TARGET)

(c) < 0.8 mmol/l (LOW)

DYNAMIC STATE ASSESSMENT

i) Potassium

(a) ≥ 0.5 mmol/l per day (RISING RAPIDLY)

(b) < 0.5 mmol/l per day (RISING)

6.4.2.3 State of catabolites

STATIC STATE ASSESSMENT

i) Urea

(a) > 30 mmol/l (HIGH)

(b) <= 30 mmol/l (TARGET)

ii) Creatinine

(a) > 350 µmol/l (HIGH)

(b) ≥ 150 µmol/l to ≤ 350 µmol/l (TARGET VALUE)

(c) < 150 μmol/l (LOW)

DYNAMIC STATE ASSESSMENT

i) Urea rate of change

(a) ≥ 10 mmol/l per day (RISING RAPIDLY)

(b) < 10 mmol/l per day (RISING)

ii) Creatinine rate of change

(a) ≥ 100 μmol/l per day (RISING RAPIDLY)

(b) < 100 μmol/l per day (RISING)

(c) +/- 20 μmol/l per day (STABLE)

(d) > 50 μmol/l per day (FALLING)

6.4.2.4 Urine volume

DYNAMIC STATE ASSESSMENT

i) Urine production rate

(a) urine volume > 1 l/day (TARGET)

(b) urine volume > 500 ml/day to < 1000 ml/day (LOW)

(c) urine volume ≤ 500 ml/day (oliguric) (CRITICALLY LOW)

6.4.2.5 Acid-base state

STATIC STATE ASSESSMENT

i) Blood pH (in acute renal failure concerned with treating metabolic acidosis)

(a) >= 7.3 ,and <= 7.45 (TARGET VALUE)

(b) > 7.2 ,and < 7.3 (LOW)

(c) <= 7.2 (CRITICALLY LOW)

ii) Base excess

(a) < -10 mmol/l (LOW)

(b) ≥ -10 mmol/l (TARGET)

iii) Suspected lactic acidosis. (This will initially observed as a falling pH and base excess despite the patient having received CVVHD treatment for 12 or more hours. The measured values will be in the ranges: base excess ≤ -10 mmol/l; lactate plasma concentration ≥ 5 meq/l, and pH ≤ 7.2.)

6.4.2.6 Cardiovascular state

STATIC STATE ASSESSMENT

i) Systolic blood pressure below 70 mmHg (CRITICALLY LOW).

ii) Refractory hypotension, occurs when the patient is in a state of hypotension which has not responded to any intervention such as drug therapy.

iii) Patient suffers a cardiac arrest.

6.4.2.7 Haemostasis

DYNAMIC STATE ASSESSMENT

i) The patient is haemostatically stable.

ii) If the patient is suffering a uncontrollable bleed.

iii) There is evidence the patient is suffering continuing controlled blood loss.

6.4.2.8 ITU dependency

STATIC STATE ASSESSMENT

If patient is ITU independent (i.e. they no longer require the level of care provide by the ITU).

6.4.2.9 Anticoagulant tolerance

STATIC STATE ASSESSMENT

i) The intolerance of prostacyclin will be indicated by a fall in the patient's blood pressure (hypotension) and a slowing of the heart rate (bradycardia).

ii) Coagulation times

(a) PTT >= twice normal

(b) PTT < twice normal

6.4.2.10 Respiration

The patient is suffering from ARDS (adult respiratory distress syndrome), shocked lung)

6.4.2.11 Body weight

Estimate of patient weight

6.4.3 Patient's Treatment State Assessment

The treatment actions which have an impact on the CVVHD decision making protocol are listed below.

6.4.3.1 Potassium treatment

i) The patient has received insulin and dextrose to reduce the plasma potassium concentration and no change has been observed.

ii) A bolus of potassium chloride given to the patient 1 hour or more previously

6.4.3.2 Treatment for acid base disorders

Patient receiving treatment aimed at correcting acidosis.

6.4.3.3 Surgery

The patient received any surgery in the previous 24 hours.

6.4.3.4 CVVHD treatment state

The state of the CVVHD treatment is defined by the possible actions in the decision tree

and the predetermined fixed settings. The CVVHD treatment decision making advising on the treatment set up is affected by the states defined below.

FILTER STATE

The time of the last filter change. The age of the filter which affects the decision making and require classification are:

i) Last filter change less than 24 hours ago

ii) Last filter change 72 hours ago.

iii) The filter was changed < 72 hours previously.

TREATMENT TIME

The time the CVVHD treatment has been running:

i) CVVHD has been administered for >= 2 days

ii) The patient having received CVVHD treatment for >= 12

BLOOD IN DIALYSATE

Blood observed in the dialysate circuit needs to be recorded.

FLOW STOPS

Any blood flow stoppage in the extracorporeal circuit.

DIALYSATE COMPOSITION

The timing of the addition of potassium to the dialysate divides into two bands:

i) Addition of potassium began more than 6 hours ago.

ii) Potassium added <= 6 hours ago.

FLUIDS

The calculation for the replacement fluid volume requires:

i) The planned fluid input volume.

ii) The ultrafiltrate volume.

In addition to a record of the ultrafiltrate volume, the decision making needs to know when the ultrafiltrate volume has been below 100ml/hour for two consecutive hourly measurements.

6.5 TRUTH OF KNOWLEDGE BASE

As discussed in section 3.3.5 applying the mental model of belief, knowledge is acquired through the entertaining of beliefs and then assenting to them. Then by the behaviourist's model the acquired knowledge is applied in actions. Thus, through experience in a domain a knowledge base of propositions is constructed relating to solving problems in the domain. The notion of expertise is centred on the assumption that the more experience gained in a domain leads to more knowledge of the domain. Thus, using a clinical expert as an initial source of clinical knowledge is a good starting point for constructing a knowledge base. However, using authority as source of truth, as in justified true belief, has been described as a non-philosophical source; non-philosophical because authorities disagree and accepting truth should involve some critical philosophical reflection. Therefore, any knowledge base elicited from an expert source needs to tested according to the three philosophical tests of truth: correspondence; coherence, and pragmatism.

The correspondence test of truth can be applied to the propositions describing the patient state, and the state of their treatment; the truth of the proposition relying on the observation of the phenomena which is described by it. The observation can proceed the proposition, or for confirmation of a proposition the observation can be the verification of its truth.

The nature of clinical propositions describing the state of patients varies from the single measurement proposition to the grouping of single measurements into a diagnostic categorisation. The general form of the single measurement proposition is "(proposition subject) is (subject property) at (time and date) for (patient x)," the time and the patient identifier fix the time and space the proposition relates to; for example , "Potassium is 4.0 mmol/l at 06:50 on 23/2/96 for patient number 234567." This proposition is based on a single observed measurement of plasma potassium concentration for patient 234567 taken at 06:50. The diagnostic, or high level propositions, are of the form, "Patient number 234567 is in renal failure at 14:00 on 25/3/96." The diagnostic proposition is arrived at by the amalgamation of a number of individual measurements into a single concept of which there is prior knowledge. Thus the process of arriving at the diagnostic proposition is a more complex relying on observation, reason and deep conceptual knowledge. A similar situation applies to treatment propositions where they vary from specific measurements of treatment to general descriptions of the patient treatment. For example, the dialysis extracorporeal blood flow is 100ml/min at 10:00 for patient 234567; which could be part of the proposition "patient 234567 receiving CVVHD treatment."

For the single measurement propositions the observation should define the proposition, thus the truth is confirmed by a prior observation; starting with a proposition and measuring to see if is true is the other way to test its truth. This is applied particularly in diagnostic decision making where a hypothesis is proposed for the diagnosis and this is either confirmed or denied through further observation. For the clinical protocol above the correspondence test is applied to pre-defined propositions and when they correspond to an observed state the condition becomes true. When the proposition is true then specified actions are recommended in response to the material state.

Coherence theory can be applied to a set of observations for logical coherence with one

another. This is done by applying conceptual knowledge of what the relationship of the propositions is expected to be. Any logical exceptions can be used to decide when another observation is required to confirm the initial observation. The coherence test is more relevant to the higher level diagnostic state propositions than the single measurement end of the spectrum of knowledge.

Coherence theory can also be applied to a protocol by logically testing it against knowledge from another source for consistency. The knowledge used for coherence checking could have varying levels of established truth within it; from scientific knowledge as the best established to other clinical opinion as the least established. Considering the analogy of the spectrum of truth described in chapter 3, the knowledge used in the consistency test at the first level should be set against the knowledge with the highest level of established truth. In the field of medicine this is knowledge of medical science, including physiology and pathophysiology. At the other end of the spectrum of truth is other clinical opinion, where the clinical opinion represents the view of another authority and thus does not necessarily represent truth. Therefore, the most fundamental coherence test which can be applied to a clinical protocol is that of consistency with the established scientific theoretical concepts. Where large scale clinical trials are available they can also form the basis for another level of knowledge coherence testing. Other clinical opinion can be used as a basis for comparison, but not for the judgement of absolute truth. The proving of the knowledge base pragmatically has more value philosophically than using one authority's opinion in preference to the other. Unless the opinion of one of the authorities has been rigorously proven to be true using the tests described here. The classifications used in medical science are similar to those used in clinical practice. Therefore, the scientific knowledge applied in the coherence test will relate directly to the corresponding clinical specialism.

Performing the coherence test requires the deductive linking of propositions. Thus, the result of the coherence test is a web of knowledge threaded by logic. The web formed by this process can then be used to give deep justification to the knowledge used in the operation of a decision support system in addition to justifying the truth of the knowledge base.

Following the application of coherence testing the most valuable test of truth in the field of technology applied to medicine is the pragmatic one. This test operates at a higher level, and is a test of the whether the knowledge applied in a practical scenario fulfils its purpose. For example, the highest level purpose of CDS is to improve patient care. To prove the truth of a knowledge base in this context would require the proof of an improvement in patient care. Ultimately this would involve large scale clinical trials, similar to those required for new drug therapies.

At a lower level of the protocol structure decision goals can be attached to each of the decision options, the knowledge contained in each decision node can then be tested pragmatically. The testing of the knowledge base in this way can then be done as part of the initial knowledge base development and during the application of the CDS system to a particular patient. During development testing of the CDS system the conditional propositions can be modified to try and ensure the purpose of the decision is satisfied. Then during the application of the CDS system, if the goals of the decision are not being satisfied then a strategy beyond the scope of the system needs to be tried, for example intervention from a clinical expert. Therefore goals attached to each decision node are important to test the pragmatic validity of applying the knowledge base to a patient. One medium for pragmatically developing and testing the knowledge base is in the form of a computer program. The development of the computer based protocol is described in chapter 7.

6.5.1 Knowledge Base Coherence Testing

The knowledge in each of the decisions of the treatment protocol can be classified as either decision goals, or conditional propositions. Decision goals define the function of the decision when it is in the active, or affirmative, state. Logically the knowledge can be tested for relevance to the diagnosis of the patient state, and for consistency with knowledge of the function of the treatment. Patients treated with CVVHD in the ITU are generally suffering from ATN. The pathophysiology of this condition was defined in section 5.3.3. Table 6.1 shows the comparison between protocol decision goals and the defined pathophysiology and treatment function for option T1 of decision A1. For example

one of the treatment goals is to reduce plasma potassium to less than 4.5mmol/l, this is a relevant goal as a patient suffering from ATN will be suffering from hyperkalaemia due to their bodies inability to excrete potassium using their kidneys. Moreover, the CVVHD process removes excess electrolytes from the patients plasma. Therefore the goal is logically consistent with the characteristics of the patient state and the function of the treatment. These types of logical coherence check can be done in formal way as shown in table 6.1, in addition to informal checking during knowledge elicitation.

The conditional propositions of the protocol can be similarly checked for logical consistency with knowledge of the likely patient state and the treatment function. For example, high levels of urea and creatinine are consistent with the patient not being able to excrete them due to lack of kidney function. Although the raised concentration may be due to a change in the volume of the plasma for example when the patient is dehydrated, which is excluded by the other parts of the treatment condition.

By explicitly showing that the protocol does not contradict more established knowledge it is possible to test the reasonableness of its contents and the functionality of its advice. The advantage of including this as a formal stage of knowledge validation is to question the knowledge early in development and to construct a knowledge base which is built on the foundations of previously defined scientific truth. Moreover, it provides a basis for reasoned justification when the knowledge is applied to generate decision advice.

6.6 SUMMARY

The material problem analysis in chapter 5 identified the treatment used for a patient suffering with ATN on the ITU is CVVHD. In this chapter the models of decision making developed in chapter four have been applied to the analysis and modelling of CVVHD decision making process. The model of the clinical decision making process provides the basis for a computer based simulated decision making advice system described in the next chapter.

Table 6.1a Coherence test of decision goals, for decision A1, option T1.

Decision Goal	Patient state knowledge (Willats, 1987, and Eccles, 1993)	Relevance and reasonableness of goal	Knowledge of haemodialysis (Sargent and Gotch, 1989)	Relevance of action to goal
Potassium in the range 3.5 to 4.5 mmol/l within 6 hours of beginning CVVHD, and then to stay within these limits.	Normal potassium 3.5 to 4.8 mmol/l. Hyperkalaemia can cause cardiac arrest and is associated with ARF. Hypokalaemia can cause respiratory failure and muscle paralysis.	Control of potassium is a relevant goal. The limits proposed are reasonable at this stage of development.	Reduces potassium concentration in the blood flow by diffusion and convection across the dialysis membrane.	Haemodialysis is able to remove potassium from the patient's plasma. Action is relevant.
Phosphate in the range 0.8 to 2.0 mmol/l within 2 days of beginning CVVHD treatment, and then to stay within these limits	Normal phosphate 0.8 to 1.35 mmol/l. Phosphate is raised in renal failure. Acute Hyper-phosphataemia above 1.35 mmol/l causes hypocalcaemia which can be life threatening.	The link with hypocalcaemia is the main threat to life. Perhaps control of calcium concentrations is equally relevant. Upper limit of the goal range requires clarification.	Haemodialysis reduces phosphate concentration in the blood by diffusion and convection across the dialysis membrane.	An effective treatment for reducing phosphate plasma concentrations Action is relevant.

Table 6.1b Coherence test of decision goals, for decision A1, option T1

Decision Goal	Patient state knowledge (Willats, 1987, and Eccles, 1993)	Relevance and reasonableness of goal	Knowledge of haemodialysis (Sargent and Gotch, 1989)	Relevance of action to goal
Base excess above -10 mmol/l within six hours of starting treatment, and then to stay above this limit.	Normal range -2.3 to +2.3 mmol/l (pH around 7.36-7.44) Renal failure → metabolic acidosis, base excess < -6 mmol/l (pH < 7.36) Reduction of base buffer due renal failure can lead to many clinical problems, including cardiac failure.	Relevant to control buffer levels in the presence of metabolic acidosis. The level of base excess to set requires further testing. At present it is between -6 and -10 mmol/l.	Buffer in the dialysate solution diffuses into the patient's plasma to increase buffer levels in the patient.	Increases amount of base buffer in the patient's plasma. Action is relevant.

Table 6.1c Coherence test of decision goals, for decision A1, option T1

Decision Goal	Patient state knowledge (Willats, 1987, and Eccles, 1993)	Relevance and reasonableness of goal	Knowledge of haemodialysis (Sargent and Gotch, 1989)	Relevance of action to goal
urea < 30 mmol/l within 2 days of beginning CVVHD, and then to stay below this limit..	Normal urea is in the range 2.5 to 6.6 mmol/l. Ideally in ARF blood urea should be kept below 35 mmol/l. High urea is an indicator of impaired renal function High urea is a symptom of uraemia which produces effects similar to systemic poisoning.	Goal is relevant to the treatment of uraemia. The limit should be approximately 30 to 35 mmol/l. The time for achieving the goal should perhaps be extended.	Urea is removed from the patient's plasma by diffusion and convection into the dialysate.	An effective treatment for the treatment of uraemia, removing urea, creatinine and the unidentified uraemic toxins

Table 6.1d Coherence test of decision goals, for decision A1, option T1

Decision Goal	Patient state knowledge (Willats, 1987, and Eccles, 1993)	Relevance and reasonableness of goal	Knowledge of haemodialysis (Sargent and Gotch, 1989)	Relevance of action to goal
creatinine < 350 μmol/l within 2 days of starting CVVHD, and then to stay below this limit.	Normal creatinine is in the range 44-124 μmol/l High creatinine is taken as an indicator of impaired renal function and a symptom of uraemia. Paginni (1992) ARF occurs between 265 μmol/l and 442 μmol/l.	Reduction of creatinine is part of compensating for the lost renal function of the patient. The levels of the goal are reasonably consistent with the patient state knowledge.	Creatinine is removed by diffusion and convection into the dialysate.	Haemodialysis is an effective treatment for the control of the levels of creatinine.

Table 6.1e Coherence test of decision goals, for decision A1, option T1

Decision Goal	Patient state knowledge (Willats, 1987, and Eccles, 1993)	Relevance and reasonableness of goal	Knowledge of haemodialysis (Sargent and Gotch, 1989)	Relevance of action to goal
To keep the patient in the state of fluid balance prescribed by the physician for each 24 hour period; where the CVVHD fluid balance is the balancing figure in the total patient fluid balance equation.	"Accurate fluid balance monitoring is essential since overhydration readily produces pulmonary oedema." Patients with renal failure are unable to remove excess water from their bodies. Fluids are required to administer drugs and nutrients to the patient.	Due to the threat to the patient's life accurate fluid control is important.	Ultrafiltration of fluid from the patient's plasma passing through the dialysis allows for the removal of excess fluid.	Haemodialysis can be used to provide fluid "space" in the ARF patient.

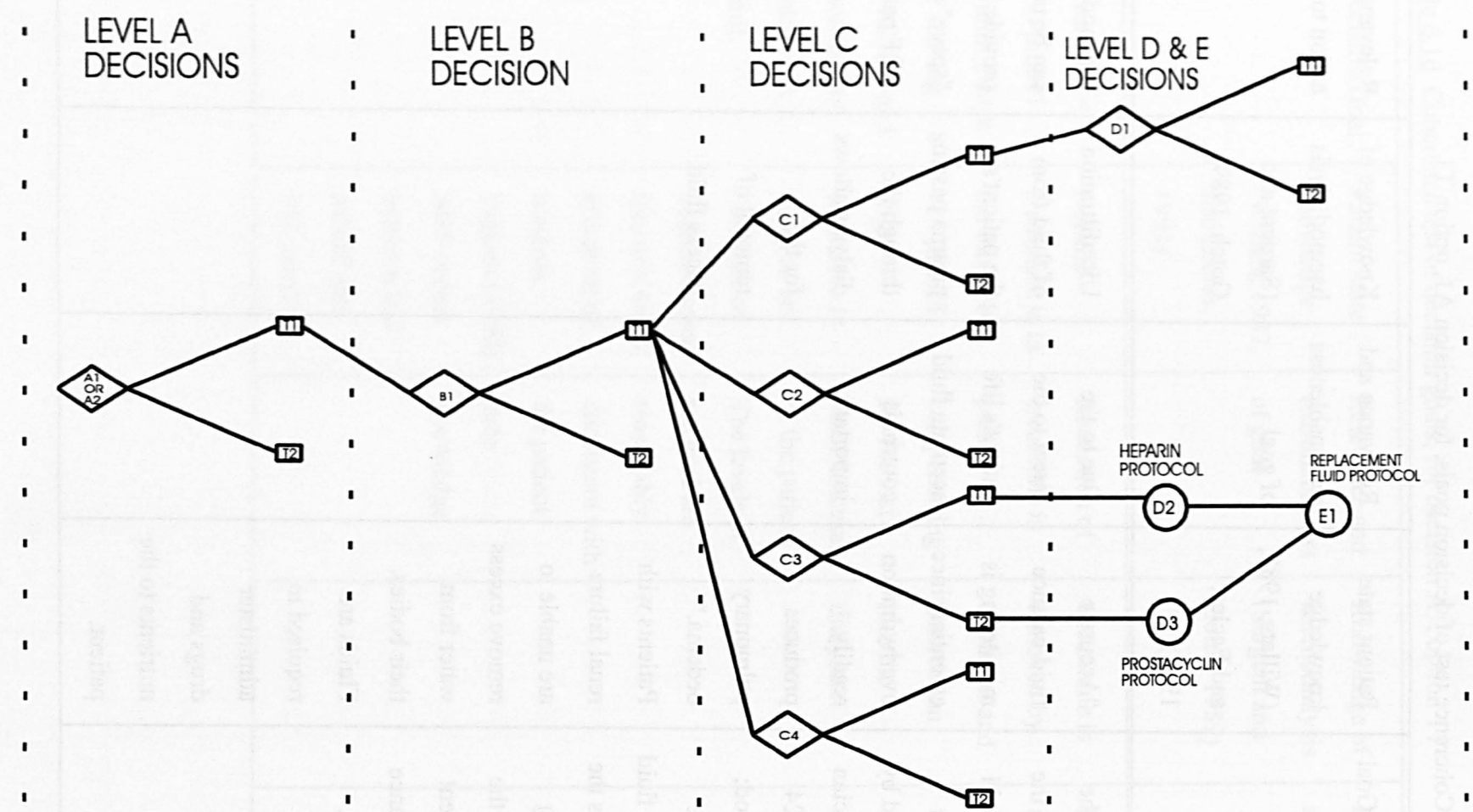


Figure 6.1 Decision tree for CVVHD management

CHAPTER 7

COMPUTER SYSTEM DESIGN AND DEVELOPMENT

7.1 INTRODUCTION

The analysis in the previous two chapters provided a model of the clinical problem, and of the clinical decision making which can be used to control CVVHD treatment. In ontological terms the previous chapter defined the material and idealistic problems to be addressed by the decision support system. In terms of figure 4.11 the detail of the material clinical problem and a model of the relevant clinical decision making has been defined. This chapter describes the development of a computer system proposed for helping to alleviate the clinical problem and to provide treatment advice to the user. The computer system is to act as an information source for the clinical decision maker during assessment of the clinical problem and during their decision making process, figure 7.1.

The clinical problem centres on the management of acute renal failure (ARF) patients on a general ITU. This breaks down into two main problems:

i) Maintaining the fluid balance in ARF patients requires accurate fluid balance calculations.

ii) An expert with experience in managing the CVVHD process will not be available 24 hours a day to offer advice to staff operating the process.

It is proposed to address these problems by the application of a computer based decision support tool with the following functions:

i) A program for charting the fluids for patients receiving CVVHD, presenting numerical and graphical displays of hourly and cumulative patient fluid balance.

ii) A program which offers patient specific advice to the decision maker during the decision making process.

Applying the classifications developed in chapter 4, the first function of the decision support tool can be classified as a knowledge support system. The fluid charting program contains information which can add to the decision maker's knowledge of the material problem being faced. The second program of the proposed system truly provides decision support as it actively simulates the decision making process and offers justified advice, or opinions, on the decision state.

The aim of this chapter is to describe the development of the two functional components of the system, within an integrated systems design. The description will include: specification of the system requirements; specification of the system design; the design and development of the knowledge support system; and the design and development of the decision simulation component.

7.2 SYSTEM REQUIREMENTS

As shown in figure 7.1 the computer system acts as an information store and provider to the clinical decision maker. This information needs to be relevant to the clinical problem and to the clinical decision making process. Therefore the computer system requirements are founded on the problem analysis in the previous two chapters, where the fluid charting system adds to the decision makers knowledge of the problem and the decision support directly simulates the decisions to be made.

In addition, in addressing the clinical problem other qualities are required of the computer system. These general qualities describe how the computer system will interact with the user and perform its function. The general system requirements were derived from visits to, and discussions with, the staff at the Mayday ITU, the renal unit at St Helier, and St

George's Hospital. Supplementary to these visits, references describing the requirements for clinical decision support in intensive care, and expert systems in general (Hunter et al., 1991, Ambroso et al., 1992, Oravec and Travis, 1992, Plant, 1992 and Eliot, 1992) were used to define the requirements. The requirements specified below include the system user groups and the general characteristics required in the system.

7.2.1 User Groups

To determine system requirements it is important to first establish who the end users are likely to be. The system will be required to work in a number of scenarios with different users, or user requirements, in each scenario. It is envisaged that an operational system will be required to work in the following scenarios.

7.2.1.1 Clinical

The main function of the system will be to work in a general ITU on a daily basis. In this situation the following group of users will directly or indirectly interact with the system:

i) The ITU consultant who may not be an expert in managing CVVHD.

ii) A general medical registrar on call throughout the hospital.

iii) Junior doctors working full-time on the ITU.

iv) Specialist ITU nurses with additional experience or training in operating haemodialysis.

v) The dietician concerned with the patient's nutritional needs.

vi) The pharmacist concerned with the patient's drug therapy.

vii) Patients with acute renal failure. The patients treated on the ITU will be of adult

size.

The nurse will have the most interaction with the system. A diagram representing a possible clinical scenario is show in figure 7.2. Addressing the clinical need is the prime concern during development of the system, although the other user groups described below will also have their own requirements for the system.

7.2.1.2 Management

The people primarily interested in management information that could be taken from the system are:

i) The nursing manager responsible for the ITU.

ii) The consultant in charge of the ITU.

7.2.1.3 Maintenance

There are two main pieces of equipment in the CVVHD system which will need maintenance:

i) The haemodialysis equipment. The computer-based management system could be used as a tool in maintaining its effective operation and in this situation the end user would be the ITU nurse or a technician.

ii) The computer-based management system. In the maintenance of the management system itself, a computer professional would be the end user.

If the system is to operate practically on an ITU, the requirements of these groups of end users must be taken into account.

7.2.1.4 System evolution

For the system to be effective after it is first implemented it must be easy to update in order to adapt to technical and medical innovations. The end users that will require access to the system to carry out updates will be:

i) A computer expert

ii) A clinical expert

7.2.2 Clinical User Requirements

7.2.2.1 Design approach

The approach of the project will be to develop a clinical patient management system which emulates current clinical practice. This approach has been adopted to promote the usability of the product. Moreover, a user centred approach will be adopted in the design. Documentation will be produced throughout the design process and manuals on the system operation will be written. The four main stages of the design process of the project development are:

i) Assessment of system requirements, including an analysis of the clinical problem;

ii) The early design phase, to include early prototyping of the system;

iii) Development and testing;

iv) Final acceptance of the system following satisfactory test results.

7.2.2.2 Inputs

Wherever possible, the aim should be to make the data capture automatic, through direct

interfacing between the computer and the dialysis equipment. Thus, the data entry tasks of the nurse should be kept to a minimum. However, there will also have to be a capability to capture some data through manual entry.

The screen interface, where possible, will emulate the present paper method for displaying data. Prompts for recording data will appear on the screen at a pre-determined time. It should be possible to study all the input data on the screen, whether captured automatically or manually. Where necessary it must be possible to easily correct mistakes made in inputting the data. To make effective use of the database only data that are acted on should be recorded.

7.2.2.3 Output

Where possible the output displays should emulate the present method for representing the patient data. If there is no common way of representing the data a graph display will be used. The use of a colour display could be used to enhance the capabilities for producing clear graphs. It should be possible at any time to easily obtain a print-out of what is shown on the screen. The screens displaying output and input information should be easy to move between. The system will be required to produce the following reports:

i) A paper summary of the patient's state to be kept on the ITU files;

ii) A plan for the CVVHD therapy for the next 24 hour period.

It would aid the production of reports if the system has some word processing capability.

7.2.2.4 Time response

The database system is replacing a pen and paper system that offers instant data access in the form of a paper chart. Therefore, the database should have as instant response as possible. The knowledge base is offering a decision support function to the medical staff, so it should act so as not to slow down or inhibit the physician's decision process.

7.2.2.5 Integration

The aim is to integrate the system with local ITU and hospital wide networks. This will allow the automatic transfer of data on the patient to and from other parts of the hospital. Integration is one of the major benefits of computer systems and from papers on expert systems it seems that past systems have not fully exploited the potential in this area (Oravec and Travis, 1992, Hunter et al., 1991).

7.2.2.6 Knowledge base

The knowledge base used to offer advice on a patient's CVVHD treatment must display the following characteristics:

i) It must be able to be interrogated by the physician on any suggestion put forward;

ii) To explain its behaviour;

iii) To demonstrate clearly that decision making based on recognised medical knowledge has been used;

iv) To have the capability to be easily updated as medical knowledge changes.

The knowledge to be used will be elicited during interviews with a clinical expert and by observing the CVVHD process. The clinical expert whose knowledge will be used in the knowledge base is Dr Steve Morgan, a nephrologist and ITU consultant.

7.2.2.7 Testing strategy

The fluid charting system and the decision support system will be developed and tested separately. The main stages of testing are:

i) Testing the functionality of the system;

ii) Testing off-line, in real time, using historical data from patients;

iii) Parallel testing of the system in real time on a patient undergoing treatment.

7.2.2.8 Reliability

Taking the computer system as a whole it should meet the reliability standards specified for the dialysis equipment, that is it should not fail more often than the dialysis equipment. The computer needs to be protected from computer viruses. The database will be required to perform validity checks on the input data, and to present reports on any spurious input. For example spurious data could arise where a patient is being moved. It would be desirable to present an indication of the reliability of a suggestion offered in the decision support function. In relation to computer system failure there must be adequate back-up to allow for near complete information retrieval. Resorting to pen and paper records should be a final option. To help achieve good back-up the following steps should be taken:

i) Regular saving of data to the hard disk from the temporary memory store of the computer.

ii) Regular back-up of data on the computer hard disk to a remote data medium.

iii) An uninterruptable power supply to provide a continuous power input to the computer.

7.2.2.9 Maintenance of equipment

The computer system could offer advice on the maintenance of the dialysis equipment. This will include advice on when to change the 'soft' parts of the dialysis equipment, for example the filter change. Moreover, the system could offer advice on the setting up of the equipment for a new patient. For ease of maintenance of the computer system a modular design approach will be adopted. This should aid the fault finding and repair of system faults.

7.2.3 Clinical System Administration Requirements

7.2.3.1 Training

There are conflicting user requirements in this area:

- On the one hand there is a management need to keep costs to a minimum. This would demand on the job training of staff.

- Whilst previous work (INFORM Consortium, 1990) has shown that one of the most important factors in implementing a new computer system is the training of staff; nurses have expressed a preference for this formal training to take place away from the concerns of caring for a patient.

A major criterion for judging the success of a system is how much it is used by the medical staff. Adequate training is needed to encourage system use. Therefore, formal training away from the pressures of patient care should be offered if possible. To support the training of staff help screens will be required. The general help screens will offer advice on how to use the system, whilst specific help screens for the knowledge base will offer advice on the decision making process.

7.2.3.2 Resources

The system will be implemented on a bedside IBM compatible PC. A printer local to the ITU ward will also be needed. This will involve having a connection to the networked printer on the ITU ward. The cost of the hardware required for the implementation of the system on the ITU will be met jointly by the Mayday University Hospital and City University.

7.2.3.3 Security of information

A password will be required to gain access to the system. The level of access into the

system will vary with the needs of the end-user. For example the consultant will have access to more system capabilities than the nurses. Any data copied onto data media remote from the bedside computer hard disk will also be protected.

7.3 SYSTEM DESIGN

The system requirements above specify the need for an integrated and modular system structure, with two modules clinically specified in the system: the fluid charting information system, and the CVVHD decision support system. The aim of this section is to specify the system design which these two modules are part of. This includes the:

i) Specification of the structure of the renal replacement therapy (RRT) management system.

ii) Specification of all the sub-systems of the RRT management system.

7.3.1 System Structure

The RRT management system is intended to be one of the components in a total patient data management system (PDMS), where, the total PDMS is concerned with the management of all patient data and information. Other components of the PDMS will be concerned with other aspects of patient management, such as ventilator therapy. Figure 7.3 shows how the sub-systems of the RRT management system will be linked with each other and with the ITU PDMS. The four sub-systems of the RRT management system are:

i) The user interface, through which all user observed data enter the system, and all information is presented to the user.

ii) The system manager which controls information and data flows, and manages the system operation.

iii) The data and information system, where all data and information are stored.

iv) Decision support sub-system, which will offer advice to the clinicians and nurses on the management of CVVHD.

A detailed description of the intended purpose and function of these sub-systems follows.

7.3.2 User Interface

7.3.2.1 Purpose

The main purpose of the user interface is to provide a user friendly front end to the system for the clinical staff. It is intended that the clinical user will not require detailed knowledge of how the system operates. A graphical user interface will be used, utilising a point and click windows approach. A rollerball will be used to perform the point and click operation. The information and data presented will be in a format familiar to the clinical staff, using recognised clinical terms and language.

7.2.3.2 Function

Functions of the user interface:

i) Data input medium - initially this will be via a keyboard, with the possibility of automatic data input to be added in the future.

ii) System gateway - windows with menus and icons for the selection of system data and functions. The structure in the windows system will be similar to the structure in the information system. When a menu item or icon is selected the opening of all relevant files will be automatic.

iii) System introduction and initial help screens - description of how to get started for the clinical user.

iv) System set up - to allow for the tailoring of the system to different operating

environments on both the clinical and technical level.

v) Knowledge base maintenance and update interface - to allow for direct access, maintenance and updates to the knowledge base.

vi) System administration interface - for maintaining and updating the system operation. To include administration of the password structure to be used for access to different levels of the system.

Each of these six functions will be contained in a separate module of the user interface sub system. The user interface will be implemented using an approach similar to that of the windows environment. Its development will follow the development of the other sub systems.

7.3.3 System Manager

7.3.3.1 Purpose

To control:

i) The flows of data and information around the RRT management system, in addition to the flows to and from the other components of the PDMS.

ii) The processes and tasks that need to be performed between the different sub-systems or modules. For example, the user may request a simulation of urea kinetics of A. Smith. The manager will then retrieve the necessary information and data, order the simulation from the DSS and return the results to the user.

In addition to this the system manager should act as a central connector into which other systems, yet to be defined, are plugged into.

7.3.3.2 Function

In fulfilling the first of the purposes outlined above the system manager is essentially enabling and controlling communication in the system. This involves performing the following functions:

i) Interpreting encoded incoming messages into a language understood by the sub-system receiving the message. For example converting data code from the data and information sub-system into a form readable by the DSS.

ii) Providing a clear route for communication between sub-systems.

iii) Ensuring the data and information required arrive at the correct destination in the time required.

iv) Sorting and packaging data and information.

v) Finding and requesting data and information.

vi) Dealing with requests for data and information.

vii) Logging the outstanding requests.

viii) Sending data and information for storage in the data and information sub-system.

The second purpose of the system manager is essentially to perform the role of a general manager. Where the role of a general manager is the organisation of a group to achieve a desired goal; here the group consists of the sub-systems of the RRT management system. To fulfill the second purpose the system manager could offer the following functionality:

i) Definition of the system goals

ii) Ensuring the system goals are being satisfied.

iii) Administration of the processes and tasks performed by the other sub-systems.

An important aspect of the management of the system is that any tasks are performed in a timely manner.

7.3.4 Data and Information System

7.3.4.1 Purpose

To store all patient specific data and information for current manipulation and possible future recall. The four main components of this are:

i) Data and information capture

ii) Data and information processing

iii) Data and information management

iv) Data and information presentation

Information will be presented on the screen with the option of a paper copy of any of the on screen displays.

The components of the patient specific data include data relating to patient state and treatment state, as specified in the problem assessment chapter. These contents of the data and information system define the view of the material patient and treatment state. Thus any decision advice offered by the decision support system is dependent on the contents of the data and information system.

In addition to data relating to the material problem, information on the outputs of the

system processes also have to be stored. For example when running the simulated decision making its recommendations will need to be stored for future decision evaluation, and for comparison with the actual actions taken. Similarly the output of the patient state assessment and the simulation module will also be stored.

Information from individual patient's could be combined within the system to produce data on the patient populations for use in research and medical audit. Other non patient specific information relates to the administration of the computer system. A detailed development record giving details of any system updates will have to be incorporated. Furthermore, records relating to the authorised users will be part of the administrative function.

7.3.4.2 Function

The primary function of the data and information system centres on patient specific data and information. All these data and information stored must be identified with an individual patient. Therefore, central to the primary function is a module containing the patient identifiers, as shown in figure 7.4. This shows the following modules:

i) Patient identification data, which will include their hospital number, surname, first name and date of birth.

ii) Fluid volume data, containing all the measurements and analysis of the fluid input and output volumes for the patient.

iii) Lab results summary chart giving details of laboratory measurements of the patient's measured blood variables.

iv) Blood-gas analyser results for plasma electrolytes and acid-base variables.

v) Patient state assessment, partially to be entered by the clinician and the remainder derived by classification of input data into ranges.

vi) Treatment state assessment to be entered by the clinician.

vii) CVVHD treatment advice module, to include the module input, the advice offered and the actual course of action taken with some measure of outcome.

viii) Simulation input data and output results.

The data items in the above modules are defined in subsequent sections. The other required modules of the information system which are not patient specific are:

i) Module for the collection and storage of statistical patient data, e.g. average duration of CVVHD treatment.

ii) CVVHD inventory and maintenance management, for stock ordering and machine maintenance scheduling.

iii) Development record, giving details of any updates made to the computer system.

7.3.5 Decision Support System

7.3.5.1 Purpose

To offer advice to the clinical staff on the operational management of the renal replacement therapy. The decision support will be offered for the period of time the patient is receiving the renal replacement therapy. The simulated decision making will be based on the three tier model of decision making developed in chapter 4. The first stage of patient management is to establish the current patient state then to apply the CVVHD therapy to reach the desired state. Within the decision support system the patient and treatment state assessment feeds into the therapy management module. The monitoring decisions required will be performed outside of the decision support system. Treatment advice is generated depending on the state assessments. The goal of the advised therapy action is to bring the patient state variables into a predefined target range within a specified time frame. Prior

to the decision support system recommending a course of action it will be simulated using a model of the material domain. The prediction from this model based simulation is then compared to the goal state to evaluate the likely effectiveness of the decision.

7.3.5.2 Patient state assessment

The full diagnosis of patient state will be carried out externally to the CVVHD management system. It is envisaged this is either done by the physician or another part of the patient data management system. However, some simple classification of patient variables into ranges will be carried out by the system.

During the RRT management system development the patient state assessment will be entered by the physician from a list of options describing patient state. The states of the patient to be assessed are defined in section 6.4.1 of the previous chapter. The concepts used to describe the patient states used in the system could be encoded using a system such as Read codes (Computer Aided Medical Systems Limited, 1994).

7.3.5.3 Treatment state assessment

The treatment state assessment falls into two categories: CVVHD treatment state, and other treatment state. The first is important to assess the present operating state of the CVVHD treatment, while assessment of other treatment feeds directly into the conditions used in the treatment advice decision tree.

7.3.5.4 Monitoring state assessment

During the initial system development it will be assumed that all the required monitoring resources are available to the physician. Moreover, it is assumed that the data set required for the material problem assessment, figure 4.8, is fixed and the timing of the measurements is either defined by the system or by the clinician supervising the patient. It was not explicitly specified during development that the system should offer monitoring decision support other than that which is implied by the structure of the information system, for

example in the fluid charting. Thus, at this stage of development no monitoring state assessment is included in the system.

7.3.5.5 CVVHD treatment advice module

The function of this module is to choose the recommended options for CVVHD treatment, which are then tested in the simulation module. The options for CVVHD treatment and the knowledge used to make the choices is defined in the decision tree in chapter 6. The decision tree uses a rule based protocol at the decision nodes for defining the advice offered. The advice offered by the treatment advice module is tested by running a simulation of the material domain in the simulation module of the DSS.

7.3.5.6 Simulation module

Quantitative or qualitative models as patient simulators are needed to assist prognosis and treatment planning (Carson et al., 1991). This module tests the chosen therapy settings through simulation of the patient state and the proposed treatment. The therapy settings could be those offered by the RRT management system, or they could be chosen by the physician. Simulation offers the capability to predict the decision outcome before implementation, and thus the potential effectiveness of the chosen therapy settings can be evaluated prior to implementation. Evaluation of the potential effectiveness being performed by comparing the predicted outcome with the decision goals. Figure 7.5 shows how the use of simulation and prior evaluation adds complexity to the choice stage of the decision making process. Here the choice stage is a three stage process where the output of the decision tree is followed by the action simulation, and finally the predicted decision evaluation prior to implementation. The outputs from each of the three stage process are: the recommended course of action with goals and justification for the action; the result of the simulation in relation to the goals, and a predicted evaluation of whether the goals will be achieved.

To evaluate the chosen action the simulation model needs to be able to predict the values of the goal variables. For example when the choice is made to start CVVHD a complete

simulation model would be required to predict what the patient's plasma potassium concentration will be after 6 hours of treatment. If the predicted concentration is within the target range the decision goal is satisfied. Thus the action proposed represents the optimum solution according to the patient and treatment simulation. However, if it is predicted the that goal will not be satisfied then the user will be advised that the chosen treatment may not be adequate. Justification of the predicted effectiveness of the proposed action will be offered to the user in the form of: a quantification of the predicted change in the goal variables, and the difference between the predicted outcome and the goal.

Taking the recommendation to begin CVVHD treatment as an example a complete simulation model will need to predict the patient's: fluid volume change; plasma potassium concentration; plasma phosphate concentration; urea plasma concentration; creatinine plasma concentration, and base excess.

Each of these goal variables are then evaluated as described above. Depending on the evaluation and the users judgement an action will then be performed. According the model of decision making in section 4.2.3 the action will be followed by a new problem assessment and an evaluation of the action outcome. During evaluation of outcome the effectiveness of the action taken and the accuracy of the simulation will be assessed.

The simulation module needs to be able to simulate changes in the patient state and the treatment state. Candidate models for the simulation of patient state include:

i) A single compartment model of urea kinetics. (Leypoldt et al., 1991, and Sargent and Gotch, 1980)

ii) Comprehensive model of the dynamic exchange processes during haemodialysis, including creatinine, potassium, urea and water distribution. (Thews and Hutten, 1990, and Thews 1992)

iii) A systems simulation model of renal dialysis (Uttamsingh, 1981, and Leaning et al., 1985)

iv) The course of ARF modelled by creatinine kinetics. (Moran and Myers, 1985)

v) A single pool heparin model (Sargent and Gotch, 1989)

For the model of the processes in the dialyser the models of continuous haemodialysis described by Pallone et al. (1989) and Sigler and Teehan (1987) could be used. An introductory description of these models is given below; for a fuller description the reader is referred to the references cited.

7.4 SIMULATION MODELLING OF HAEMODIALYSIS

Kinetic modelling has been used extensively to model haemodialysis. Such models allow for the prediction and control of substances during haemodialysis treatment. This section reviews some of the quantitative models of the dialysis process. These models may be useful in the problem of haemodialysis management if they can fulfill the goal for mathematical modelling defined by Sargent and Gotch (1980):

"The ultimate goal of mathematic modelling is to elucidate the effect of the various biochemical processes described and through greater understanding of these processes to be able to modify treatment or to predict clinical therapy for the better management of the haemodialysis patient."

The better management of the patient is one of the goals of the decision support system being designed. Therefore, the use of mathematical models of dialysis is a viable option for the simulation of treatment.

7.4.1 Single Pool Urea Kinetics

Urea kinetic modelling is a quantitative approach for controlling urea concentration (BUN), for evaluating patient nutrition, and for prescribing and monitoring patient's haemodialysis therapy. Urea is a major product of protein catabolism and is used as an indicator of uraemia. Sargent and Gotch (1980) proposed a single pool model of urea kinetics for

dialysis patients, figure 7.6, and the model is reported to have gained large popularity (Liberati et al., 1993). The single pool is an approximate representation of total body water and the urea is assumed to be evenly distributed in it. The model applies the principle of mass conservation to model urea kinetics. The pool contains the mass of urea in the body, the flow into the pool is urea production, and the outflow, the urea clearance from the body. The mass of urea in the pool is taken to be the pool volume, V, multiplied by the urea concentration, C. Urea is generated from protein catabolism in the liver. This is represented in the model by a single generation rate with dimensions of mass per unit time, G. For a dialysis patient the clearance of urea from the body has two components, the residual clearance of the kidney, K_r, and the clearance of the dialysis process, K_d. Thus, the rate of change of mass in the single pool can be expressed in the equation:

$$\frac{d(VC)}{dt} = G-((K_r+K_d)C) \tag{7.1}$$

$$V\frac{dC}{dt} + C\frac{dV}{dt} = G-((K_r+K_d)C) \tag{7.2}$$

In normal physiology, homeostasis, the change in urea concentration and total body water volume are negligible. This can be considered to be the steady state condition where dialysis is not required. In this condition the equation is:

$$G = K_rC \tag{7.3}$$

Consideration of this equation is important in the use of raised BUN as an indicator of renal function. From equation 7.3 it is obvious that either raised protein catabolism or decreased renal function can cause increased BUN. For the correct patient management it is important that the correct cause is identified. Moreover, for the patient with a varying volume of total body water the BUN could vary with state of hydration; in a dehydrated state BUN could be increased just because of lack of fluids.

The general solution of equation 7.1 can be used in two ways: to establish patient parameters (V and G) from clinical data, and to predict the effect of therapy changes and prescribe dialysis treatment to achieve clinical goals. Before use as a predictive tool the

patient parameters have to established. When applied to intermittent haemodialysis management this requires the establishing of the patient's dry weight, V_o, the change of weight between treatment and G from measurements of BUN post and pre-dialysis. Once these have been calculated the model can then be used to determine the required dialysis clearance, the duration of dialysis sessions, and the interval between them.

Leypoldt et al. (1991) applied the model to the prescription of maintenance haemodialysis for chronic renal failure patients. The model was applied to the time period of a week, T. The assumptions used in the application of the single pool model were: a time averaged BUN concentration TAC_{urea} is the same during inter and intra dialysis treatment; the residual renal clearance is constant; the dialysis clearance during treatment is constant, and the rate of urea generation, G, is constant. For a total dialysis treatment time in the week of t_d equation 7.1 can be rearranged to:

$$G = TAC_{urea} (K_r+K_d t_d/T) \tag{7.4}$$

This approach is a simplified version of the technique proposed by Sargent and Gotch, requiring less measurements and being simpler to apply.

Application of the single pool model to the management of acute renal failure in the ITU will require estimating the patient parameters V and G, then the application of these parameters to predict what the patient's urea concentration will be following a period of treatment. This will be more complicated for the acute renal failure patient as they are not only suffering from a loss of renal function, but often changes in their catabolic rate and in their total body water volume.

7.4.2 A Simulation Model for Renal Dialysis

An objective of the model described by Uttamsingh (1981) and Leaning et al., (1985) was to provide good predictions of patient state under a given course of dialysis. The predictions were intended to be used to improve the treatment of the patient, minimising dialysis time, avoiding periods of toxicity. The other objectives of the model were: to

explain hidden physiological responses caused by dialysis, and to investigate various hypotheses of kidney function and fluid-electrolyte dynamics, in particular neuroendocrine control.

The model of a patient receiving dialysis contains sub-models of the: thermoregulatory system; cardiovascular system; fluid and electrolyte balance; kidney function; urea and creatinine dynamics; haemodialysis machine (ultrafiltration and diffusion of urea, creatinine, potassium and sodium), and models of the hormones renin, angiotensin, aldosterone and ADH. These are represented by sixteen first order differential equations and fifty algebraic equations. Operating the model requires six patient state parameters to be estimated and 23 input variables. The predicted outputs from the simulation of haemodialysis are: mean arterial blood pressure; weight loss; plasma sodium; plasma potassium; plasma urea; and plasma creatinine.

The model has been tested for normal physiology without dialysis and applied to the management of chronic renal failure patients. When applied to acute renal failure it was found that repeated parameter estimates were required as the renal function varied with the course of the renal failure.

The problem with this model and other large models is that of identifiability and the estimation of parameters. Moreover, the model needs a large number of inputs and considerable processing power for its operation. Therefore it is likely to be of limited use in the acute clinical setting where timely decision making is required.

7.4.3 A Comprehensive Model of Haemodialysis

Thews and Hutten (1990) expressed the views that the complex dynamic behaviour of the most relevant state variables and their interaction during haemodialysis should be taken into account for optimisation of the exchange processes during treatment. Furthermore they believed that this could only be achieved by employment of a model considering relevant patient and treatment parameters.

Their model is indeed comprehensive and includes sub-models for the following substances: urea; creatinine; vitamin B_{12} (as an indicator of middle molecules, molecular weight between 500 and 5000g/mol); potassium; sodium; oxygen; chloride; acetate; water, and acid-base status (CO_2, pH and bicarbonate). The principle of mass balance is applied in the following models:

i) Models of creatinine and vitamin B_{12} represented by three compartments of intracellular, interstitial and plasma fluid.

ii) Urea, potassium and sodium in two compartments of intra and extracellular fluid.

iii) Chloride in three compartments: extracellular; intra-erythrocyte cells, and intra other cells.

iv) Acetate in a single extracellular compartment

v) The oxygen model uses two compartments: arterial, and venous blood.

vi) Water is distributed in three compartments: plasma, interstitial, and intracellular fluid.

vii) The model of acid-base status consists of three sub-models: Eight compartments for CO_2 - interstitial, intracellular, and 6 in the blood (vascular space), and a similar structure for H ions (pH) and for bicarbonate.

The complete model consists of 50 coupled differential equations, more than 50 state variables, and several non-linear relationships. So there is a large data gathering burden on the user and a high processing requirement.

The model can be used to analyse the exchange processes during haemodialysis. Specifically it allows for the exploration of the effect of changing control parameters of dialysis therapy on the homeostasis of fluid, electrolyte and acid-base balance. Thews

(1992) describes the application of the model to studying the effect of varying:

i) Dialysate composition: sodium; potassium; bicarbonate, and acetate.

ii) Dialysate device parameters: ultrafiltration rate, and rate of blood flow.

iii) Control parameters: dialysate sodium concentration profile, and ultrafiltration rate profile.

The simulation was run for 124 dialysis sessions of chronic renal failure patients on bicarbonate (89 sessions) and acetate (35 sessions) dialysis. The results of the simulation are described in detail in Thews (1992). The model can also be used to plan the optimum dialysis course for an individual, with the prediction of the course of therapy and of likely complications. Although this model would allow for the prediction of the majority of the decision goal variables it does have the same disadvantages for use in the ITU as the previous model described, section 7.4.3.

7.4.4 Single Compartment Model of Creatinine Kinetics

Moran and Myers' (1985) model was used to predict the relationship between creatinine clearance and plasma creatinine concentration during the course of acute tubular necrosis (ATN). Creatinine was used as the filtration marker during ATN as it provides a clinically useful indication of filtration rate. The authors defined two distinguishable phases of ATN characterised by creatinine clearance:

i) Maintenance phase, often 1 to 2 weeks in length. The clearance is depressed to 5 to 15% of normal.

ii) Resolving phase, a progressive rise in clearance. It can be up to 8 weeks before the clearance is back in the normal range.

These were modelled using a single pool model of creatinine. The structure of the model

is similar to the single pool model of urea kinetics discussed above. The assumptions in the application of the model were that: production rate of creatinine into the pool was constant; the volume of distribution approximates to the total body water; changes in total body water may be equated to changes in weight, and creatinine is a reliable filtration marker. The study showed that the plasma creatinine concentration alone was not a sufficient predictor of GFR. In particular it was found that rising creatinine concentration could be associated with rising creatinine clearance.

The main problem with the application of the model in the ITU is the assumption that creatinine production remains constant. The authors admit that no study has been made of the stability of creatinine production during ATN. This assumption could be particularly limiting in the ITU, where the patient is likely to be in a highly catabolic state. If this problem can be overcome the model could be used to predict the creatinine plasma concentration and the creatinine clearance.

7.4.5 Modelling of Heparin Activity

Biological sensitivity to and elimination of heparin has been found to vary widely so Sargent and Gotch (1983) proposed a single compartment model of heparin kinetics to take account of this. The parameter modelled is the clotting time prolongation in response to the heparin loading.

The single compartment model has a constant infusion rate I_r. This is multiplied by a linear sensitivity to heparin factor S to convert infusion rate to clotting time response. The response of the system, R, is proportional to the mass of heparin introduced, and the output is first order and a product of the elimination constant K and the response R.

$$\frac{dR}{dt} = I_r S - KR \qquad (7.5)$$

In the steady state condition where the rate of response is constant:

$$I_r = \frac{KR}{S} \qquad (7.6)$$

This can then be used to calculate the required infusion rate in the steady state. S and K are patient specific parameters which have to be determined. S can be determined by use of the step response of the patient to a bolus dose of heparin. K is calculated by taking two clotting time responses and performing an iteration until K is determined. This model could be applied to predicting the change in the patient's measure clotting time for a given infusion of heparin.

7.4.6 Simulation of Continuous Arteriovenous Haemodialysis

Pallone et al. (1989) developed a model to predict the performance of continuous arteriovenous haemodialysis (CAVHD). From patient and dialysate input variables this model of CAVHD predicts: hydraulic and oncotic pressure distributions in the dialyser; filtration rate; blood flow, and total, diffusive and convective clearances of urea. Therefore it could be used to model the convective and diffusive clearance of urea across the dialysis membrane. However, several limitations of the model were reported including: systematic over estimates of blood flow rate and the filtration rate; difficulty in calculating the parameters defining the conductance of urea, and most significantly it has only been tested using bovine blood in the extracorporeal circuit.

Sigler et al. (1987) modelled solute transport in the continuous haemodialysis circuit. Using the model studies were performed on fifteen critical care patients. The model was used experimentally to demonstrate the advantages of continuous arteriovenous haemodialysis over continuous arteriovenous haemofiltration. This required the sampling of blood from the arterial and venous end of the dialyser, in addition to the sampling of the waste dialysate. The solute concentrations in these samples were measured and combined with the measured flow rates to calculate the solute clearances. The solute clearances calculated were: urea; sodium; potassium; creatinine; phosphate; bicarbonate; calcium, and glucose. Applying this model to the calculation of CVVHD clearances would require

considerably more sampling and measuring of blood and dialysate than is routinely performed on the Mayday ITU. Furthermore, the extra data gathered would only inform the calculation of dialysis clearances; they would not wholly inform the simulation of the patient goal variables as required.

7.4.7 Haemodialysis Simulation Summary

The simulation of patient and treatment state is highly complex due to the unstable nature of ITU patients. To model all the patient's goal variables would require a large complex model of the type proposed by Thews (1990). However, for application of a model in routine clinical practice the model needs to be simple with a minimum number of variables to be measured and processed (Sprenger et al., 1983). Therefore it is proposed that the model to be implemented in the initial development is Sargent and Gotch's single pool model of urea kinetics. This is a simple, well established model which has been previously applied to the management of chronic maintenance haemodialysis.

7.5 SYSTEM DEVELOPMENT

The development of the system design will proceed by building prototype sub-systems, and finally a complete prototype system. The first sub-systems to be developed are the ones which address the expressed clinical need. The clinical need for accurate fluid charting suggests the need for a computer based fluid charting system, which is a component of the information system. The other clinical need identified is for advice on the operation of CVVHD treatment. Therefore the second prototype system to be developed will be the CVVHD advice system. The design and development of these components of the system design is described below, in addition to a discussion of the development of other components of the system design.

7.5.1 Computer Based Fluid Charting

The fluid charting system is one of the components of the data and information system as described in section 7.3.4. At the Mayday ITU this is performed manually using paper

charts. The initial clinical need to be addressed is an automation of this process, which it is anticipated will make charting easier and more accurate.

The volumes of fluid which need to be measured or estimated have been described in the systems analysis in chapter 5. These can be classified as fluid input volumes for drug delivery, nutrition, and colloid volumes; and fluid outputs volumes corresponding to blood losses, urine, gastric fluid loss, insensible losses, and sweat losses. For an ATN patient the balance of these fluid inputs and outputs is the CVVHD treatment, where there can be a net fluid removal or addition to the patient. The majority of the fluid input and output volumes are directly measured, however the insensible losses and the sweat losses are estimated. Alternative estimates for and models of the insensible respiratory and skin losses were given in chapter 5. It was concluded that the quantitative models described would give more patient and ambient sensitive estimates of the insensible losses. However, the accuracy of the models for the prediction of patient's insensible losses in the ITU requires further testing before they can be implemented. Although this is a problem which does need addressing it is only a sub-problem of charting a patient's fluid balance. Moreover, performing the required testing to evaluate the accuracy of the quantitative insensible loss models is beyond the immediate scope of this project. Therefore, without further data available on the use of models in the ITU the present clinical practice will not be changed (for 70 kg man an estimate of total insensible loss of 500ml/day is used). Although it is obvious from the different estimates and from the models of insensible loss the losses will vary with factors not included in this estimate. Thus it is not an optimum and an alternative more accurate technique does need to be found.

The layout of the computerised charts reflects the layout of the manual charts used for fluid charting in the Mayday ITU. The paper charts were used as a model for the computer charts to ensure inclusion of the fluid volumes which are typically monitored for an ARF patient, and to have some inherent familiarity in the system for the user. The features of the computer system which go beyond the present paper based system have been specified in consultation with Dr Morgan and Dr Collinson.

To test the spreadsheet operation and to show some of the possible graphical presentations,

data from an ITU patient have been entered into the system. The data entered represent eight days of data for a patient who has received haemodialysis on the ITU at the Mayday Hospital. The patient identifiers are all fictitious, and the dates have been set at an arbitrary time. The fluid and haemodialysis data match those recorded on the bedside paper chart. The core temperature data have been defaulted to 37.5°C, apart from a period of four hours on the 8/6/95 where the temperature has been artificially inflated to show the calculation of sweat volume. Additionally the target data have been set artificially to be close to the actual fluid balance.

7.5.2 Fluid Charting System

It is intended that the fluid charting system should chart all the patient fluid volume data, estimate the insensible losses, and offer fluid planning advice to the nurse. The computer based charts have been modelled on the existing bedside chart, with additions to give the computer based system the capabilities specified in the system requirements. The system has been developed on a PC in a Windows environment.

The present paper-based system resembles a spreadsheet, so all the initial development of the system has been carried out on the spreadsheet application, Excel 4.0. Additional reasons for choosing Excel are that it has capabilities for once only entry of all data items, statistical analysis of data, straight forward graphing of data, and has the mathematical functions required to construct quantitative models when required. By linking spreadsheet cells data can be shared between numerous locations, thus ensuring each data item only has to be entered into the system once. Included in Excel's statistical capabilities is the ability to calculate data trends. Calculating the trend in data has been highlighted in previous studies (European survey of computers in intensive care, 1990) as being one of the properties of data that is useful in a clinical setting. Around the spreadsheet based charts two other main components need to be constructed:

i) A database to store past patient data.

ii) A user interface to simplify and automate system operation.

Figure 7.7 shows how the spreadsheets interact as part of this system. There is one set of active spreadsheets for the patient who is presently being monitored on the ITU. Onto these spreadsheets data for the patient are entered, either via the user interface or from the database. The user enters and views all the data through the spreadsheets and their related graphs. All the processing of data is carried out on the spreadsheet. When the patient data no longer need to be displayed, for example when the patient is discharged from the ITU, then the data are sent to the database and the spreadsheets are cleared ready to load in the next patient's fluid data.

An operational system will need a custom built user interface. The purpose of the interface is to make the system practical for users who have no knowledge of the operation of the application the system has been written in; at present this is Excel. However, during development the user interface will be the one offered by Excel, so knowledge of its operation will be required to develop and operate the system.

7.5.3 Fluid Chart Design

Figure 7.8 shows the six different charts in the fluid charting system and where there are connections between them. These are:

i) PATIENT IDENTIFIERS - records and displays the identifiers used for each patient.

ii) BEDSIDE CHART - records, displays and calculates all the hourly and accumulated values presently recorded on the paper bedside fluid chart.

iii) INSENSIBLE AND SWEAT LOSS ESTIMATES - calculates and displays the estimated patient fluid losses. The model used to calculate the insensible and sweat losses is stored and called up from the adjacent model component.

iv) SUMMARY FLUID CHART - summarises the hourly values from the connected charts.

v) DOCTOR'S SUMMARY CHART - shows the patient fluid chart data at twelve hourly intervals.

vi) FLUID PRESCRIPTION CHART - used to plan twelve hourly fluid target input, output and balance volumes.

A detailed description of each of the charts is given below. The description includes an illustration of the chart and its associated graphs. In addition to tables defining the data items shown in the chart. Each chart is described in terms of:

i) AIM - the purpose of the chart.

ii) LAYOUT - a brief description of the main points to note about the chart layout.

iii) INPUTS - the data flows into the chart.

iv) CALCULATED FIELDS - the calculations, where relevant, on each chart.

v) GRAPHICAL PRESENTATION - a description of the graphical output generated from the charts.

vi) OUTPUTS - the flow of outputs from the chart to other charts in the system.

vii) DESIGN OPTIONS - possible alternatives in each of the chart designs.

7.5.3.1 Patient identifers (TABLE 7.2 & FIGURE 7.9)

AIM: To enter the patient details required to uniquely identify all the entered and the processed data in the system with the patient it refers to.

LAYOUT: The layout of the chart is based on the present paper based bedside chart. The identifiers selected from the bedside chart are taken in an attempt to make the association

of the data easy without too much duplication of information already recorded on the paper based chart.

INPUT: All the patient identifiers are entered into the chart via the user interface. The patient data items only have to be entered into the charting system once per patient.

OUTPUT: Hospital number, surname, first name and date of birth are linked to all of the other patient specific charts. These items appear in the top of each of the other charts and on the first page of each of the chart's printed output. Moreover, the identifiers appear on each of the graphs output from the system as well.

DESIGN OPTIONS: A unique ITU number allocated to the patient on admission to the ITU could be used as the main unique patient identifier. This number would give information on which admission the related data refer to.

7.5.3.2 Bedside chart (TABLE 7.3 & FIGURE 7.10)

AIM: This chart records all relevant hourly measurements, thus replacing the present paper bedside fluid chart. All the hourly fluid input and output volumes are recorded, and the patient's core temperature is recorded for use in estimating the patient's sweat losses.

LAYOUT: Again the structure of the layout is based on the present paper bedside chart. All the measurements are recorded against time, for the fluid values this represents the volume in the hour preceding the time shown. The fluid inputs are entered on the left hand side, followed by the fluid output data and the calculated fields on the right. A new chart is created for each new twenty four hour period with the relevant start date recorded at the top of each one.

INPUT: The patient identifiers come automatically from the identifiers spreadsheet. All the measurements will be entered at the bedside by the ITU nurse via the user interface.

CALCULATED FIELDS: From the data entered the following are calculated on the

spreadsheet:

i) Accumulated urine output.

ii) Ultrafiltrate (dialysate output-dialysate input).

iii) Hourly and accumulated input fluid volume.

iv) Hourly and accumulated output volume.

v) Hourly and accumulated measured fluid balance (fluid input-fluid output).

The accumulated totals show the volumes for the 24 hour chart only, i.e. the totals do not include any brought forward totals from previous days' charts.

GRAPHICAL PRESENTATION: It is possible to plot the variation of any of the quantities on the chart, or the trend in their variation, against time. From a group of seven possible graphs three were specified by the clinicians as being useful presentations. The graphs showing trends in data were not liked as it was felt that by extracting the trend from the data some information was being lost in the presentation.

The preferred graphs are shown in figures 7.11 to 7.13. The measure fluid balance graph, figure 7.11, shows the hourly and accumulated fluid balances for the patient. This graph is useful as an overall summary of the pattern of the patients fluid balance over the twenty four hour period. Related to this graph is figure 7.12 showing the total inputs and output volumes together. The graph of ultrafiltrate volume, figure 7.13, is useful to monitor the performance of the dialysis filter. It can be seen from the graph that after the filter is changed, around 20:00 hours, the ultrafiltration volume increases more than three times.

OUTPUTS: The measured balance figures are linked to the summary fluid chart for the corresponding day. Fluid data from the chart are linked to the doctor's summary chart. Data from the chart are transferred to the database upon completion of the fluid charting

for the patient.

DESIGN OPTIONS: The accumulated totals for the fluid quantities could include the brought forward values, thus showing totals for the whole charted period not just a single 24 hour period. This would give an instant idea of the long term fluid balance of the patient. Colour could also be introduced to enhance the on screen display of the chart; in particular to distinguish between fluid inputs, outputs and totals.

7.5.3.3 Insensible loss estimate (TABLE 7.4 & FIGURE 7.14)

AIM: To calculate, display and record an estimate for the patient's insensible and sweat volumes. The different basis for making these estimates was discussed in section 5.5 and 7.5.1. The present model to be adopted is the same as the one used on the ITU at the Mayday.

INPUTS: The patient identifiers and temperature come automatically from linked cells on the identifers and the bedside chart respectively. The patient weight is entered from the patient state assessment module of the information system.

CALCULATED FIELDS: The models of insensible loss use in the system at present are based on current clinical practice, these are:

i) Insensible loss = (500/70) ml/kg/day

ii) Sweat volume = (500/70) ml/kg/day/every 1°c rise in temperature above 37.5°C.

GRAPHICAL PRESENTATION: A bar graph showing the insensible loss and sweat loss is included in figure 7.15. The input data have been artificially increased for the first four hours to show how sweat loss is calculated and displayed. This graph will convey more information to the user where a model which takes into account varying patient and environmental conditions is used to estimate the losses.

OUTPUTS: The totals for the estimated losses are automatically transferred to the fluid chart summary and the doctor's summary chart.

DESIGN OPTIONS: The model used to estimate the losses could be changed to one of those proposed in section 5.5, although this would require further evaluation of the models prior to implementation.

7.5.3.4 Summary fluid chart (TABLE 7.5 & FIGURE 7.16)

AIM: The two main aims of the summary chart are:

i) To show the patient fluid balance after all the measured and estimated variables have been included.

ii) To be a planning aid to the nurse, offering advice on the fluid balance to aim for at the end of the next hour.

LAYOUT: As for all the charts the variables are recorded against time. The first half of the spreadsheet displays past information and the second half of the chart shows target, or future, information.

INPUTS: The measured balance and the insensible losses are taken directly from the relevant spreadsheets. The prescribed target balance is linked into the fluid prescription chart.

CALCULATED FIELDS:

i) The estimated losses are taken off the measured balance to arrive at an estimate of the actual fluid balance for the patient.

ii) The planned fluid balance is calculated by a linear division of the 12 hour prescribed balance from the fluid prescription chart. Thus spreading the required

fluid loss or gain for the patient evenly over the 12 hours producing the minimum rate of change in the patients fluid volume.

iii) The revised target balance is intended to be a guide to the nurses for the fluid balance to be achieved in the next hour. It is the target fluid balance for the hour less the accumulated error bought forward. Thus any previous excess fluid removal or overload can be adjusted for in the next hour. It can be calculated using the formula:

(Revised target balance at time, t) = (Accumulated target balance at time, t) - (Accumulate aggregate balance at time, t-1)

Thus, from figure 7.16, on 8/6/95 the accumulated actual balance at 1400 hours is -315.7 ml and the planned accumulated balance for 1500 hours is -375 ml. Then the revised fluid balance for the hour 1400 to 1500 hours is -59.3 ml, i.e. the patient needs to lose approximately 60 ml of fluid in the next hour.

GRAPHICAL PRESENTATION: Illustrations of the graphical output from this spreadsheet are shown in figures 7.17 to 7.18. Where the estimated fluid losses are varying, then the graphs from this chart can provide potentially more information on the patient's fluid balance than the bedside chart.

OUTPUTS: There are no flows of data directly to other charts in the system.

DESIGN OPTIONS: The chart could be split into two, one only summarising past fluid data and the other presenting hourly target advice. Additionally either chart could be expanded to show more data. For example more fluid variables could be included to give broader advice to the nurse on the fluid inputs and outputs required to meet the fluid balance target at the end of the next hour.

7.5.3.5 Doctor's summary chart (TABLE 7.6 & FIGURE 7.19)

AIM: To summarise the fluid data for the patient using a time period relevant to the physician's decision making.

LAYOUT: The time period used here is 12 hours, taken between the hours of 0:01 to 12:00 and 12:01 to 24:00 in each 24 hour period. The time periods were chosen to be centred around the midday ward round. The timings are recorded against the corresponding date. The layout of the remainder of the chart is similar to the other charts, with the inputs on the left, followed by the outputs and the calculated fields on the right.

INPUTS: All the data input are captured automatically from the bedside chart and the insensible loss chart.

CALCULATED FIELDS: All the inputs from the other charts are summed into 12 hour totals on this chart. The aggregate fluid balance is the summation of all the values in the preceding columns. On the example chart shown the bought forward fluid balance has been added into the accumulated aggregate balance. Therefore, the total in the accumulated column shows the on-going fluid balance, not just a summary total for the single chart.

GRAPHICAL PRESENTATION: The graph displaying the largest amount of information is the plot showing the period and accumulated aggregate balance, figure 7.20. The graph plotting the actual fluid data shows that the initial charted balance prior to dialysis beginning was above 5000 ml and after eight days the charted balance is now below -4000 ml. In addition a histogram showing the half day totals for urine output could be useful in following the course of ARF in the patient, figure 7.21.

OUTPUTS: The period totals of the aggregate fluid balance values are shown on the fluid prescription chart.

DESIGN OPTIONS: The time interval used to summarise the data could be changed, to say one summary per day.

7.5.3.6 Fluid prescription chart (TABLE 7.7 & FIGURE 7.22)

AIM: For the doctor to prescribe the 12 hourly fluid balance, and to allow for the calculation of ultrafiltrate volume required for specified variations in the other fluid volumes.

LAYOUT: The layout of the chart is designed to be similar to the doctor's summary, so enabling comparison between the planned fluid volumes and the actual fluid volumes.

INPUTS: The target fluid balance, crystalloid input, colloid input and the estimate of other fluid losses are entered via the user interface. The actual balance is linked to the doctor's summary chart.

CALCULATED FIELDS: The ultrafiltrate is calculated as the difference between the target balance and the estimates of the other fluid variables. So for a required fluid input the volume of ultrafiltrate needed to provide the necessary fluid space can be easily calculated. The difference column is merely the difference between the actual and planned fluid balance. As mentioned previously the planned targets are artificial and hence the differences are all small.

GRAPHICAL PRESENTATION: The graph plotted in figure 7.23 shows how the aggregate fluid balance follows the prescribed fluid balance.

OUTPUTS: The target fluid balance is linked to the fluid summary chart.

DESIGN OPTIONS: The time period could be changed in a similar manner to the doctor's summary chart. The output to other charts could be extended to include an hourly breakdown of all the prescribed fluid input volumes.

7.5.3.7 Database

AIM: To record all data entered by the medical staff, and to allow for retrieval of data back into the spreadsheet system.

INPUTS: The data recorded on the fluid balance charts.

LAYOUT: The structure of the database will be based on the structure of the charts it is linked to.

OUTPUTS: All recalled data on a patient required by the user.

7.5.4 Further Development of Fluid Charting System

The fluid charting system described above will form the basis for future development of the fluid charting system. However, the present system consists of a spreadsheet and network database for inputting and storing all the patient data. The operation of the system could be simplified by using only a database, where the present spreadsheets are replaced by database forms. This is with the proviso that the database application used has all the data analysis and presentation capabilities presently specified in the spreadsheet application. The database used will be dictated by the availability of database applications and their suitability for meeting system requirements. The type used will be either relational or object oriented. To allow for integration with the object oriented decision support module an object oriented database would be preferable.

Even without the above mentioned changes before an operational fluid charting system could be offered: the database must be developed; many of the processes in Excel need to be automated, and the user interface has to be designed. The optimistic estimate for completing the database development using available resources went beyond the time available within the PhD project. This time estimate allowed for time spent automating processes within Excel, designing a user interface, prototype testing on the ward, and for some time spent in the cycle of test and development. It was felt that the sole pursuit of the development of an operational fluid charting system would not have made a sufficient contribution to knowledge. Thus, despite the fluid charting system existing as an early prototype the project development moved onto the decision support module design and development.

7.5.6 Other Components of Data and Information System

The set of modules to be included in the data and information system were specified in the system design. The first two modules have been specified above in the description of the fluid charting system. The charts summarising the laboratory data and the blood gas analyser results are shown in figures 7.23 and figures 7.24. The layouts of these charts were based on the existing paper based records. The information required in the patient and treatment assessments was specified in the chapter 6. The treatment advice module inputs and outputs were specified in the decision tree structure of chapter 6. The model-based simulation input and output data will depend on the model being used. The non patient specific modules required in the system have not yet been specified.

7.5.7 Decision Support System Development

The operation of decision support was modelled in figure 4.16. The model showed decision support operating in parallel to the decision maker, offering them advice at each stage of the process. Therefore a decision support system requires an in built model of decision making to operate. The in built model of decision making adopted here is the five stage process shown in figure 4.8.

As discussed in chapter 4 clinical decision making has three tiers: patient state assessment; treatment, and monitoring. The five stage decision making model was used in section 4.2.4 to represent these tiers operating together, figure 4.13. The requirement for the decision support system is to support CVVHD treatment decision making. The system is only considering one treatment option for the patient. Thus, the system's patient state decision making is simplified to only an assessment of patient state. Moreover, the monitoring decisions are made externally to the system, and the product of the monitoring activity is entered into the data and information system. Thus it is only the treatment decision making which is represented in full in the system. Figure 7.25 represents a model of the systems internal decision making, which is a simplified version of the full decision making representation in figure 4.13.

The decision support system's patient and treatment assessments come from externally entered data and internally generated patient data classifications. The evaluation is performed by comparing the goals of the previous decision with the present assessments. The treatment options are represented by the structure of the decision tree. Clinical knowledge attached to the decision nodes is used to choose the options to recommend. The structure of the decision tree output is a set of recommended actions with attached goals and justifications. The recommended action is then simulated using the most recent patient and treatment state assessment to produce a predicted outcome. The simulation offers the user an assessment of the likely effectiveness of the advice offered. During the implementation of the users chosen action they record whether they acted on the advice or not. After further patient and treatment data input the cycle repeats.

A complete DSS decision simulation includes all the stages described above. However, during the early phases of system development decision evaluation will be performed externally to the DSS. This is because the knowledge base used to make the decisions and define the goals is still a naïve one, and requires further complex testing before implementation. Until such testing is completed the validity of goals as a basis for judging the decision effectiveness will not be known. Thus the initial decision support system will consist of three main components: patient and treatment state assessment; treatment advisor, and patient and treatment simulation. The basis for the treatment advisor is the decision tree defined in the previous chapter. Derived from this the patient and treatment state assessments were also defined. Moreover, a candidate set of kinetic models for haemodialysis simulation have been previously defined .

The main function of the system is to make CVVHD treatment recommendations to the user. Moreover, the decision tree is at the hub of the decision simulation. Thus the development of the decision support system began with the programming of the decision tree.

7.5.7.1 Coding the CVVHD decision tree

The first issue to be addressed is how to encode the decision tree. Specifically the problem

with the coding is to find a technique which can be used to naturally represent the decision tree model, so that the program structure is a transparent representation of the model already developed. More generally the other qualities the implementation language should have are: it should be easy to update and maintain, and allow for integration with other applications. The language must be easy to update as clinical decision support is developed by iterative prototyping (Heathfield et al., 1991). Moreover, integration of decision support is a basic requirement which is reflected in the system design, figure 7.3.

Object-oriented design techniques seek to mimic the way that people form models of reality. Typically the reality referred to is a material one, and objects are thought of as material entities with attributes and behaviour in the material world. An object in a computer program is not a material object it is an expression of the abstract conceptual model of the object. An object can be more usefully thought of as a representation of the idealistic abstractions formed of reality, whether that reality is material or idealistic. Examples of models of material objects are obvious, such as the descriptive model of a car: four wheels, a chassis, an engine, and a gearbox with the ability to move forward and backwards. The strength of object oriented programming applied in artificial intelligence is in the representation of models of idealist reality such as the model of a decision. So object oriented programming can be used to produce a transparent representation of the decision tree.

The advantages of object oriented programming over procedural languages include: encapsulation; inheritance, and polymorphism (Parsons, 1994). Encapsulation is the combining of object states and functions into a single file. This allows for easier maintenance than with more procedural languages. Changes can be made to an object definition without having to change code throughout the program. Inheritance is the derivation of one class, the sub-class, from another class, the base class. Through inheritance the attributes and functions of the base class are part of the sub-class. Thus the sub-class relationship is a type of the base class. Related to inheritance is aggregation, where a class can be composed of other classes or contain other classes. In the first instance the containment class is built from component classes. In the second the class contains other classes but they do not form part of its structure. Polymorphism is the ability

of classes of object to respond to the same message in different, class specific ways. Polymorphic functions have the same name but different implementations for different classes.

All of the previously mentioned characteristics of object oriented promote the reuse of code. Encapsulation of a class allows for the multiple creation of objects from the class. Inheritance allows sub-classes to re-use code in the base classes. Aggregation allows for the re-use of existing classes as components for new ones. While polymorphism is the reuse of symbols, operators and names, to apply to different object behaviours. It was because of these reported advantages and the representational power of object oriented programming that it was selected to encode the decision tree.

7.5.7.2 Software design

To allow for the economic use of code the decision tree, figure 6.1 has to be broken down into its constituent parts and common features of those parts defined and represented. There are two categories of decision in the decision tree. The first catagory of decision is essentially the choice between two courses of action, and the second is the calculation of a numerical value. Eight of the decisions are of the type one and three are type two decisions. The structure of the program for type one decisions will be considered first.

The basic unit of the type one decision is a decision node, figure 4.9. Each node has two possible options or states, action A or action B. Each option has a separate set of conditions for determining when it should be active, or "true". The sequence for choosing between options begins with testing the conditions using the patient and treatment assessment. After the conditions are tested the results are combined logically to generate the DSS advice. The results of the condition testing are logically combined to ensure that the safest course of action is chosen. So every decision has: a state which represents the results of the condition test and the advice offered; logic for choosing between the two possible options, and a set of conditions which define when the options are active. All decision nodes have a state, so they can be represented by the same structure in the system. Moreover, the logic for choosing the state from the two possible actions is common to all

decisions. However, the functions or conditions which make the options active are unique to each decision. Thus it is possible to define the hierarchy of the decision tree with the generalised structure in figure 7.26. The general decision class at the top of the hierarchy consists of the decision state structure and the logical combination function. Below this are a number of sub-classes defining the conditions for activating the options of each of the type one decisions.

The C++ code for the general decision class, decision.h, and the decision state class, state.h, are in appendix D. The files are documented to explain their function and commented on in the program code to explain individual sections and lines. All the comments follow the double parallel lines, //. The file state.h defines the class state which is a component of the decision class. The decision class is defined in the decision.h file. This class defines the data structure of a decision using the component data type state. It also declares and defines the logical function for choosing which action to recommend. Table 7.8 is the truth table for this logic function. From the table it can be seen that intervening action will only be recommended when there are positive indications for intervention, and no contra-indicators for intervention. The logic function in decision.h has been derived from the truth table.

As shown in figure 7.26 the individual decision functions are defined in different class declarations. So for each of the decisions in the tree there are separate files declaring their functions. Whilst the data structure and high level function are inherited from the decision base class. Taking decision A1 as an example, figure 7.27 represents the structure of the function defining files. File dec_a1.h declares the rule based functions which are used to activate the begin RRT and the do not begin RRT options. The advice to be offered to the user is also defined here. The functions, including the advice, are defined in dec_a1-f. Each of the functions uses its own data type defined in classes a1_con1svar to a1_con01svar. These data types define the patient and treatment assessments which feed into the decision functions. Thus they form a data interface between the assessment modules and the decision tree module. For decision A1 there are six conditional functions which depend on the treatment and patient state assessments. The output of the decision is the advice to either begin RRT or not to begin RRT. Therefore, the decision is run before

beginning treatment. Once treatment has begun decision A2 is run in place of A1. The structure of decision A2 and all the other type one decisions in the tree are similar to those of A1. The functions for all these decisions are defined in section 6.3.1, and their C++ coding is similar to the code for decision A1.

The type two decisions are simpler as they consist of a numerical output which is produced by a quantitative function. For example the volume of replacement fluid volume can be simply calculated as shown in a single file. Only this one file is required; it contains the single function required to calculate the volume, and the variables used are fed in directly from the information system.

7.5.7.3 Software testing

The decision tree programs have been tested for functionality by running them using the files main-da1.h to main-dd2.h in combination with the test files test_a1.h and test_a1.cpp. Main-da1.h controls and runs the testing of the decision node A1, while test_a1.h initialises the test values in the decision data objects according to the test number selected. The connection between these and the other programs is shown in figure 7.28. From the figure it can be seen that the test programs act as artificial data input to the decision node, while the main program is essentially the decision sequence controller.

There are eight test data states set by the test programs, test_a1.h and test_a1.cpp. For decision A1 six of the tests set each of the six conditions of the decision node to active individually, figures 7.29 and 7.30. Figure 7.29 illustrates the operation of test five where condition 3d is activated, and the decision advice correctly given is to begin renal replacement therapy. Test 6 (figure 7.30) prompts the advice to not begin treatment. The seventh test (figure 7.31) sets all of the data objects to the active state to test the advice when all conditions are active. The eighth is the default test when all the conditions are inactive. Thus the first six tests ensure the functioning of the six individual test conditions, and the seventh and eighth the functioning of the logical conflict control. Other combinations of conditions could be activated by the addition of other test numbers to the test program.

The test programs initialise the values of the condition data objects, a1con1svar etc.. The initialisation is performed by the function iniat_var in each of these data objects. The values set in the iniat_var function depend on the value at a point in the test array. The values in the array are set by the test number in the test program. The activation of the conditions in the decision functions depends on the initialised test values of the condition variables. Each of the conditions are set to active by different positions in the test array. Thus any number of tests can be defined where each decision condition is turned on or off by the array.

All of the files of decision A1 are invoked by the decision node control program main-da1.h. Running main-da1.h performs the following functions:

- Creates the decision objects to be tested

- Creates data objects for each of the decision conditions and initiates their values according the test number entered

- Runs each of the decision conditions to determine the decision state

- Invokes the advice function to determine decision node advice and outputs the advice to the screen

Main-da1.h has been run successfully for all eight test conditions described above (figure 7.32). Thus the functionality of the decision node A1 has been validated. The functionality of all the other decision nodes has been tested using the same technique (figures 7.33 to 7.40). Thus the function of all of the decision nodes has been proven, and all were found to operate as expected. Thus proving the concept of modelling decisions as objects with states and decision functions.

The next stage of development of the decision tree will include connecting together the decision nodes to produce a unified treatment advisor. The other required elements of the future development of the complete treatment advisor are: the advice justification

component; attachment of goals to the advice, and the meta control of the decision tree for controlling several decision cycles. Moreover, the integration of the decision tree with the data and information system will be required in a fully operational system. The work described above on the functional units of the decision tree is a good foundation for the future development of the fully operational treatment advisor.

7.5.7.4 Other components of the decision support system

The other components required in the decision support system are: the patient and treatment state assessment, and the simulation component. The designs for these other components is at the conceptual stage. The patient and treatment state assessments required in the decision making simulation are defined in section 6.4. Some of the assessments required will be entered directly by the users whilst others will be derived from classifications of patient data. The system classifications will be performed on patient electrolyte, urea, creatinine, urine volume, and acid-base data using the bands defined in section 6.4.1. The other data not already entered into the information system, could be gathered by a series of direct questions to the system user.

It was proposed in section 7.4 that the model to be implemented in the initial development is Sargent and Gotch's (1980) single pool model of urea kinetics. This means initial simulation development will proceed with the simulation of only one of the patient goal variables; plasma urea concentration. Using a model based on Sargent and Gotch's in a prototype will allow for the testing of the feasibility of using a quantitative model to predict treatment outcomes in the ITU. The other models of the goal variables, although required in the complete management of the patient are too complex and unproven to use in the early stages of development.

7.6 SUMMARY

This chapter has described the design and development of a prototype computer based RRT management system building upon the clinical analysis in chapters 5 and 6. In addition to the clinical analysis the design has also used the general system requirements for a clinical

decision support system in the ITU defined in this chapter. In compliance with these requirements the system design produced is an integrated design incorporating the modules of the RRT management system with a general ITU PDMS. From the RRT management system design the two prototype sub-systems developed were the fluid charting module and the treatment advice module. The fluid charting module has been designed to record and present fluid volume data, and to act as a fluid balance planning aid. The treatment advice module design has been based on the decision tree model of CVVHD decision making described in chapter 6. The functionality of the nodes of the decision tree has been validated by encoding them using object oriented programming. This was used to allow for ease of updating and maintenance of the program code. Moreover, using object oriented tools and techniques allowed for a natural representation of the decision tree model, thus demonstrating the use of the tools and techniques for the implementation of models of the idealist reality.

The following discussion chapter reviews the major issues raised in this and previous chapters.

TABLE TITLE: DATA TYPE CLASSIFICATION

The table below gives a description of the data classification used in tables 2 to 7.

DATA TYPE	DESCRIPTION
RD	Raw data, entered onto the chart via the user interface by medical staff.
SD	Data which are part of the structure of the blank chart, and therefore do not have to be entered into the chart.
CD	A calculated value. Calculated using other data in the charting system.
LD	An input which originates from another fluid chart, and is automatically linked into the chart. By linking the data any change in the original data is shown automatically in the linked, or destination, data.

Table 7.1 Fluid chart data classification

CHART NAME: PATIENT IDENTIFIERS

EXCEL FILENAME: FLUHDPAT

ITEM NO.	TITLE	DEFINITION	DATA TYPE
HDP1	HOSPITAL NO	The unique seven digit number allocated to the patient by the hospital	RD
HDP2	SURNAME	The patient's last or family name	RD
HDP3	FIRST NAME(S)	The patient's first names	RD
HDP4	DATE OF BIRTH	The patient's date of birth	RD
HDP5	ADMISSION DATE	The date of the patient's admission to the ITU	RD
HDP6	PATIENT'S WEIGHT	The most recent measurement or estimate of the patient's weight	RD

Table 7.2 Data definitions for the pateint identifiers chart

CHART NAME: BEDSIDE CHART

EXCEL FILENAME: FLUBSCHT

ITEM NO.	TITLE	DEFINITION	DATA TYPE
BSC1	HOSPITAL NO	Equivalent to data item HDP1 on the identifiers chart	LD
BSC2	SURNAME	Equivalent to data item HDP2 on the identifiers chart	LD
BSC3	FIRST NAME(S)	Equivalent to data item HDP3 on the identifiers chart	LD
BSC4	DOB	Equivalent to data item HDP4 on the identifiers chart	LD
BSC5	DATE	Date at 0800 hours when the data began on the attached chart	RD
BSC6	TIME	The time, to the nearest hour, the readings were recorded. B/FWD signifies the fluid balance bought forward from the previous 24 hour chart	SD
BSC7	CORE TEMP	The hourly recording of the patient's core body temperature (set to a default level of 37.5 C).	RD
BSC8	PMP SPD	The volume of blood being pumped into the dialysis blood circuit per minute	RD
BSC9	VEN PRS	The pressure reading in the venous return line in the dialysis blood circuit	RD
BSC10	DIAL INF	The volume of dialysate infused into the dialyser in the preceding hour	RD
BSC11	HEP	Total volume of heparin infused into the patients blood system	RD
BSC12	REP FLU	The volume of replacement fluid introduced into the patient in the dialysis circuit	RD
BSC13	FLSH	Definition uncertain	RD
BSC14	TPN	Volume of total parenteral nutrition	RD
BSC15	NG	Volume of entral nutrition delivered to the patient	RD
BSC16-19	INFUSIONS	Four columns for entering the volume of drug infusions. The nurse enters the name of the drug in the top of the column.	RD

Table 7.3 Data definitions for the bedside chart

CHART NAME: BEDSIDE CHART

EXCEL FILENAME: FLUBSCHT

ITEM NO.	TITLE	DEFINITION	DATA TYPE
BSC20-21	BOLUS	Two columns for entering the volume of injections. The nurse enters the name of the drug in the top of the column.	RD
BSC22	COLL	The total volume of colloids given to the patient	RD
BSC23	DIAL O/P	The volume of used dialysate collected in the waste bag in the dialysate circuit	RD
BSC24	NG DRAIN	The volume of output via the naso-gastric drain	RD
BSC25	GAST O/P	The volume of output from the patient's bowel	RD
BSC26	BLD DR	Volume of blood drained from the patient	RD
BSC27	URIN	Volume of urine output	RD
BSC28	URIN- ACC TOT	Accumulated total of the urine output from 0700 hours on the date indicated	CD
BSC29	ULT FILT	The volume of ultrafiltrate removed in the haemodialysis	CD
BSC30	TOT I/P HR	The total volume of fluid input for the hour	CD
BSC31	ACC I/P	The accumulated fluid inputs delivered to the patient since 0700 hours on the date indicated	CD
BSC32	TOT O/P HR	The total volume of fluid output for the hour	CD
BSC33	ACC O/P	The accumulated fluid outputs delivered to the patient since 0700 hours on the date indicated	CD
BSC34	HR FLU BAL	The measured fluid balance (i/p-o/p) for the hour	CD
BSC35	ACC FLU BAL	The accumulated measured fluid balance for the patient since 0700 hours on the date indicated. The first number in this column is the previous 24 fluid balance, and is linked to the accumulated fluid balance on the previous days chart.	CD & LD

Table 7.3 Data definitions for the bedside chart

CHART NAME: INSENSIBLE LOSS ESTIMATES

EXCEL FILENAME: FLUINSEN

ITEM NO.	TITLE	DEFINITION	DATA TYPE
INS1	HOSPITAL NO	Equivalent to data item HDP1 on the identifiers chart	LD
INS2	SURNAME	Equivalent to data item HDP2 on the identifiers chart	LD
INS3	FIRST NAME(S)	Equivalent to data item HDP3 on the identifiers chart	LD
INS4	DOB	Equivalent to data item HDP4 on the identifiers chart	LD
INS5	PAT WEIGHT	Equivalent to data item HDP6 on the identifiers chart	LD
INS6	DATE	Date at 0800 hours on the attached chart	RD
INS7	TIME	The time, to the nearest hour, the estimates relate to	SD
INS7-8	INSENSIBLE LOSS	The hourly and accumulated estimates for the insensible loss	CD
INS9	CORE TEMP	Equivalent to data item BSC7 on the bedside chart	LD
INS10-11	SWEAT LOSS	The hourly and accumulated estimates for the sweat loss	CD
INS12-13	TOTAL INSENSIBLE + SWEAT LOSS	The sum of the estimates for sweat volume and insensible loss	CD

Table 7.4 Data definitions for the insensible loss estimate chart

CHART NAME: SUMMARY FLUID CHART

EXCEL FILENAME: FLUCHTSUM

ITEM NO.	TITLE	DEFINITION	DATA TYPE
CHT1	HOSPITAL NO	Equivalent to data item HDP1 on the identifiers chart	LD
CHT2	SURNAME	Equivalent to data item HDP2 on the identifiers chart	LD
CHT3	FIRST NAME(S)	Equivalent to data item HDP3 on the identifiers chart	LD
CHT4	DOB	Equivalent to data item HDP4 on the identifiers chart	LD
CHT5	DATE	Date at 0800 hours on the attached chart	RD
CHT6	TIME	The time, to the nearest hour, the readings were recorded.	SD
CHT7-8	MEASURED BALANCE	Equivalent to data item BSC34 and BSC35 on the bedside chart	LD
CHT9-10	INSENSIBLE AND SWEAT LOSS	Equivalent to data item INS12 and INS13 on the insensible estimates	LD
CHT11-12	AGGREGATE FLUID BALANCE	The measured fluid balance less the estimated insensible and sensible sweat loss	CD
CHT13-14	TARGET FLUID BALANCE	The prescribed fluid balance for the corresponding period split into 12 equal amounts	LD & CD
CHT15-16	DIFFERENCE	The aggregate balance less the linear target balance	CD
CHT17	REVISED TARGET BALANCE	The balance in the next hour required to achieve the state where the accumulated aggregate balance is equal to the prescribed accumulated target balance. It is calculated by subtracting the accumulated aggregate balance at the end of last hour from the accumulated target balance at the end of the next hour.	CD

Table 7.5 Data definitions for the summary fluid chart

CHART NAME: DOCTOR'S SUMMARY CHART

EXCEL FILENAME: FLUDRSUM

ITEM NO.	TITLE	DEFINITION	DATA TYPE
DRS1	HOSPITAL NO	Equivalent to data item HDP1 on the identifiers chart	LD
DRS2	SURNAME	Equivalent to data item HDP2 on the identifiers chart	LD
DRS3	FIRST NAME(S)	Equivalent to data item HDP3 on the identifiers chart	LD
DRS4	DOB	Equivalent to data item HDP4 on the identifiers chart	LD
DRS5	TIME PERIOD	The twelve hour time period up to the time shown. For the chart shown either 00:01 to 12:00, or 12:01 to 24:00	SD
DRS6	DATE	The date at the end of the corresponding time period	RD
DRS7-8	TOTAL CRYSTALLOIDS	The total crystalloids entered on the bedside chart in the period and accumulated over the time periods. This is calculated by linking the bedside chart and calculating the period total on the doctor's summary	LD &CD
DRS8-9	COLLOIDS	The total colloids entered on the bedside chart in the period and accumulated over the time periods. This is calculated by linking the bedside chart and calculating the period total on the doctor's summary	LD & CD
DRS10-11	TOTAL INPUTS	The twelve hour period totals and the accumulated totals of the fluid input volumes	CD
DRS12-13	ULTRAFILTRATE	The total ultrafiltrate entered on the bedside chart in the period and accumulated over the time periods. This is calculated by linking the bedside chart and calculating the period total on the doctor's summary	LD & CD
DRS14-15	URINE	The total urine volume entered on the bedside chart in the period and accumulated over the time periods. This is calculated by linking the bedside chart and calculating the period total on the doctor's summary	LD & CD
DRS16-17	OTHER MEASURED LOSSES	The total of the other losses entered on the bedside chart in the period and accumulated over the time periods. This is calculated by linking the bedside chart and calculating the period total on the doctor's summary	LD & CD
DRS18-19	INSENSIBLE & SWEAT LOSSES	The total of the estimated insensible and sweat losses on the insensible loss estimates in the period and accumulated over the time periods. This is calculated by linking the bedside chart and calculating the period total on the doctor's summary	LD & CD
DRS20-21	TOTAL OUTPUTS	The twelve hour period totals and the accumulated totals of the fluid output volumes	CD
DRS22-23	AGGREGATE FLUID BALANCE	The period total for the fluid inputs less the fluid outputs, and the accumulated balance including the previous charted balance bought forward .	RD & CD

Table 7.6 Data definitions for the doctor's summary chart

CHART NAME: FLUID PRESCRIPTION CHART

EXCEL FILENAME: FLUPRES

ITEM NO.	TITLE	DEFINITION	DATA TYPE
PRE1	HOSPITAL NO	Equivalent to data item HDP1 on the identifiers chart	LD
PRE2	SURNAME	Equivalent to data item HDP2 on the identifiers chart	LD
PRE3	FIRST NAME(S)	Equivalent to data item HDP3 on the identifiers chart	LD
PRE4	DOB	Equivalent to data item HDP4 on the identifiers chart	LD
PRE5	TIME PERIOD	The twelve hour time period up to the time shown. For the chart shown either 00:01 to 12:00, or 12:01 to 24:00	SD
PRE6	DATE	The data at the end of the corresponding time period	RD
PRE7	TOTAL CRYSTALLOIDS	The total prescribed crystalloids, estimated and, entered as the required input for the time period	RD
PRE8	COLLOIDS	The total prescribed colloids, estimated and, entered as the required input for the time period	RD
PRE9	TOTAL INPUTS	The sum of the estimates for the next time period of colloid and crystalloid inputs	CD
PRE10	ULTRAFILTRATE	The ultrafiltrate estimate calculated from all the other prescribed fluid variables entered on the chart	CD
PRE11	OTHER LOSSES	The total fluid losses other than the ultrafiltrate estimated and entered for the time period	RD
PRE12	TOTAL OUTPUTS	The sum of the estimates for the next time period of ultrafiltrate and other fluid outputs	CD
PRE13	AGGREGATE FL BAL	Equivalent to data item DRS22 on the doctor's summary fluid chart chart	LD
PRE14	DIFF	Aggregate less target fluid balance	CD

Table 7.7 Data definitions for the fluid prescription chart

option A state	option B state	decision state
0	0	0
0	1	0
1	0	1
1	1	0

Table 7.8 Truth table for decision arbitration function

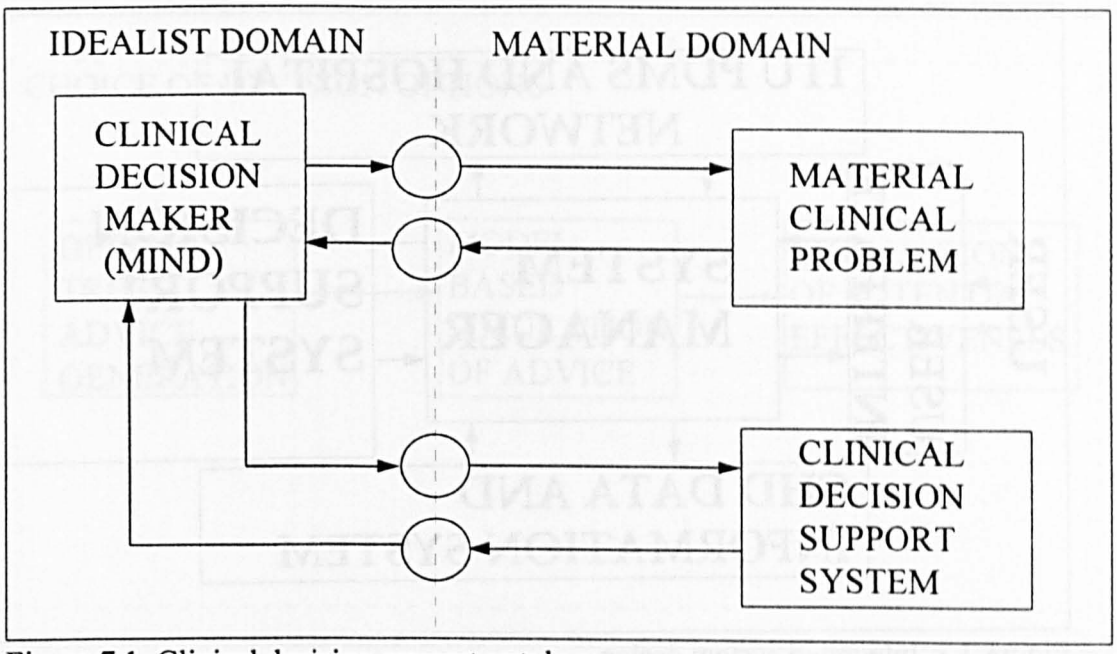


Figure 7.1 Clinical decision support ontology

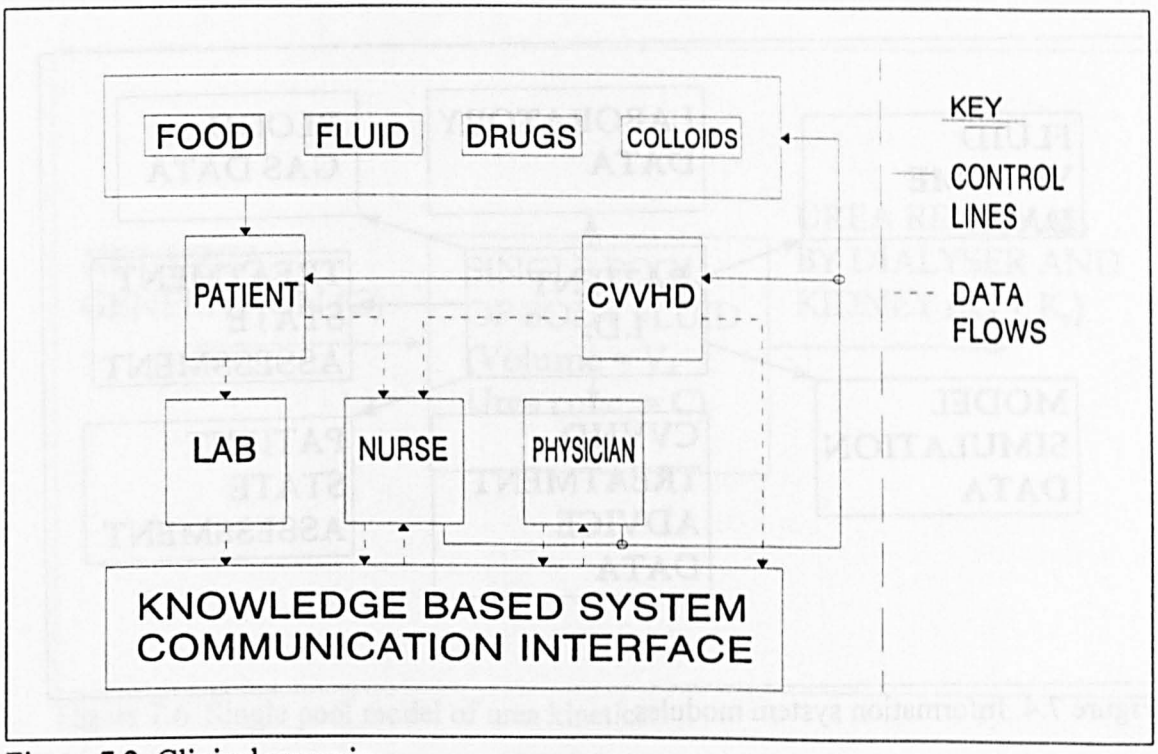


Figure 7.2 Clinical scenario

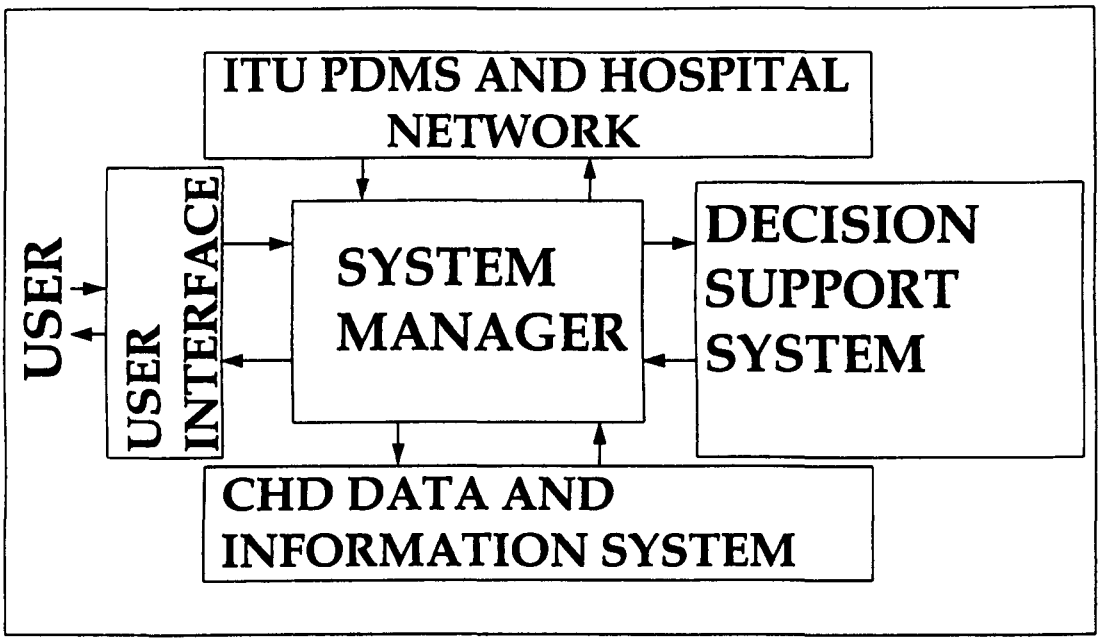


Figure 7.3 Integrated system design

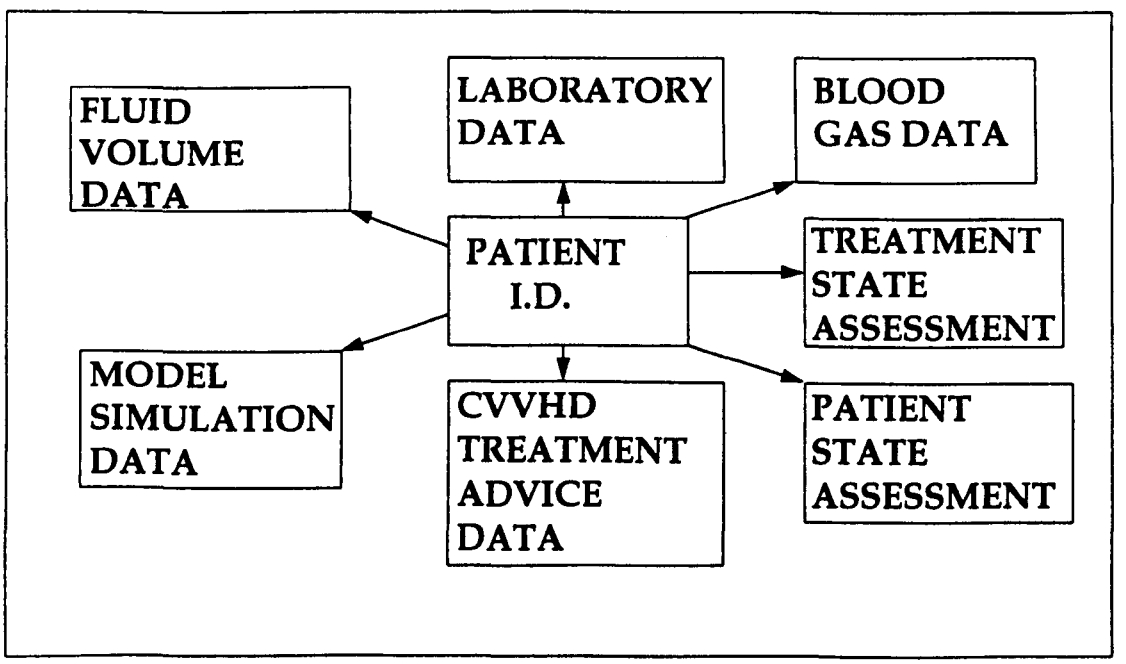


Figure 7.4 Information system modules

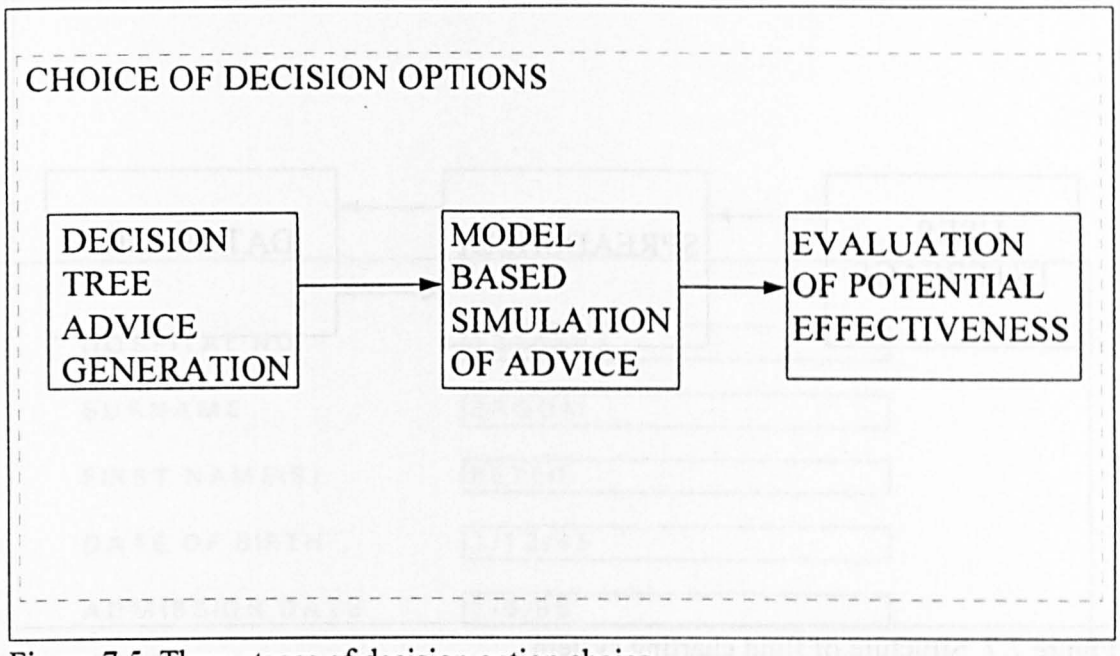


Figure 7.5 Three stages of decision option choice

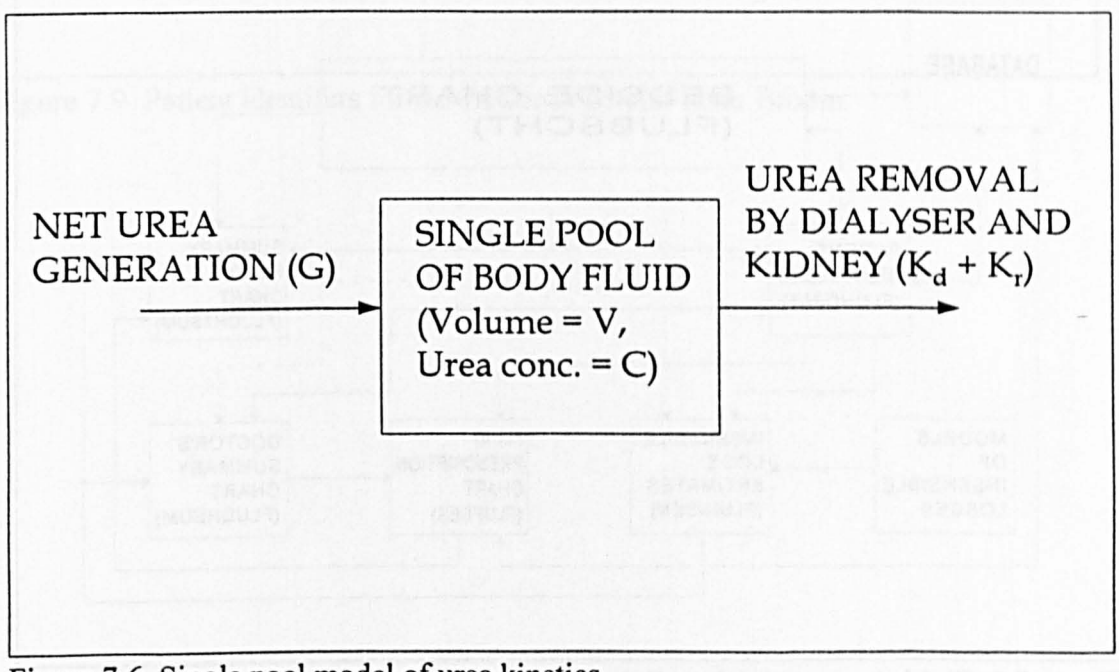


Figure 7.6 Single pool model of urea kinetics

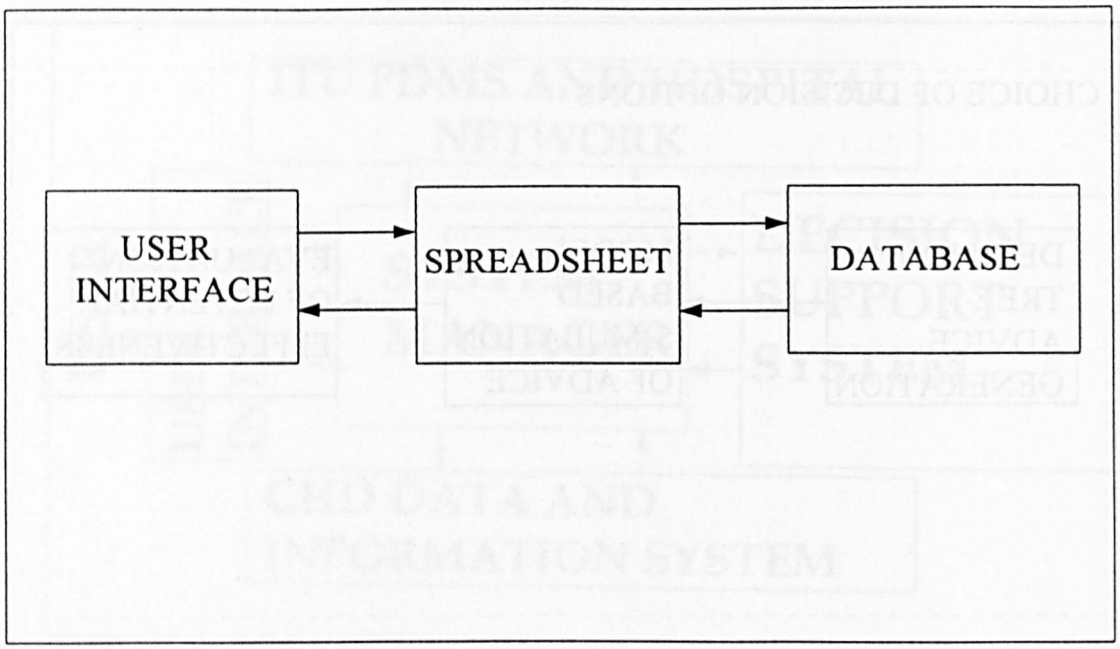


Figure 7.7 Structure of fluid charting system

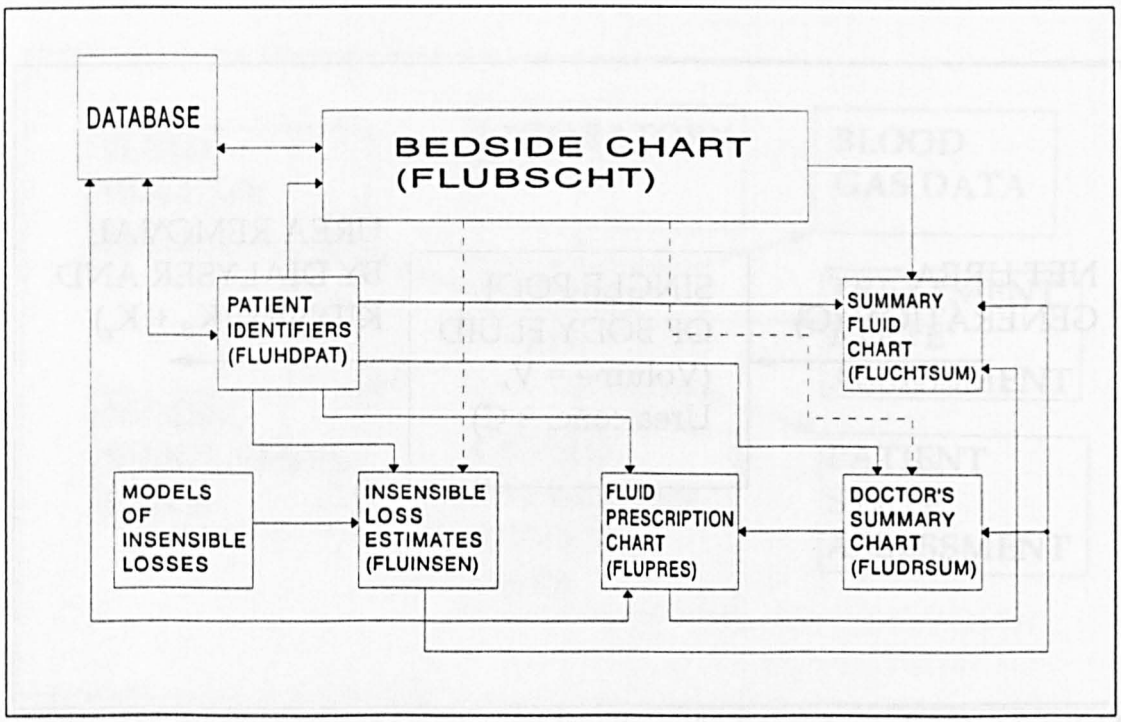


Figure 7.8 Fluid chart spreadsheet linkage

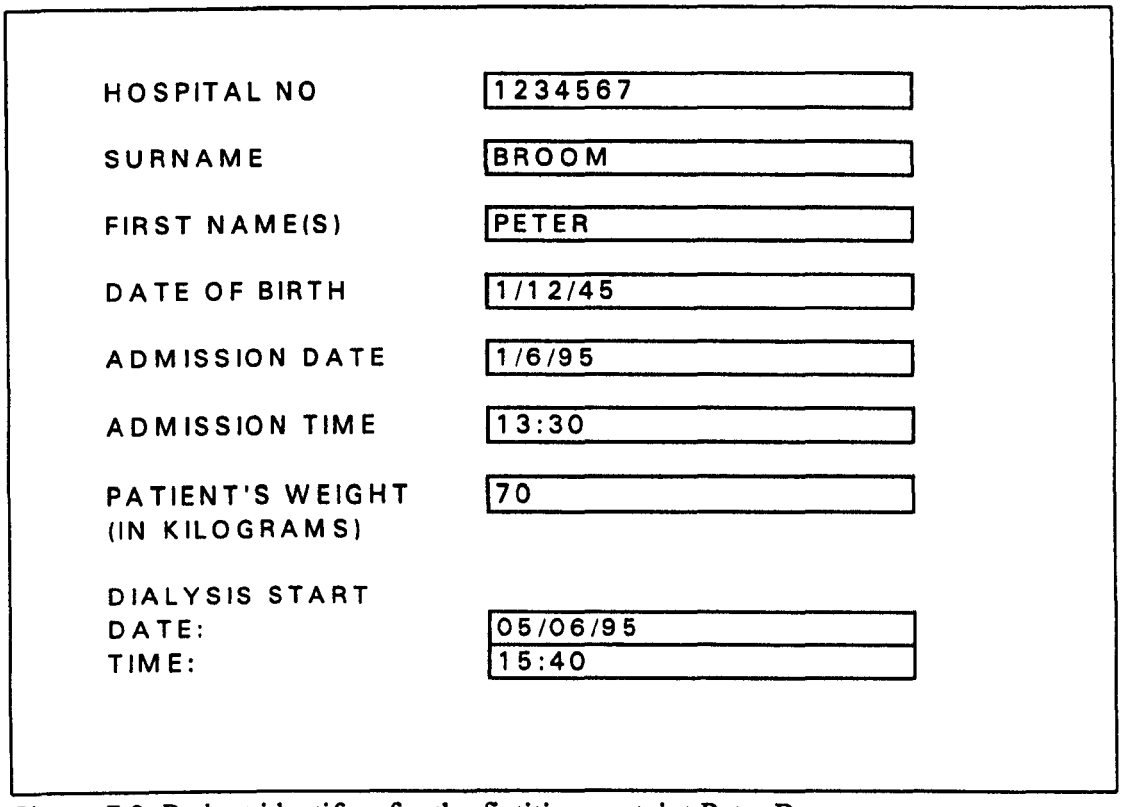


Figure 7.9 Patient identifers for the fictitious pateint Peter Broom

HOSPITAL NO 1234567

SURNAME BROOM

FIRST NAME(S) PETER

DOB 01/12/45

DATE: 8/6/95					FLUID INPUTS													FLUID OUTPUTS										MEASURED BALANCE	
TIME	TEMP	DIALYSIS					FLSH	DIET		DRUG						COLL	DIAL					URIN		TOT	ACC	TOT	ACC	HR	ACC
HOUR UP TO	CORE TEMP	PMP SPD	VEN PRS	DIAL INF	HEP	REP FLU		TPN	NG	INFUSIONS prop	alf			BOLUS drug	kcl		DIAL O/P	NG DRN	GAST O/P	BLD DR	URIN	ACC TOT	ULT FILT	I/P HR	I/P	O/P HR	O/P	FLU BAL	FLU BAL
	degC	ml/min	mmHg	ml	ml	ml	ml	ml	ml	ml	ml	ml	ml	ml	ml	ml	ml	ml	ml	ml	ml	ml	ml	ml	ml	ml	ml	ml	ml
B/FWD																													-668.2
0800	38.5	100	50	1000	2	400	12	106		7	4.2						1520					0	520	531.2	531.2	520	520	11.2	11.2
0900	38.2	100	50	1000	2	300	12	106		7	4.2						1440					0	440	431.2	962.4	440	960	-8.8	2.4
1000	38	100	35	1000	2	300	12	106		7	4.2						1350					0	350	431.2	1394	350	1310	81.2	83.6
1100	37.8	80	35	1000	2	150	12	106		7	4.2			30	120		1360	100				0	360	431.2	1825	460	1770	-28.8	54.8
1200	37.5	80	35	1000	2	150	12	106		3	4.2						1400					0	400	277.2	2102	400	2170	-122.8	-68
1300	37.5	80	35	1000	2	150	12	106		3	2.1						1320					0	320	275.1	2377	320	2490	-44.9	-112.9
1400	37.5	80	35	1000	2	150	12	106		3	2.1						1280					0	280	275.1	2652	280	2770	-4.9	-117.8
1500	37.5	100	40	1000	2	150	12	106		3	2.1						1300					0	300	275.1	2927	300	3070	-24.9	-142.7
1600	37.4	100	40	1000	2	175	12	106		3	2.1						1320				14	14	320	300.1	3227	334	3404	-33.9	-176.6
1700	37.5	100	40	1000	2		12	106		3	2.1						1340				2	16	340	125.1	3353	342	3746	-216.9	-393.5
1800	37.5	100	40	1000	2		12	106		3	2.1					100	1310					16	310	225.1	3578	310	4056	-84.9	-478.4
1900	37.5	100	40	1000	2	150	12	106		3	2.1						1300					16	300	275.1	3853	300	4356	-24.9	-503.3
2000	37.5	newfltr			2		12	106		3	2.1						100					16	100	125.1	3978	100	4456	25.1	-478.2
2100	37.2	100	80	1000	2	100	12	106		3	2.1					150	2080				1	17	1080	375.1	4353	1081	5537	-705.9	-1184
2200	37.5	100	70	1000	2	400	12	106		3	2.1					150	1780				2	19	780	675.1	5028	782	6319	-106.9	-1291
2300	37.5	100	60	1000	2	600	12	106		3	2.1			30		150	1670					19	670	905.1	5933	670	6989	235.1	-1056
2400	37.5	100	60	1000	2	600	12	106		3	2.1						1670					19	670	725.1	6658	670	7659	55.1	-1001
0100	37.5	100	60	1000	2	800	12	106		3	2.1						1630					19	630	925.1	7583	630	8289	295.1	-705.7
0200	37.2	100	60	1000	2	600	12	106		3	2.1						1570					19	570	725.1	8308	570	8859	155.1	-550.6
0300	37.5	100	60	1000	2	500	12	106		3	2.1						1600					19	600	625.1	8934	600	9459	25.1	-525.5
0400	37.5	100	70	1000	2	600	12	106		3	2.1						1600					19	600	725.1	9659	600	10059	125.1	-400.4
0500	37	100	60	1000	2	400	12	106		3	2.1						1370					19	370	525.1	10184	370	10429	155.1	-245.3
0600	37.5	100	60	1000	2	200	12	106		3	2.1						1720	150				19	720	325.1	10509	870	11299	-544.9	-790.2
0700	37.5	100	70	1000	2	800	12	106		3	2.1						1530				2	21	530	925.1	11434	532	11831	393.1	-397.1
TOTAL				23000	48	7675		2544	0	88	60.9	0		60	120	550	34560	250	0	0	21	21	11560	11434	11434	11831	11831	-397.1	-397.1

Figure 7.10 Bedside chart for Peter Broom on 8/6/95

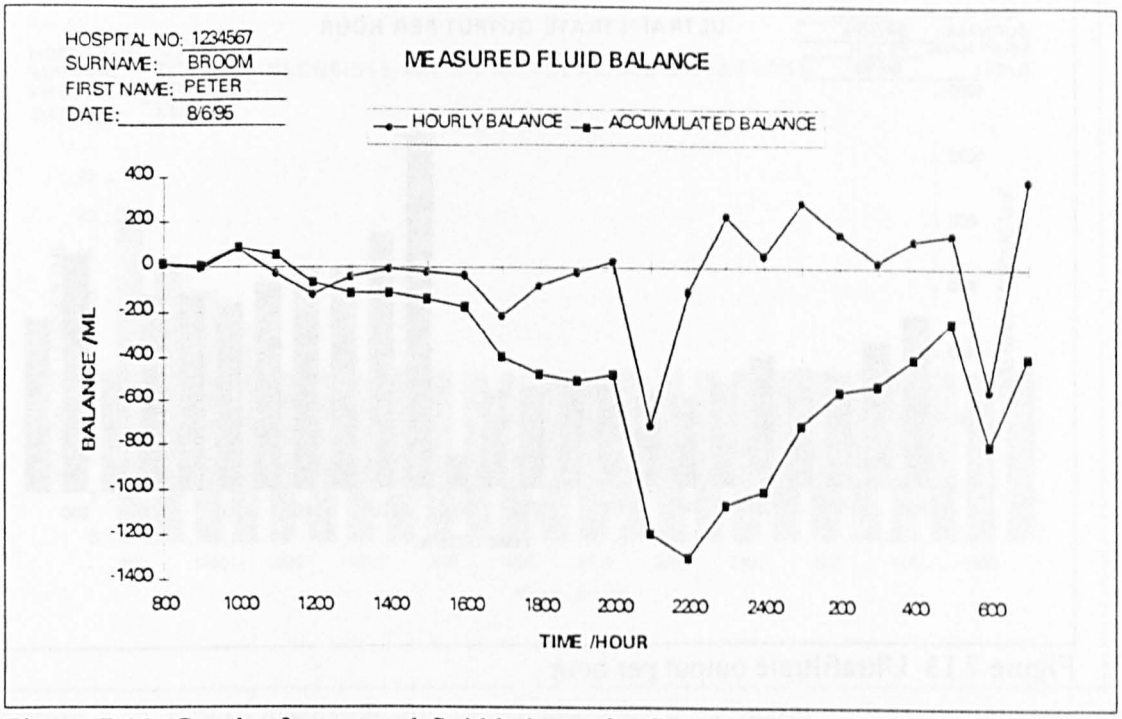
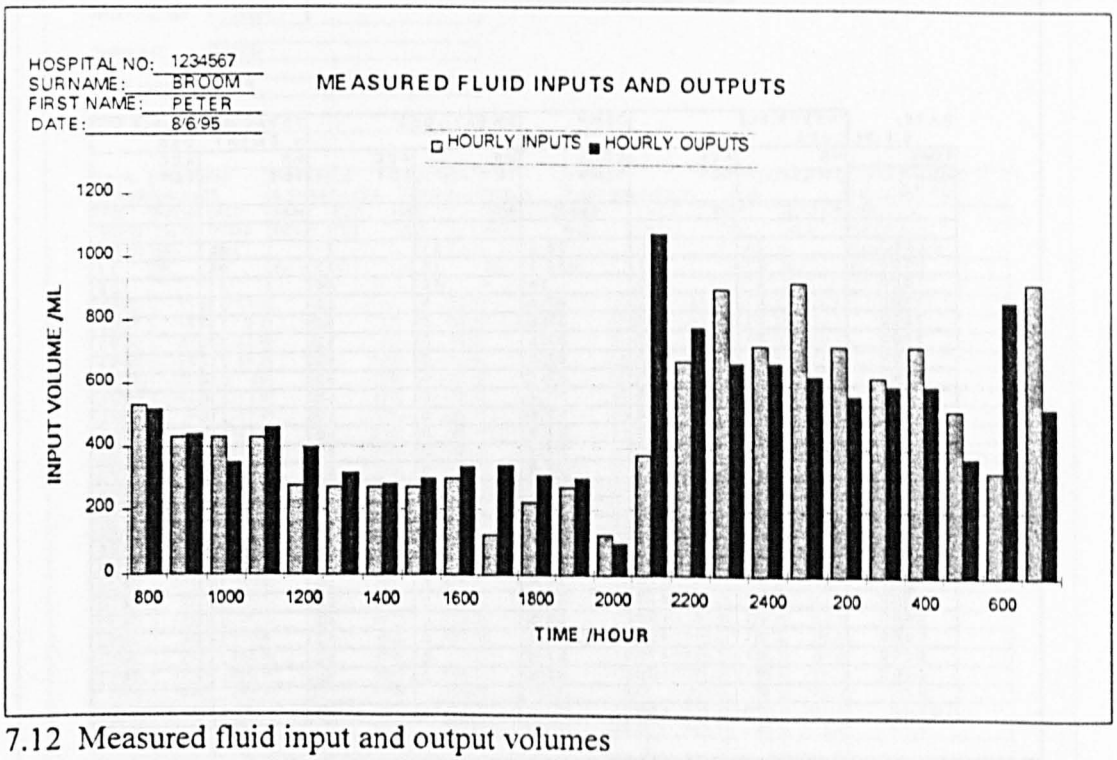


Figure 7.11 Graph of measured fluid balance for fictitious patient Peter Broom



7.12 Measured fluid input and output volumes

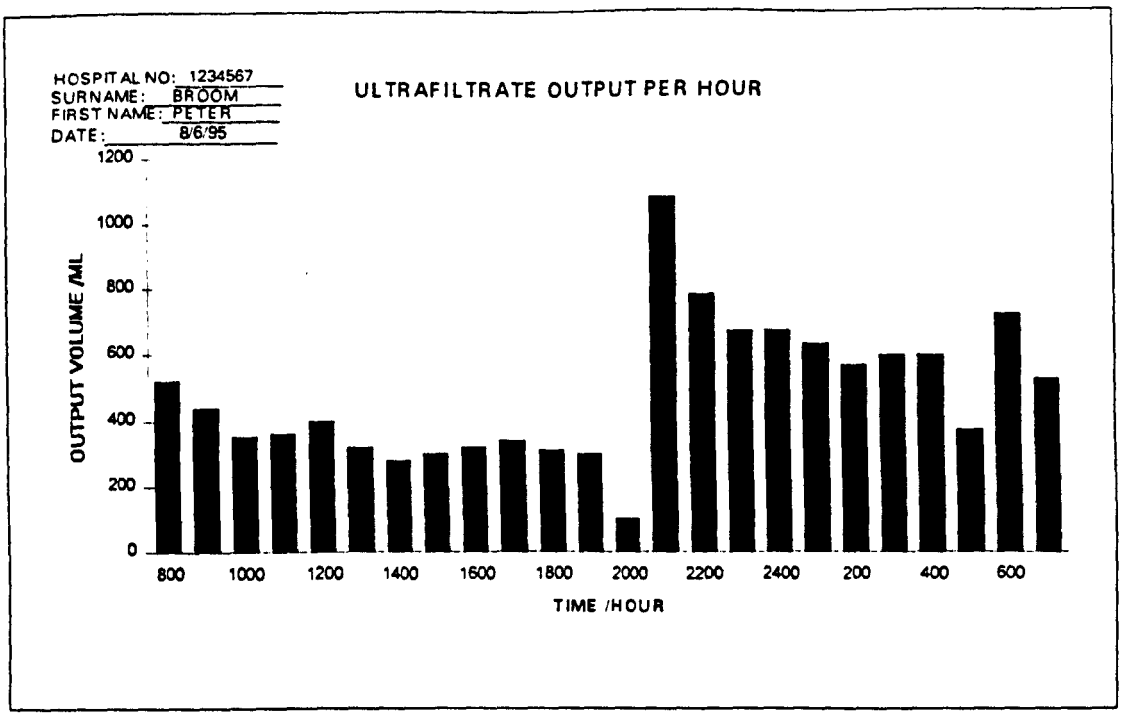


Figure 7.13 Ultrafiltrate output per hour

HOSPITAL NO 1234567

SURNAME BROOM

FIRST NAME(S) PETER

DOB 01 12 45

PAT WEIGHT 70

DATE: 8/6/95	INSENSIBLE LOSS		TEMP.	SWEAT LOSS		TOTAL INSENSIBLE + SWEAT LOSS	
TIME HOUR UP TO	HR TOT	ACC TOT	CORE TEMP.	HR TOT	ACC TOT	HR TOT	ACC TOT
	ml	ml	deg C	ml	ml	ml	ml
0800	21	21	38.5	21	21	42	42
0900	21	42	38.2	15	35	35	77
1000	21	63	38	10	46	31	108
1100	21	83	37.8	6	52	27	135
1200	21	104	37.5	0	52	21	156
1300	21	125	37.5	0	52	21	177
1400	21	146	37.5	0	52	21	198
1500	21	167	37.5	0	52	21	219
1600	21	188	37.4	0	52	21	240
1700	21	208	37.5	0	52	21	260
1800	21	229	37.5	0	52	21	281
1900	21	250	37.5	0	52	21	302
2000	21	271	37.5	0	52	21	323
2100	21	292	37.2	0	52	21	344
2200	21	313	37.5	0	52	21	365
2300	21	333	37.6	0	52	21	385
2400	21	354	37.5	0	52	21	406
0100	21	375	37.5	0	52	21	427
0200	21	396	37.2	0	52	21	448
0300	21	417	37.5	0	52	21	469
0400	21	438	37.5	0	52	21	490
0500	21	458	37	0	52	21	510
0600	21	479	37.5	0	52	21	531
0700	21	500	37.5	0	52	21	552
TOTAL	500	500		52	52	552	552

Figure 7.14 Insensible and sweat loss estimates

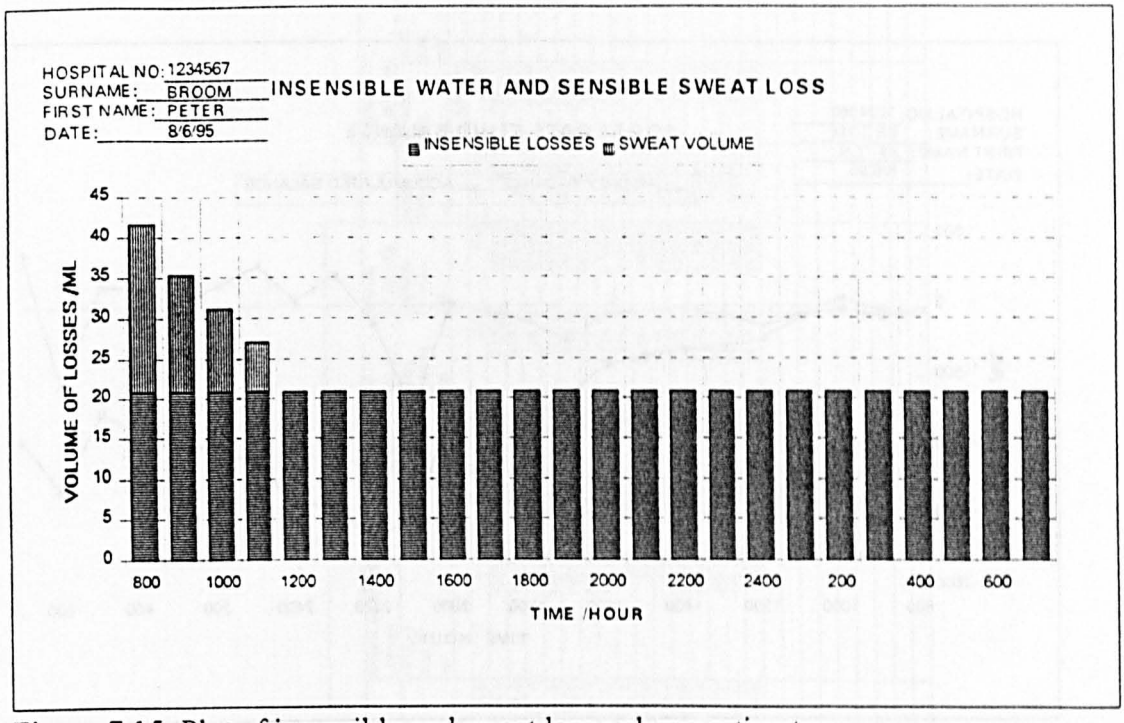


Figure 7.15 Plot of insensible and sweat loss volume estimates

HOSPITAL NO 1234567

SURNAME BROOM

FIRST NAME(S) PETER

DOB 01/12/45

DATE: 8/6/95	MEASURED BALANCE		INSENSIBLE & SWEAT LOSS		AGGREGATE FLUID BALANCE(A)		TARGET FLUID BALANCE(T)		DIFFERENCE (A-T)		REVISED TARGET BALANCE
TIME HOUR UP TO	HR FLUID BAL	ACC FLUID BAL	HR TOT	ACC TOT	HR BAL	ACC BAL	HR BAL	ACC BAL	HR BAL	ACC BAL	FOR HOUR PRECEEDING TIME SHOWN
	ml	ml	ml	ml	ml	ml	ml	ml	ml	ml	ml
0800	11.2	11.2	42	42	-30.5	-30.5	-25.0	-25.0	-5.5	-5.5	268.2
0900	-8.8	2.4	35	77	-44.2	-74.7	-25.0	-50.0	-19.2	-24.7	-19.5
1000	81.2	83.6	31	108	50.0	-24.7	-25.0	-75.0	75.0	50.3	-0.3
1100	-28.8	54.8	27	135	-55.9	-80.6	-25.0	-100.0	-30.9	19.4	-75.3
1200	-122.8	-68	21	156	-143.6	-224.3	-25.0	-125.0	-118.6	-99.3	-44.4
1300	-44.9	-112.9	21	177	-65.7	-290.0	-83.3	-208.3	17.6	-81.7	15.9
1400	-4.9	-117.8	21	198	-25.7	-315.7	-83.3	-291.7	57.6	-24.1	-1.7
1500	-24.9	-142.7	21	219	-45.7	-361.5	-83.3	-375.0	37.6	13.6	-59.3
1600	-33.9	-176.6	21	240	-54.7	-416.2	-83.3	-458.3	28.6	42.2	-96.9
1700	-216.9	-393.5	21	260	-237.7	-653.9	-83.3	-541.7	-154.4	-112.3	-125.6
1800	-84.9	-478.4	21	281	-105.7	-759.7	-83.3	-625.0	-22.4	-134.7	28.9
1900	-24.9	-503.3	21	302	-45.7	-805.4	-83.3	-708.3	37.6	-97.0	51.3
2000	25.1	-478.2	21	323	4.3	-801.1	-83.3	-791.7	87.6	-9.4	13.7
2100	-705.9	-1184	21	344	-726.7	-1527.9	-83.3	-875.0	-643.4	-652.9	-73.9
2200	-106.9	-1291	21	365	-127.7	-1655.6	-83.3	-958.3	-44.4	-697.3	569.5
2300	235.1	-1056	21	385	214.3	-1441.3	-83.3	-1041.7	297.6	-399.7	613.9
2400	55.1	-1001	21	406	34.3	-1407.1	-83.3	-1125.0	117.6	-282.1	316.3
0100	295.1	-705.7	21	427	274.3	-1132.8	25.0	-1100.0	249.3	-32.8	307.1
0200	155.1	-550.6	21	448	134.3	-998.5	25.0	-1075.0	109.3	76.5	57.8
0300	25.1	-525.5	21	469	4.3	-994.3	25.0	-1050.0	-20.7	55.8	-51.5
0400	125.1	-400.4	21	490	104.3	-890.0	25.0	-1025.0	79.3	135.0	-30.8
0500	155.1	-245.3	21	510	134.3	-755.7	25.0	-1000.0	109.3	244.3	-110.0
0600	-544.9	-790.2	21	531	-565.7	-1321.5	25.0	-975.0	-590.7	-346.5	-219.3
0700	393.1	-397.1	21	552	372.3	-949.2	25.0	-950.0	347.3	0.8	371.5
TOTAL	-397.1	-397.1	552.08	552.083	-949.1833	-949.1833	-950.0	-950.0	0.8167	0.8167	

Figure 7.16 Summary fluid chart showing aggregate fluid balance

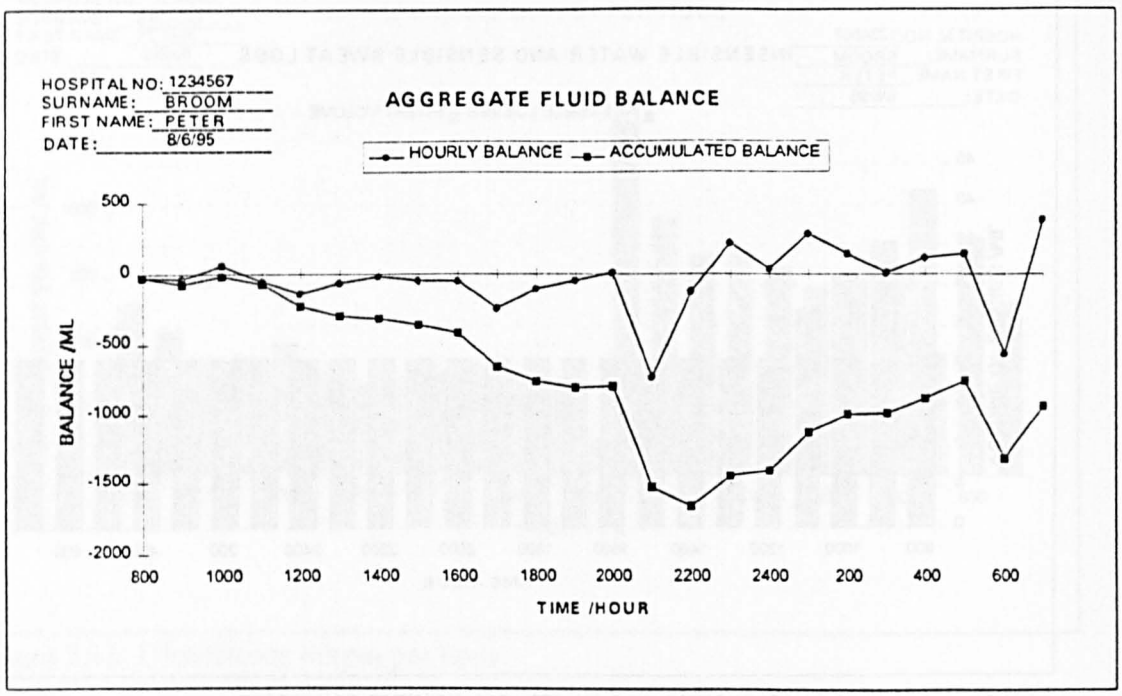


Figure 7.17 Aggregate fluid balance

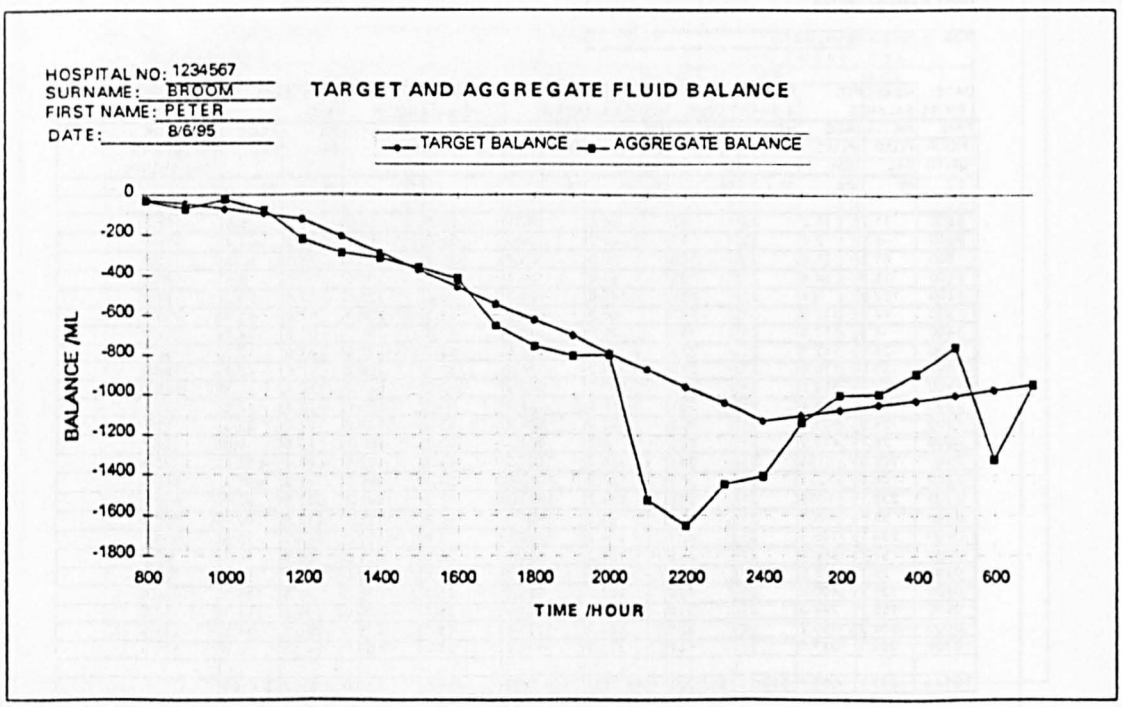


Figure 7.18 Target vs aggregate fluid balance

HOSPITAL NO	1234567
SURNAME	BROOM
FIRST NAME(S)	PETER
DOB	01/12/45

		FLUID INPUTS						FLUID OUTPUTS											
		TOTAL CRYSTALLOIDS		COLLOIDS		TOTAL INPUTS		ULTRAFILTRATE		URINE		OTHER MEASURED LOSSES		INSENSIBLE & SWEAT LOSSES		TOTAL OUTPUTS		AGGREGATE FL. BAL. (A)	
TIME	ON DATE	PERIOD	ACC	PERIOD	ACC	PERIOD	ACC	PERIOD	ACC	PERIOD	ACC	PERIOD	ACC	PERIOD	ACC	PERIOD	ACC	PERIOD	ACC
12 HR UP TO		TOT ml	TOT ml	TOT ml	TOT ml	TOTAL ml	TOTAL ml	TOTAL ml	TOT ml	TOT ml	TOT ml	TOT ml	TOT ml	TOTAL ml	TOTAL ml	TOTAL ml	TOTAL	BAL ml	BAL ml
B/FWD																		5324.0	
1200	01/06/95	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	5324.0
2400	01/06/95	3507.6	3507.6	290.0	290.0	3797.6	3797.6	4530.0	4530.0	16.0	16.0	120.0	120.0	229.2	229.2	4895.2	4895.2	-1097.6	4226.4
1200	02/06/95	3308.0	6815.6	100.0	390.0	3408.0	7205.6	3530.0	8060.0	56.0	72.0	150.0	270.0	250.0	479.2	3986.0	8881.2	-578.0	3648.4
2400	02/06/95	5411.2	12226.8	200.0	590.0	5611.2	12816.8	5820.0	13880.0	29.0	101.0	60.0	330.0	250.0	729.2	6159.0	15040.2	-547.8	3100.6
1200	03/06/95	3709.2	15936.0	0.0	590.0	3709.2	16526.0	4380.0	18260.0	4.0	105.0	200.0	530.0	250.0	979.2	4834.0	19874.2	-1124.8	1975.8
2400	03/06/95	4817.4	20753.4	200.0	790.0	5017.4	21543.4	5460.0	23720.0	0.0	105.0	200.0	730.0	250.0	1229.2	5910.0	25784.2	-892.6	1083.2
1200	04/06/95	3825.5	24578.9	700.0	1490.0	4525.5	26068.9	5030.0	28750.0	0.0	105.0	245.0	975.0	250.0	1479.2	5525.0	31309.2	-999.5	83.7
2400	04/06/95	5358.1	29937.0	0.0	1490.0	5358.1	31427.0	5350.0	34100.0	0.0	105.0	100.0	1075.0	250.0	1729.2	5700.0	37009.2	-341.9	258.2
1200	05/06/95	4564.8	34501.8	100.0	1590.0	4664.8	36091.8	5290.0	39390.0	0.0	105.0	0.0	1075.0	250.0	1979.2	5540.0	42549.2	-875.2	-1133.4
2400	05/06/95	4815.6	39317.4	700.0	2290.0	5515.6	41607.4	5410.0	44800.0	0.0	105.0	0.0	1075.0	250.0	2229.2	5660.0	48209.2	-144.4	-1277.8
1200	06/06/95	6395.1	45712.5	100.0	2390.0	6495.1	48102.5	6630.0	51430.0	0.0	105.0	0.0	1075.0	250.0	2479.2	6880.0	55089.2	-384.9	-1662.7
2400	06/06/95	5156.4	50868.9	300.0	2690.0	5456.4	53558.9	5670.0	57100.0	0.0	105.0	330.0	1405.0	250.0	2729.2	6250.0	61339.2	-793.6	-2456.3
1200	07/06/95	6742.4	57611.3	0.0	2690.0	6742.4	60301.3	6370.0	63470.0	0.0	105.0	150.0	1555.0	250.0	2979.2	6770.0	68109.2	-27.6	-2483.9
2400	07/06/95	6244.4	63855.7	0.0	2690.0	6244.4	66545.7	6450.0	69920.0	0.0	105.0	200.0	1755.0	250.0	3229.2	6900.0	75009.2	-655.6	-3139.5
1200	08/06/95	4720.4	68576.1	0.0	2690.0	4720.4	71266.1	4660.0	74580.0	0.0	105.0	115.0	1870.0	302.1	3531.3	5077.1	80086.3	-356.7	-3496.2
2400	08/06/95	4006.2	72582.3	550.0	3240.0	4556.2	75822.3	5470.0	80050.0	19.0	124.0	0.0	1870.0	145.8	3677.1	5634.8	85721.1	-1078.6	4574.8
1200																			
2400																			
1200																			
2400																			
1200																			
2400																			
1200																			
2400																			

FIGURE 7.18 DOCTOR'S SUMMARY FLUID CHART FOR PETER BROOM

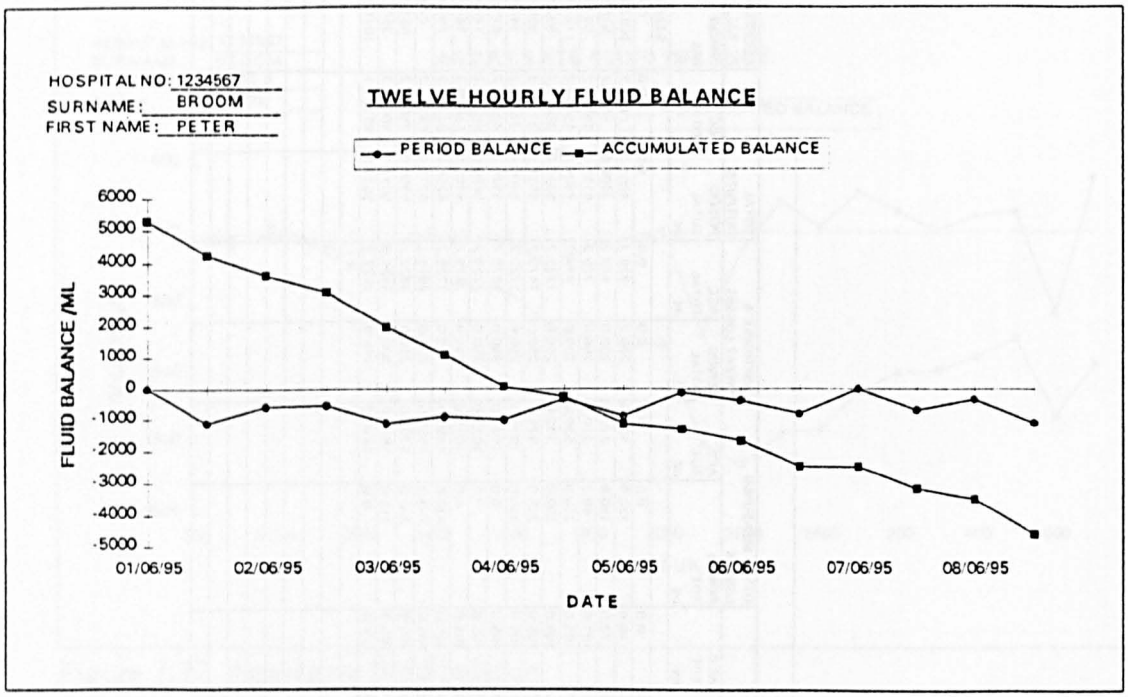


Figure 7.19 Twelve hourly fluid balance

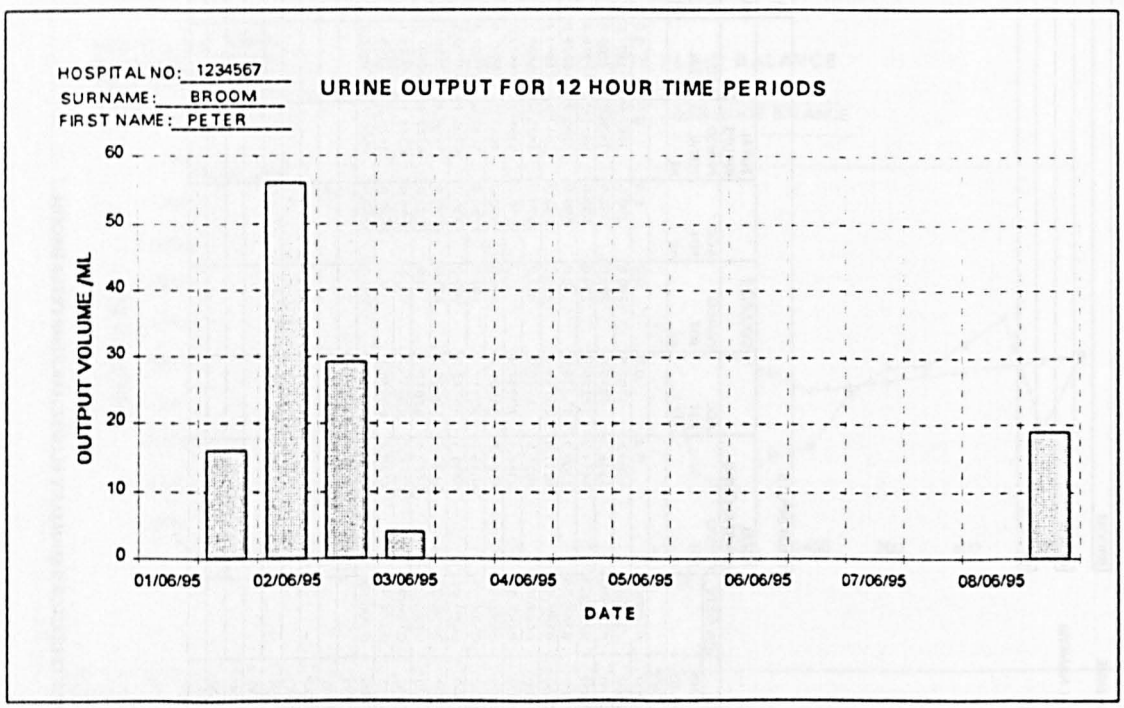


Figure 7.20 Twelve hourly totals of urine output

HOSPITAL NO 1234567

SURNAME BROOM

FIRST NAME(S) PETER

DOB 01/12/45

TARGET TIME	ON DATE	FLUID INPUT TARGETS: TOTAL CRYSTALLOIDS	FLUID INPUT TARGETS: COLLOIDS	FLUID INPUT TARGETS: TOTAL INPUTS	FLUID OUTPUT TARGETS: ULTRAFILTRATE	FLUID OUTPUT TARGETS: OTHER LOSES	FLUID OUTPUT TARGETS: TOTAL OUTPUTS	TARGET FLUID BALANCE (T)	AGGREGATE FL BAL (A)	DIFF (A-T)
12 HR UP TO		PERIOD TOT ml	PERIOD TOT ml	PERIOD TOT ml	PERIOD TOT ml	PERIOD TOT ml	PERIOD TOT ml	PERIOD TOT ml	PERIOD TOT ml	PERIOD TOT ml
1200	01/06/95							0.0	0.0	0.0
2400	01/06/95	3500.0	300.0	3800.0	4400.0	400.0	4800.0	-1000.0	-1097.8	97.8
1200	02/06/95	7000.0	200.0	7200.0	7600.0	200.0	7800.0	-600.0	-578.0	22.0
2400	02/06/95	5500.0	200.0	5700.0	5900.0	300.0	6200.0	-500.0	-547.8	-47.8
1200	03/06/95	3700.0	0.0	3700.0	4400.0	400.0	4800.0	-1100.0	-1124.8	-24.8
2400	03/06/95	5000.0	200.0	5200.0	5650.0	450.0	6100.0	-900.0	-892.6	7.4
1200	04/06/95	4000.0	150.0	4150.0	4900.0	250.0	5150.0	-1000.0	-999.5	0.5
2400	04/06/95	4000.0	0.0	4000.0	4000.0	300.0	4300.0	-300.0	-341.9	-41.9
1200	05/06/95	5000.0	200.0	5200.0	5700.0	400.0	6100.0	-900.0	-875.2	24.8
2400	05/06/95	6000.0	600.0	6600.0	6400.0	300.0	6700.0	-100.0	-144.4	-44.4
1200	06/06/95	4500.0	200.0	4700.0	4600.0	500.0	5100.0	-400.0	-384.9	15.1
2400	06/06/95	6500.0	500.0	7000.0	7600.0	200.0	7800.0	-800.0	-793.6	6.4
1200	07/06/95	4500.0	100.0	4600.0	4200.0	400.0	4600.0	0.0	-27.6	-27.6
2400	07/06/95	5500.0	0.0	5500.0	5900.0	300.0	6200.0	-700.0	-655.6	44.4
1200	08/06/95	4000.0	0.0	4000.0	4050.0	250.0	4300.0	300.0	356.7	56.7
2400	08/06/95	3500.0	0.0	3500.0	4100.0	400.0	4500.0	-1000.0	-1078.6	-78.6
1200	09/06/95	4000.0	500.0	4500.0	4000.0	200.0	4200.0	300.0		
2400										
1200										
2400										
1200										
2400										
1200										
2400										

Figure 7.21 fluid volume prescription chart

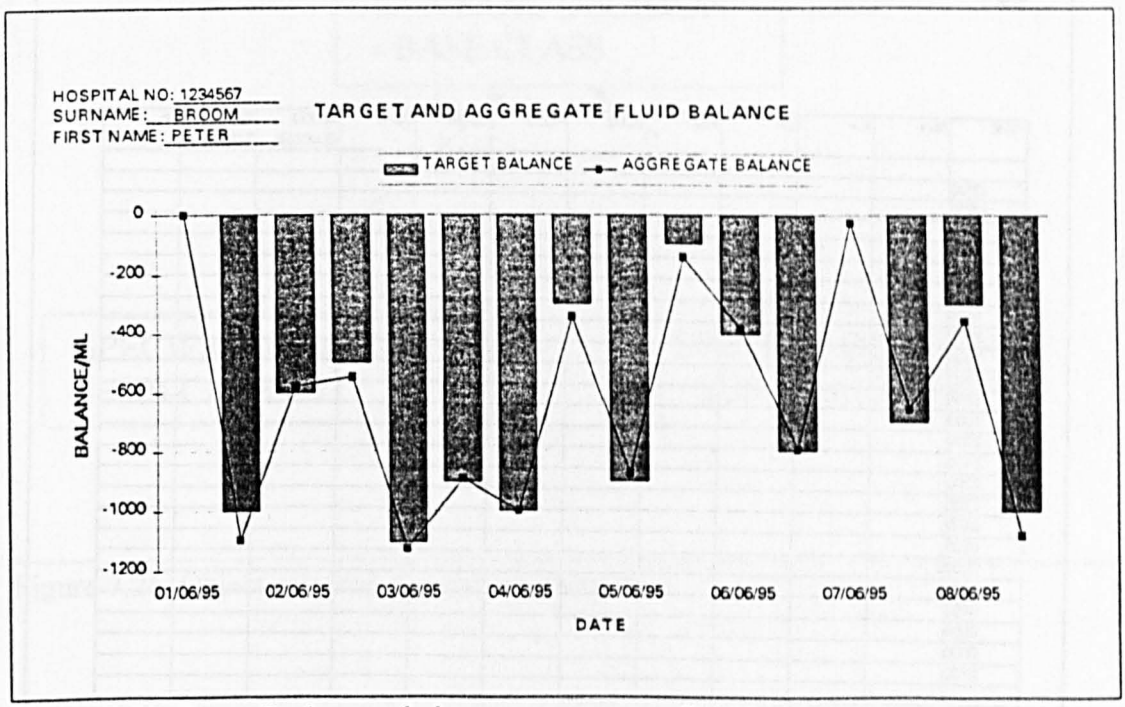


Figure 7.22 Prescribed target balance vs aggregate fluid balance

RESULTS FLOW SHEET - BLOOD

HOSP. NO.

SURNAME

FIRST NAME

DOB

Date						
Time						
Na +						
K +						
Ca2 +						
PO4-						
urea						
creatinine						
lactate						
PTT						

Figure 7.23 Laboratory results for blood tests

ITU BLOOD GAS RESULTS

HOSP. NO.

SURNAME

FIRST NAME

DOB

TIME	Na +	K +	pH	pO2	pCO2	HCO3	O2 SAT	O2 %	BLOOD GLUCOSE	BASE EXCESS	Hb
0800											
0900											
1000											
1100											
1200											
1300											
1400											
1500											
1600											
1700											
1800											
1900											
2000											
2100											
2200											
2300											
2400											
0100											
0200											
0300											
0400											
0500											
0600											
0700											

Figure 7.24 ITU blood gas analyser results

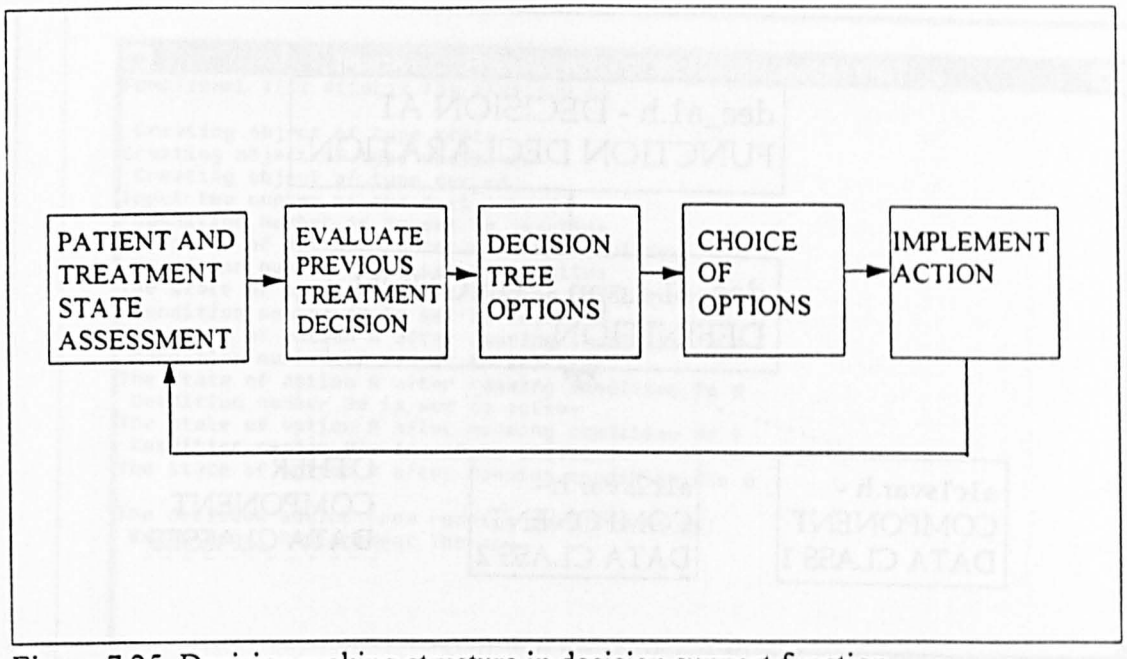


Figure 7.25 Decision making structure in decision support function

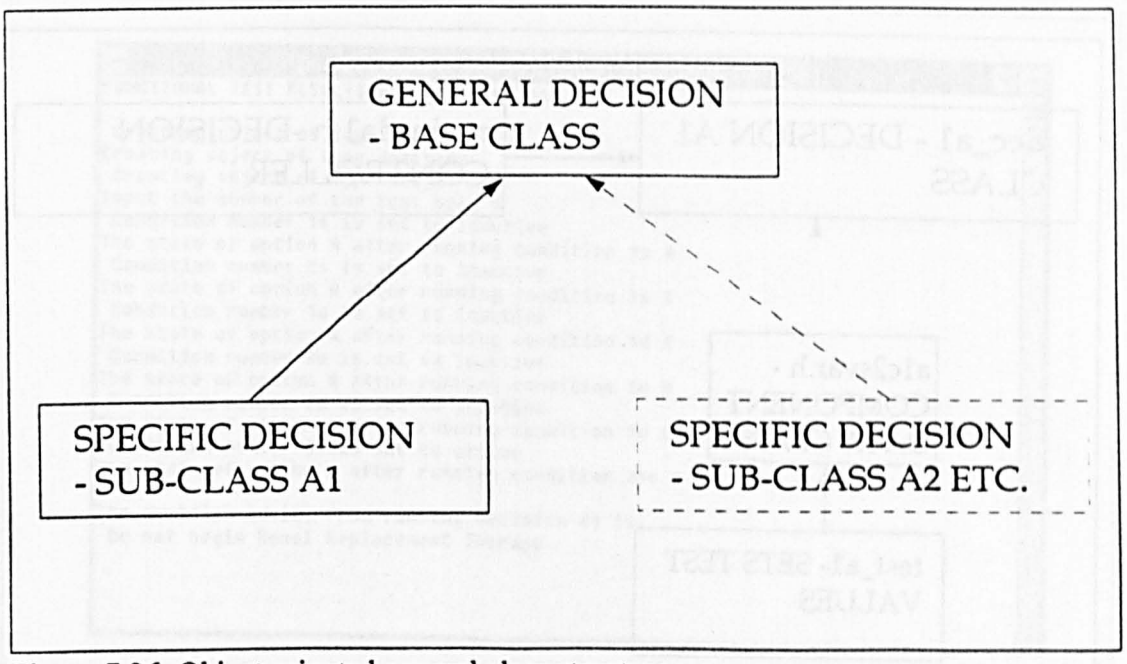


Figure 7.26 Object oriented general class structure

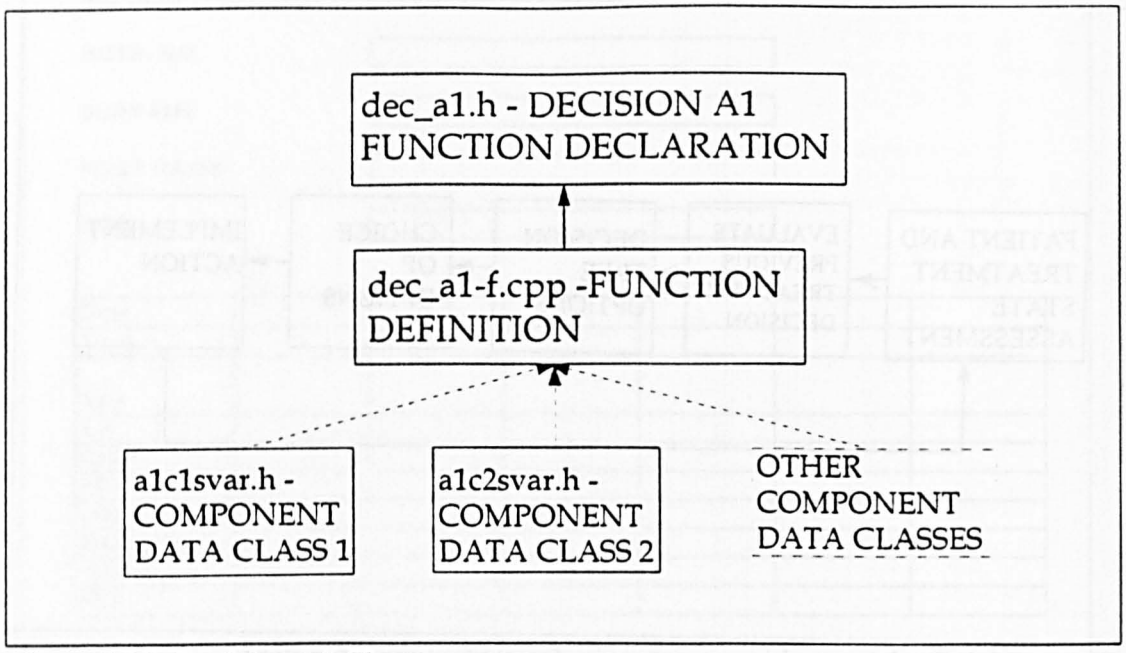


Figure 7.27 Decision A1 file structure

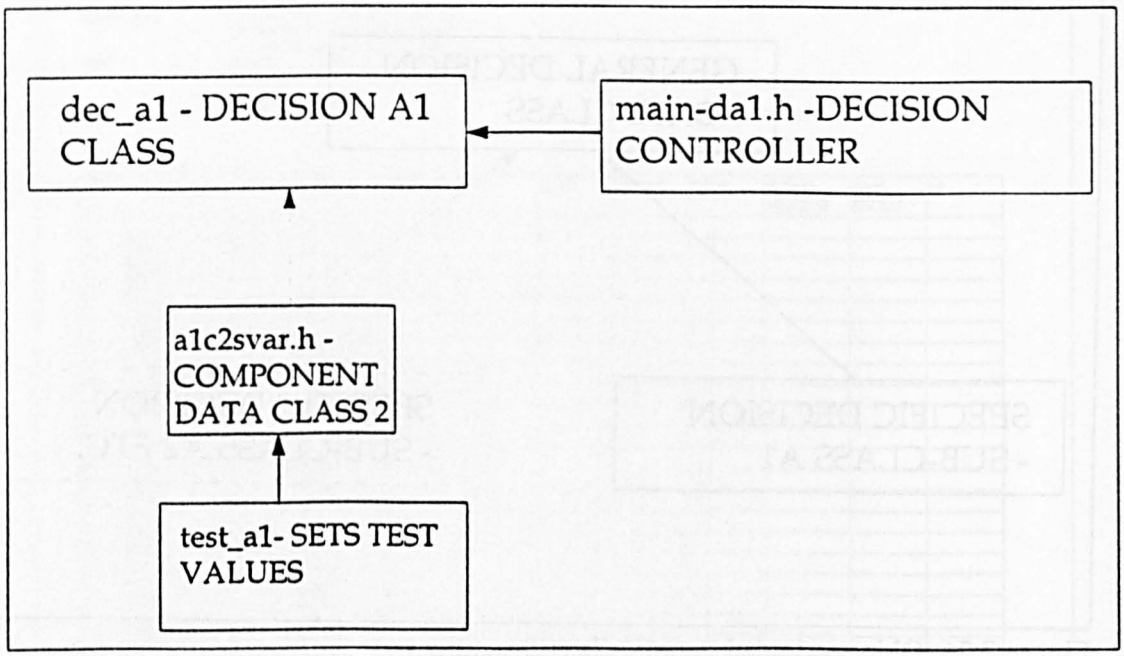


Figure 7.28 Decision A1 file testing structure

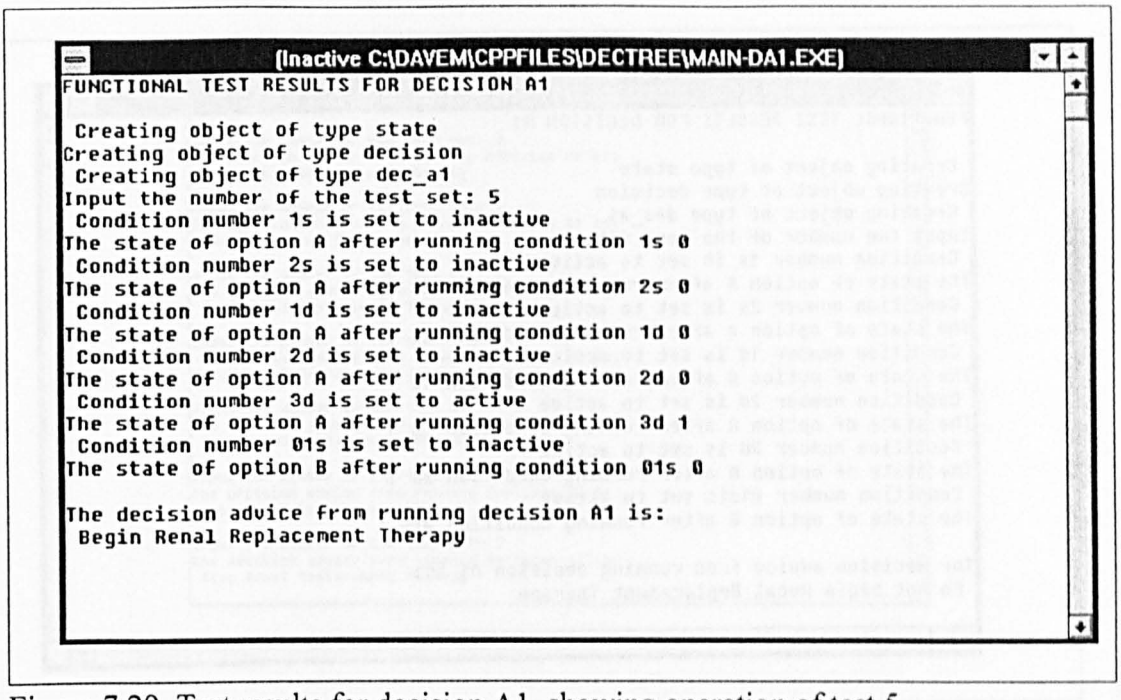


Figure 7.29 Test results for decision A1, showing operation of test 5

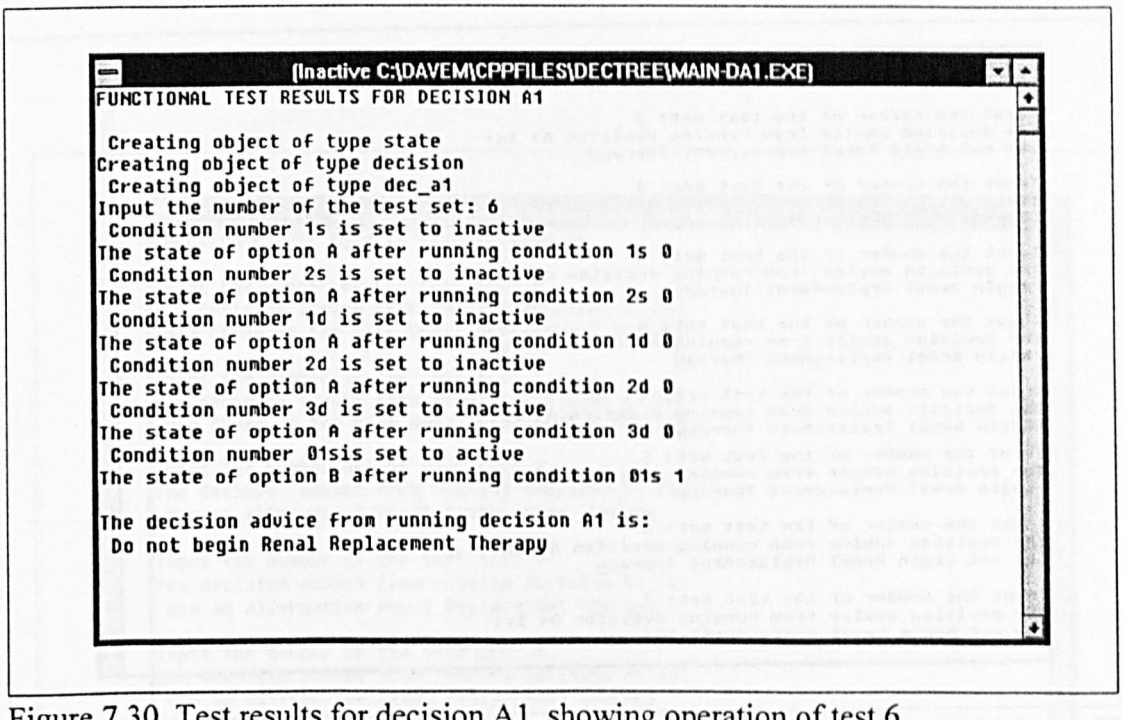


Figure 7.30 Test results for decision A1, showing operation of test 6

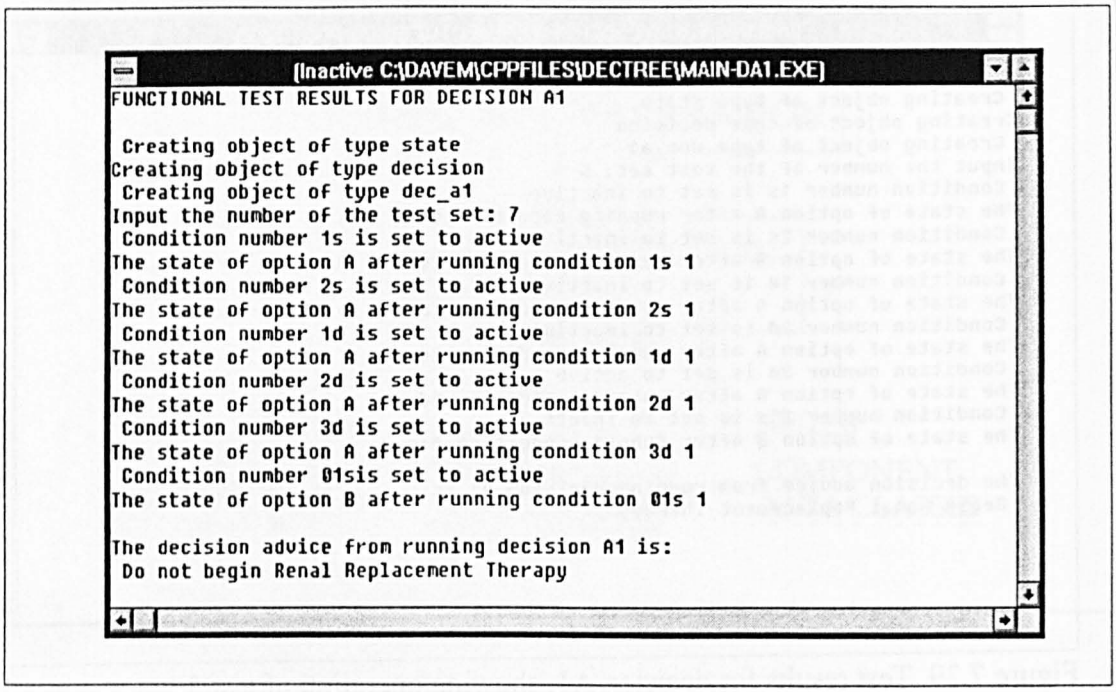


Figure 7.31 Test results for decision A1, showing operation of test 7

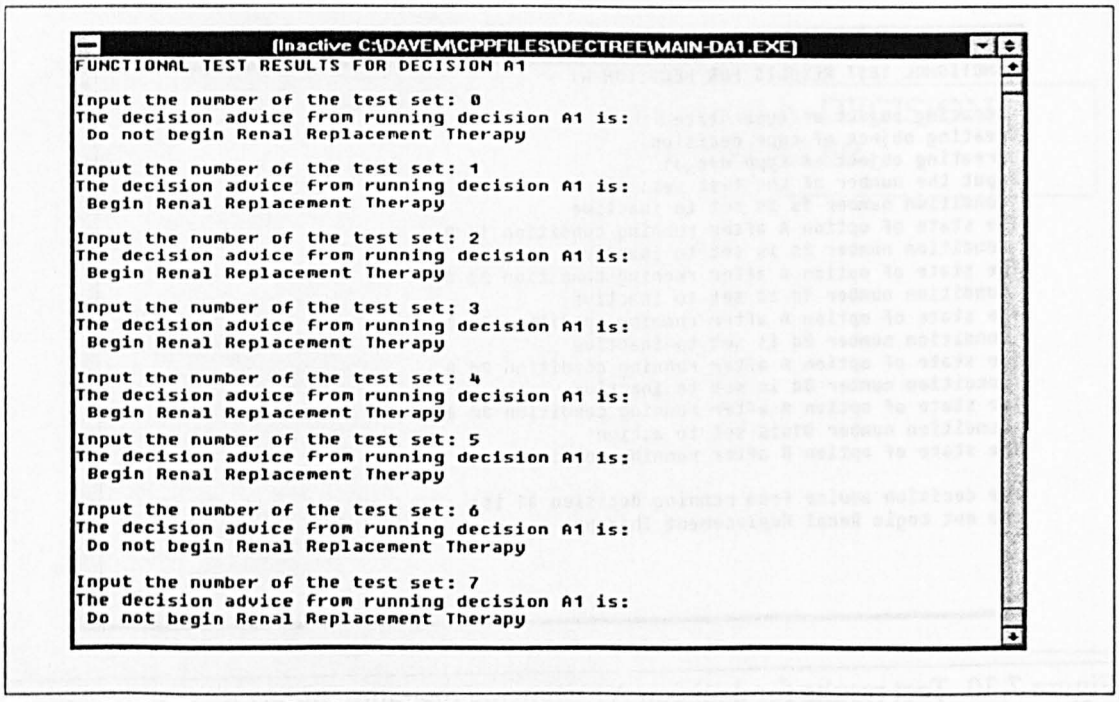


Figure 7.32 Test results from decision A1

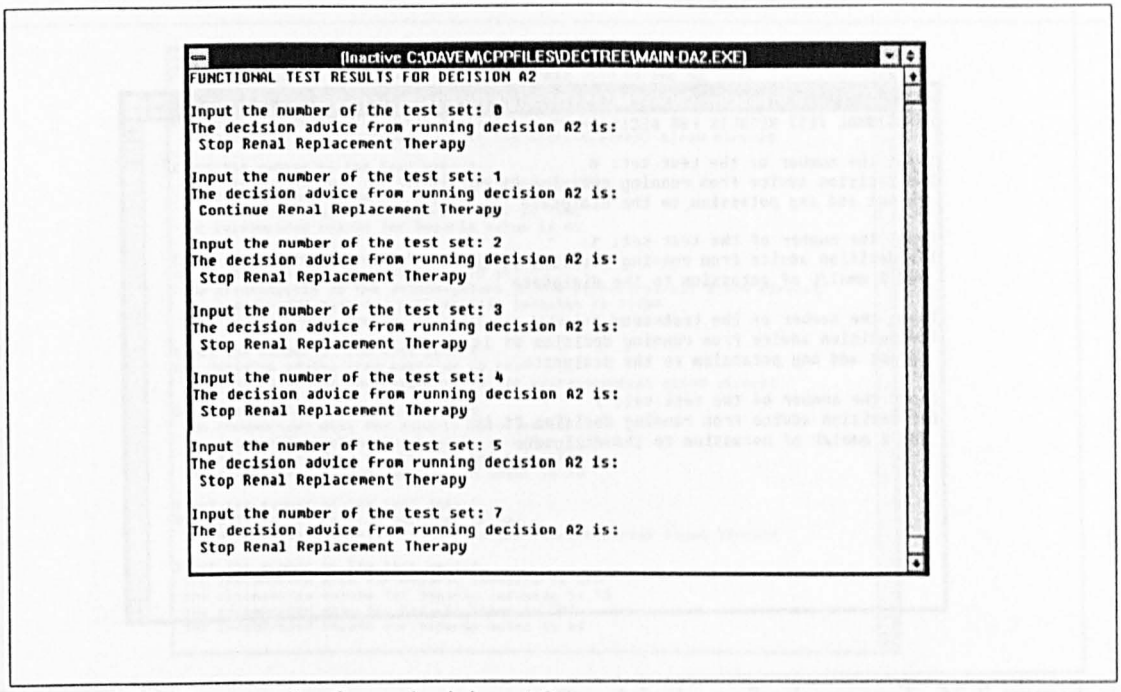


Figure 7.33 Test results from decision A2

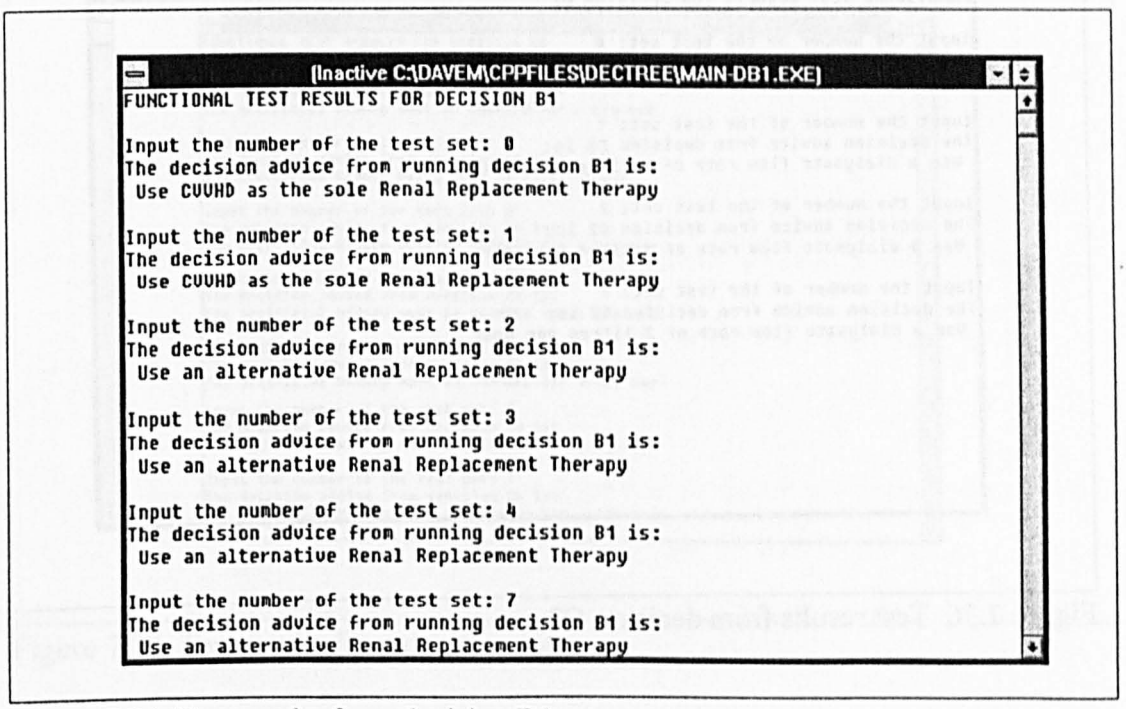


Figure 7.34 Test results from decision B1

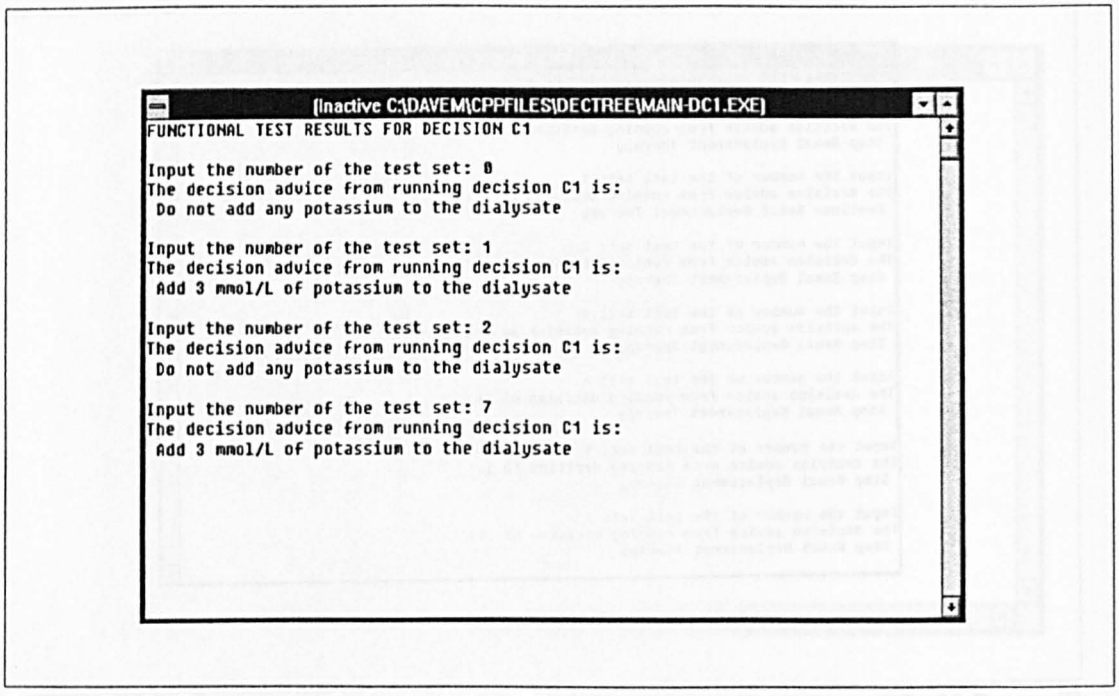


Figure 7.35 Test results from decision C1

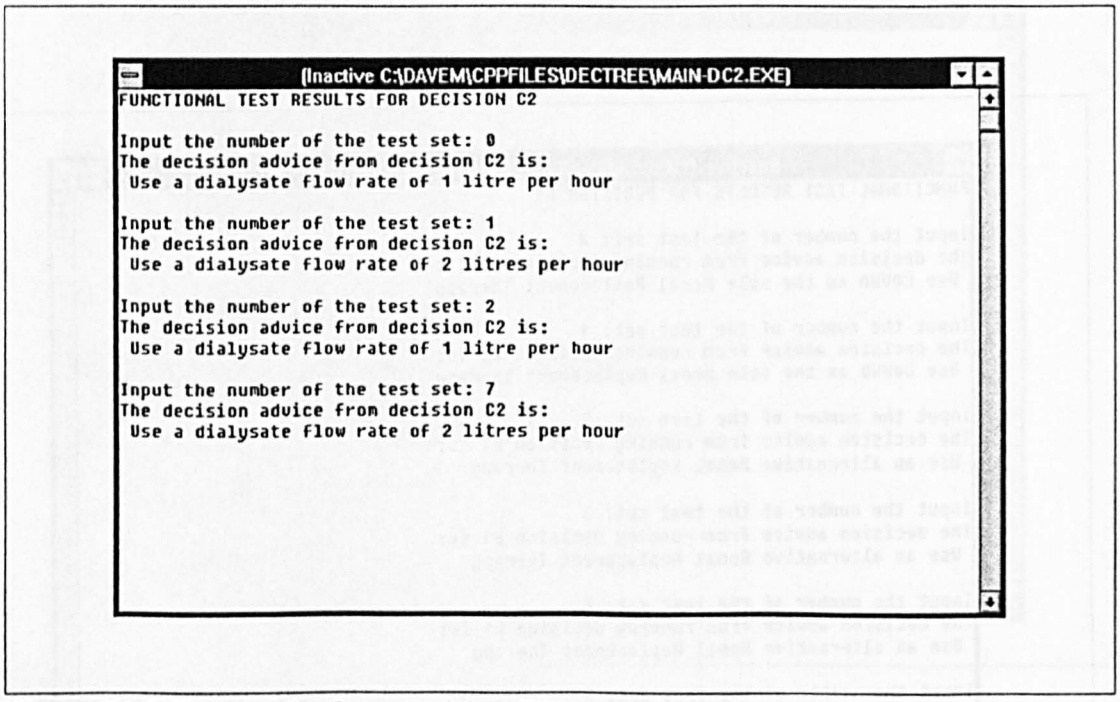


Figure 7.36 Test results from decision C2

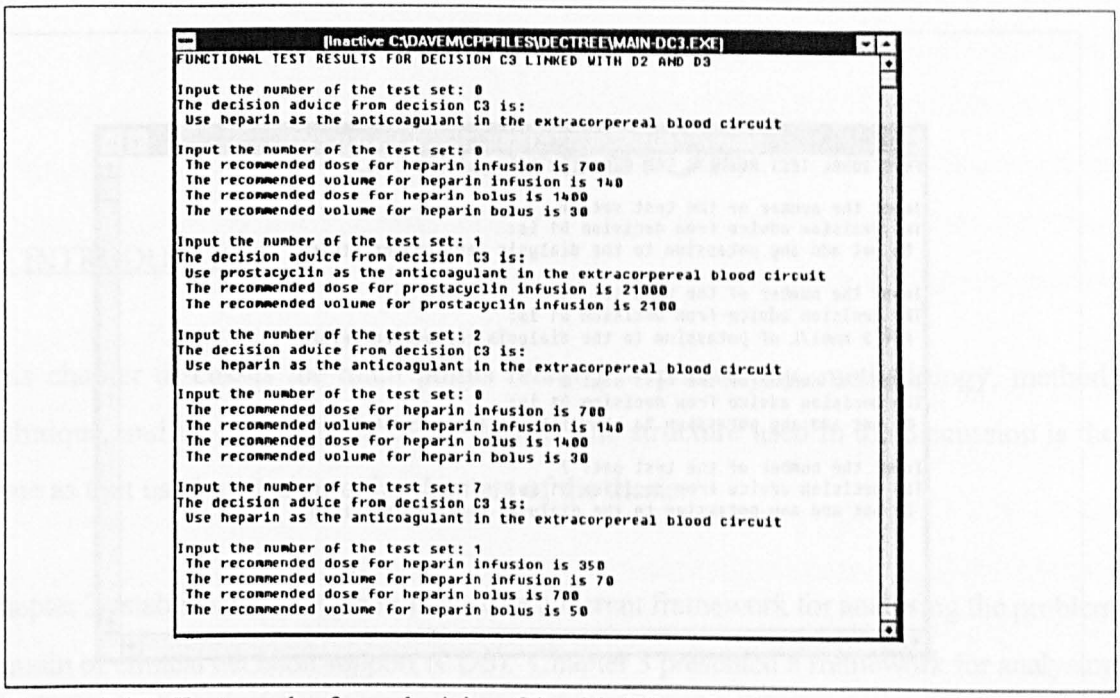


Figure 7.37 Test results from decision C3 with D2 and D3

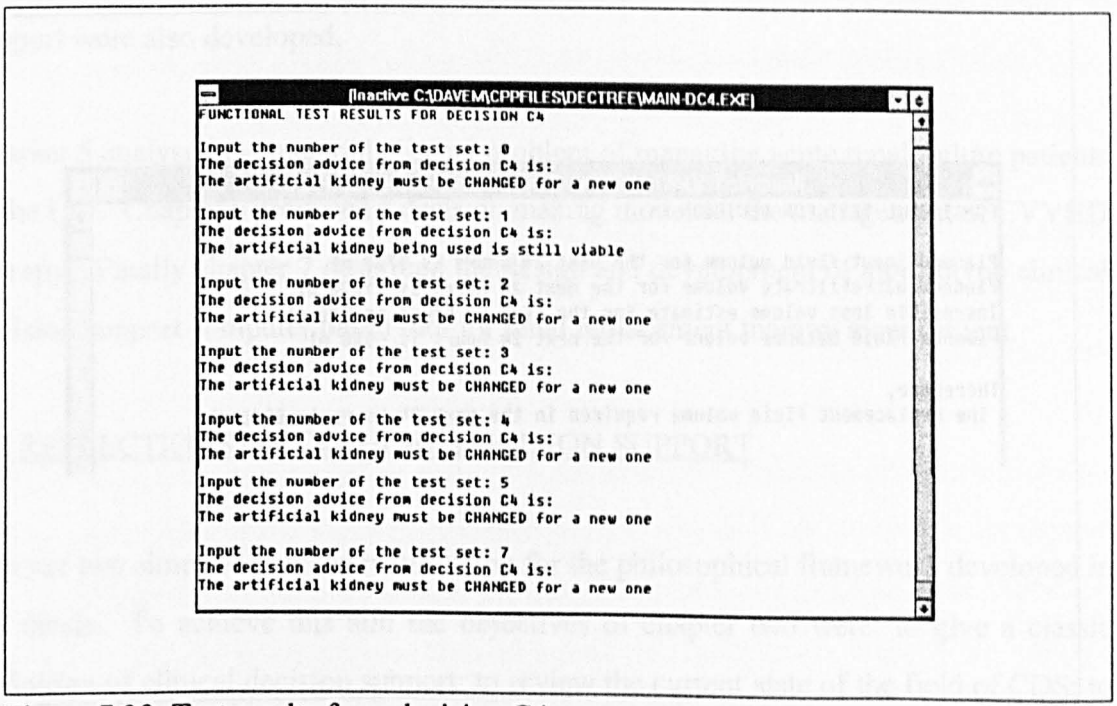


Figure 7.38 Test results from decision C4

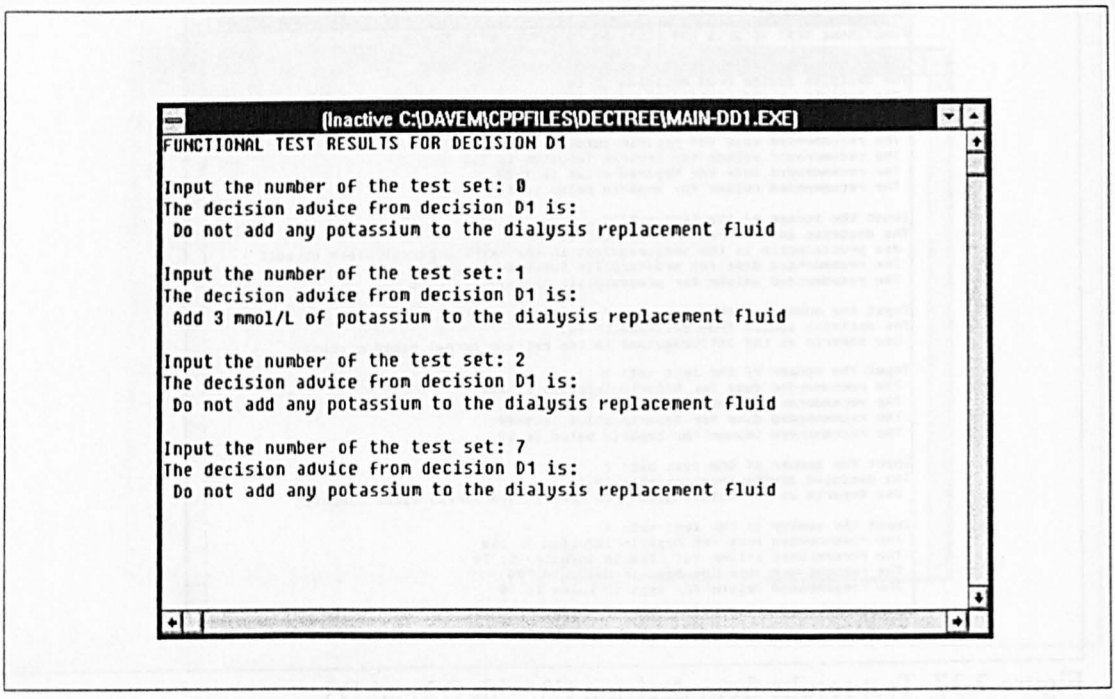


Figure 7.39 Test results from decision D1

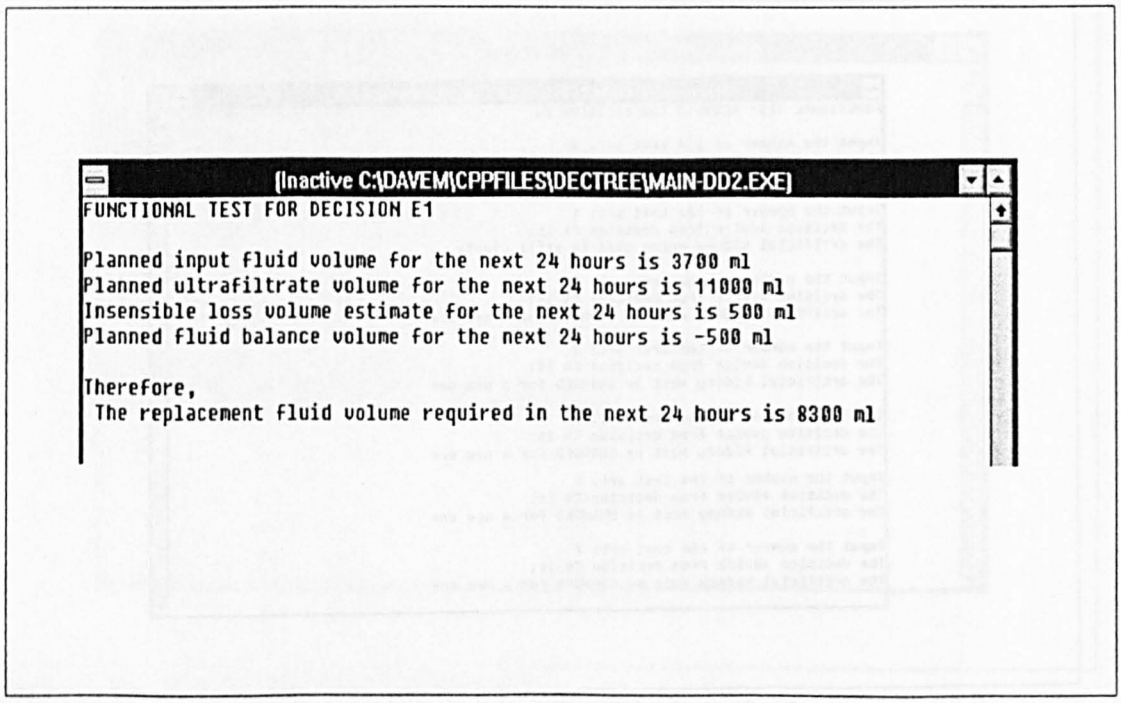


Figure 7.40 Test results from decision E1

CHAPTER 8

DISCUSSION

8.1 INTRODUCTION

This chapter discusses the main points relating to philosophy, methodology, method, technique, and tool application in the thesis. The structure used in the discussion is the same as that used to structure the chapters of the thesis.

Chapter 2 established that there is a lack of a coherent framework for analysing the problem domain of clinical decision support (CDS). Chapter 3 presented a framework for analysing CDS (figure 3.1), constructed a practical ontology and epistemology, in addition to characterising CDS in terms of technology, medicine and science. Chapter 4 applied the ontology and epistemology in an analysis of clinical decision making and of clinical decision support. From this analysis process models of decision making and decision support were also developed.

Chapter 5 analysed the material clinical problem of managing acute renal failure patients in the ITU. Chapter 6 produced a decision making model for the management of CVVHD therapy. Finally chapter 7 described the design and development of a prototype clinical decision support computer based tool for renal replacement therapy management.

8.2 REFLECTIONS ON CLINICAL DECISION SUPPORT

Chapter two aimed to give the justification for the philosophical framework developed in the thesis. To achieve this aim the objectives of chapter two were: to give a classic definition of clinical decision support; to review the current state of the field of CDS; to question the assumptions at the basis of CDS; to highlight inherent problems with CDS, and to justify the need for a coherent philosophical foundation in clinical decision support.

Clinical decision support (CDS) has been defined as any computer program that deals with clinical data or medical knowledge (Shortliffe, 1987). This view is a reflection of the predominantly technology centred approach in the field. This narrow technocentric view of CDS is thought to be the cause of the apparent failure of CDS technology to be widely implemented (Coeira, 1995). This lack of anticipated success has led to questioning of the basic assumptions of CDS (Coeira, 1994), and to the conclusion that a more problem focused approach is required in CDS.

Some of the fundamental problems inherent in CDS were highlighted in the views of physicians reviewed in Shortliffe (1989). Clinicians quoted in this paper expressed the belief that if a problem is messy and difficult to understand and solve for a clinician then surely it will be so for a computer system. This indicates that an important early stage in CDS development is to model clinical decision making, and to apply the understanding gained in clinical practice and in decision support models of decision making. Another inherent problem relating to the nature of clinical decision making is the notion of expertise. There is suspicion of the concept of artificial intelligence, and in particular expert systems. The concerns raised in Shortliffe (1989) question the very concept of expertise, "(Medical) expert systems suffer from the fact, in my view, the experts aren't expert and I wouldn't listen to their judgement in person. Having their views distilled in a machine wouldn't give them any more credibility.... When you find an expert who will talk on any one field, you can find another expert who will say something a little different." This implies that a better understanding of the concept of clinical expertise, and clinical knowledge, is required before attempting to effectively distil clinical knowledge into a knowledge based system.

Adopting a problem focused approach helps to analyse the inherent problems in CDS highlighted above. At the base of a problem focused approach it has been proposed that a coherent philosophy is required to construct a consistent analytical methodology for analysing the problem domain and developing future CDS systems (Heathfield and Wyatt, 1993). Such a philosophy will provide: a framework for forming a systemic view of the problem domain and the role of CDS in the domain (Lincoln and Essin, 1992; Musen, 1993), and a coherent epistemology for building a clinical knowledge base (Van Der Lei,

1993).

To build a coherent methodology on the coherent philosophy there is a need to clarify the eclectic nature of CDS. Shortliffe's definition of CDS identifies engineering and medicine as two of the disciplines in the field; while Lincoln and Essin (1992), and Seelos (1992) advise that science has a role in CDS. Therefore, a coherent philosophical framework for CDS will unify the eclectic nature of decision support, and acknowledge the role of engineering, science and medicine in the field.

8.3 AN ONTOLOGICAL AND EPISTEMOLOGICAL FRAMEWORK FOR CDS

Following on from the identification of a need for a coherent philosophy the aim of chapter three was to construct an ontological and epistemological framework for clinical decision support. The objectives of the chapter were:

i) To present an analytical structure linking philosophy, methodology, method, techniques and tools

ii) To present a systematic review of the relevant fundamental concepts of philosophy which are used to construct the ontology and epistemology.

iii) To use concepts of philosophy to construct an ontology and epistemology as the basis for an analytical framework in CDS.

iv) To apply the ontological and epistemological concepts to CDS.

v) To characterise the multi-disciplinary nature of CDS in terms of the nature of science, technology and medicine.

vi) To state the ethical codes defining good clinical behaviour.

Figures 3.1. and 3.2 show how a coherent philosophy is the foundation for building a

coherent methodology. At the core of philosophy is an analysis of what reality is, ontology, and what is knowledge of reality, epistemology. Applying an ontological and epistemological analysis produces a generic categorisation of reality and knowledge which can be used to give insight and clarity into any problem situation (Sowa, 1995). Moreover, philosophical classes represent the generic classification for building a structure that permits knowledge sharing and reuse between applications (Gruber, 1993). Therefore, by using philosophical principles and models it is possible to form the coherent basis for an analytical framework in CDS.

8.3.1 Ontology

Systematically building a philosophy begins with constructing answers to the questions: what is reality? and what is knowledge of reality? The question of what is reality can be broken down into two further questions: how many realities are there? and what are the possible natures of these realities? Traditionally there are three views of the numbers of reality: monism; dualism, and pluralism (Ferm, 1969). Monism views reality as being represented by one unifying nature. Dualism views reality as being represented by two different natures; whilst pluralism views the world as consisting of multiple realities and is the least analytical view. The views on the possible nature of reality expressed in philosophy are either: idealist, reality is essentially ideas; materialist, reality is matter only; dynamist, the only constant in reality is change or flux, and neutralism holds that reality has no identifiable nature (Ferm, 1969). Decision making and system analysis have been identified as being best represented by the classic dualist view of idealism existing with materialism, figure 3.4. The connection between the two is viewed as a dynamic energy flux. The ontological model represents a generic view of the whole of reality. Thus, it is the start point for building a generic representation of any problem and proposed solution in a domain.

8.3.2 Epistemology

Knowledge is a fundamental concept in developing knowledge based systems. However, in the field of knowledge based systems definitions of knowledge deal primarily with the

expression of knowledge in the material domain (Tansley and Hayball, 1993, Shortliffe, 1990, and Deutsch et al., 1994), whilst rational decision making involves the application of knowledge in the mind. Therefore, to model the use of knowledge in decision making requires a deeper epistemological analysis. The four epistemological questions to be addressed in an analysis of knowledge are: the nature of knowledge; the source of knowledge; the scope of knowledge, and the validity of knowledge.

The nature of knowledge is defined epistemologically as justified true belief (O'Connor and Carr, 1987). Thus the concepts applied in an understanding of knowledge are belief and truth. A belief exists in the mind, and is acquired from and expressed in an interaction with the material domain (figure 3.5). The act of believing can be viewed as the activity of acquiring a belief or expressing a belief. Acquiring a belief is an activity of the mind where a proposition is first entertained and then assented to. Expression of a belief occurs where a proposition is believed and then action is performed in accordance with the belief. Thus knowledge as a belief exists in the mind and is expressed in the material domain.

The distinction between a general belief and knowledge rests on the concept of truth. The judgement of truth has been classified as philosophical or non-philosophical. Philosophical judgements, or tests, of truth allow for critical reflection on truth. Non-philosophical truths are not explicitly based in the application of observation or reason, and therefore cannot be judged critically. Three philosophical tests of truth have been proposed for testing a knowledge base: correspondence testing, a proposition corresponds to an observed phenomena ; coherence testing, a proposition is logically consistent with prior knowledge; and pragmatic testing, if an idea satisfies a purpose then it is held to be true. The non-philosophical bases for truth are: truth from authority; truth appealing to feeling; truth by majority agreement; self evident truths which are prior to experience; and intuitive truth. These non-philosophical bases for truth are not true in the sense of being by nature open to critical question, and are thus not inherently defendable through the application of reason and observation. An important impact of this is that a statement from an expert authority should not be accepted without question as being true. The reason put forward for the questioning of truth from authority is that they often disagree and accepting one without question leads to a confusion of authority arguing against authority.

The scope of knowledge, figure 3.6, covers the whole of the ontological model. The highest level knowledge is conceptual knowledge used to make sense of reality. Below this level exists state knowledge, for example that snow is white, and know how for interacting with the external material reality. These different classifications of knowledge are tested using the philosophical tests described above. State knowledge is tested using correspondence, confirmation through observation, and coherence, confirmation through the application of logic in comparison to prior knowledge. Coherence can also be applied to know how, but the primary test of know how is pragmatism, therefore if it satisfies a predefined goal it is functionally true. Conceptual knowledge is tested over time by the application of correspondence and coherence to numerous observations of phenomena.

Having established the nature and scope of knowledge the next question to address is where does new knowledge originate from. This is particularly relevant when considering the question of what source to use when constructing a knowledge base. The source of new knowledge is considered to be phenomenological. The view of phenomenology is that empirical sensory experience is interpreted using *a priori* knowledge to form perceptions of material phenomena. These perceptions are then combined with other prior conceptual knowledge in a rational manner to form new knowledge. Thus new knowledge of a material domain will rely on the observation of that domain, and having the necessary prior conceptual knowledge to interpret the observations.

The concept of an expert is that they possess a higher than normal level of conceptual knowledge and know how of a specific domain, and more experience in the domain. This leads to the idea that experts are a good source of domain knowledge, where the assumption is that the expert has many justified true beliefs on the domain, which constitute a knowledge base useful to less experienced individuals in the domain. In a complex domain such as medicine different experiences of individual experts will lead them to develop different knowledge of a domain. Therefore, by the nature of having had different experience, observed different material phenomena, the knowledge of any expert in a field is individualised to some degree and not absolutely universal. This is consistent with the view stated above that authorities often hold different opinions on what constitutes knowledge and thus any knowledge derived from an authority requires further testing.

Therefore, evaluating an elicited knowledge base by simply comparing different expert opinion will merely expose the natural differences in opinion amongst experts. So, by nature there will always be disagreement between clinical experts, and the extrapolation of the expert knowledge model into a computer system will not change the nature of experts disagreeing. At present it is the effectiveness of an expert's knowledge which is the ultimate test of their knowledge in medicine, and provides the basis for others seeking repeated consultation with the expert (Shortliffe, 1989). The future of evaluating knowledge based systems should apply the same model when validating knowledge bases. Applying the pragmatic test to knowledge requires the explicit linking of knowledge to actions and goals for the action. Only then can the knowledge be evaluated as true or valid. Therefore within the structure of a knowledge base it is necessary to link goals for actions to any knowledge used to decide on the action.

8.3.3 Nature of Clinical Decision Support

The multi-disciplinary field of CDS includes application of processes and knowledge defined in engineering, medicine and science. Under Shortliffe's (1987) definition of CDS it is primarily a technology driven process with the goal of producing computer based tools, or artifacts, for use in clinical practice. Therefore, the main methodology of CDS is defined by technology. However, within this methodology there is a growing appreciation for the need for an analysis and understanding of the medical domain, and the role of CDS in this domain. One important philosophical aspect of the medical domain is that it is essentially a morally driven activity, where clinicians attempt to act for the good of others. Thus applying decision support systems in the medical domain means they should not offer advice, or operate in a manner, which is inconsistent with the morality defined in physicians ethical codes.

The role of science in CDS is essentially as a knowledge source and a method for solving problems which are subordinate to the main design process. The product of applying science is knowledge not technological artifacts. Therefore, its use in CDS is to find solutions to sub-problems of the design, not to describe the main methodology or the tools produced. Thus scientific knowledge can be utilised in the process of design but it does not

define the technological design process of producing a CDS tool.

8.4 DECISION MAKING AND DECISION SUPPORT

In Chapter four the ontology and epistemology of chapter three were applied to an analysis of generic decision making and the role of decision support in the process of decision making. To this end the objectives were:

i) To develop an ontological, epistemological and process model of decision making.

ii) To analyse the clinical decision making process.

iii) To develop a model of the process of rational clinical decision making.

iv) To propose a technique for analysing clinical treatment decisions.

v) To build a conceptual model of clinical decision support with an ontological and epistemological basis.

vi) To define clinical decision support in terms used in the decision analysis.

8.4.1 Ontology and Epistemology of Decision Making

Philosophy provides a basis for analysing reality and knowledge of it at a generic level. Generically decision making centred on solving a material problem has the ontology shown in figure 4.1. The problem exists in the material domain and the decision making in the realm of the mind. Thus the process begins with the mind's perception of a problem in the material domain. The product of the process is a decision action to either increase knowledge of the problem or to dynamically impact on the material problem.

The classifications of the natures of the idealist reality given in chapter three were rational, emotional, and voluntaristic. Thus if decision making is considered as an activity of the

mind acting on the material reality, it can be based on any of these natures. It can be emotional, governed by feeling, voluntaristic, driven by the will to survive, or rational, guided by the application of logic. For coherence from a consistent approach the application of rationalism in decision making is required, as opposed to romanticism or voluntarism. Emotion and free will are too variable and individual to give a meaningful basis for decision making or system analysis.

The epistemology of rational decision making rests on the logical and explicit application of knowledge during the decision making process. Thus available knowledge is maximally applied during rational decision making. Knowledge applied during decision making can be classified as: state knowledge, knowledge of material phenomena; know how, knowledge of relevant techniques, and conceptual knowledge. State knowledge can be expressed as a set of propositions. Know how or techniques can be expressed as a set of actions with a goal for the actions, whilst conceptual knowledge exists as a knowledge map, or web, of interconnected concepts with associated meanings, figure 4.6.

8.4.2 Process Model of Decision Making

Figure 4.8 shows the five stage process model of decision making derived from Bidgoli's four stage model, figure 4.7. The first stage of the decision making following the accumulation of state knowledge is an assessment of the problem. A problem exists where there is knowledge that a goal state A is different from the actual state B. Following the problem assessment is the pragmatic evaluation of the previous decision to assess its effectiveness and efficiency. Effectiveness of a decision is how well the action performed satisfies the pre-defined goal, and efficiency is a measure of the resources used to meet the goals. After evaluating the effectiveness and efficiency of the previous decision options for action are generated from knowledge of previous actions applied to similar problems. Then depending on the specifics of the state knowledge actions are chosen and implemented. Following implementation further observations of later material phenomena begin the cycle again.

Epistemologically the decision making process begins with the accumulation of state

knowledge from perceptions of material phenomena. As illustrated in figure 4.1 the source of problem knowledge which begins the decision making cycle is the observed material phenomena. If there is no knowledge of the material phenomena which constitute the problem there will be no perception of the problem state. This perception of a problem relies on prior know how and conceptual knowledge being applied to the phenomenal knowledge to form an abstracted view of the problem. Prior knowledge of strategies for solving the problem is then applied to generate options for solving the problem. Further knowledge of the previous effectiveness of the options at achieving the goals will then be applied to make the choice of options. Then know how will be applied in actions to perform the intervention in, or further assessment of, the material problem. The observation of later phenomena will produce further state knowledge of the material domain, and potential understanding of the effectiveness of the previous action.

The validity of the knowledge applied in the decision will be judged by the perceived outcome in the material domain. If the purpose or goal of the decision maker has been satisfied then it can be pragmatically judged that the knowledge applied is valid. The decision evaluation stage is thus dependent on the goals of the decision maker, which are defined during the problem assessment. The pragmatic validity of the know how and conceptual knowledge will be further reinforced by their application to similar future problem scenarios. Thus expertise is built up by exposure to similar problem and decision situations.

8.4.3 Clinical Decision Making

Three stages of clinical decision making are generally identified (Friesdorf et al., 1994): monitoring; evaluation, and treatment. The first stage is to gather information on the state of the patient in a problem assessment or evaluation of their state. Then depending on the evaluation of the patient treatment may or may not be administered. During treatment in the ITU the patient state and the treatment the patient is receiving are monitored. The relationship between monitoring, patient assessment and treatment is depicted in figure 4.12, thus if no treatment is undertaken then further monitoring may be conducted to reassess the patient's state. Each of these three decision making stages can be represented

by the process model described above. This leads to the derivation of the model of clinical decision making shown in figure 4.13. The controlling process is the patient assessment decision; depending on this assessment certain treatment and monitoring actions will be ordered. This model provides a framework for analysing decision making in an ITU, and it was applied in the analysis of the decision making controlling a patient's renal replacement therapy.

8.4.4 Clinical Decision Support

The place of decision support ontologically is as a material abstraction of the decision making process, figure 4.15. Decision support exists to offer advice to the decision maker. The functionality of decision support is essentially an epistemological one, offering information to the decision maker which gives them knowledge relevant to solving the material problem. The epistemological function is analysed in greater depth below.

Decision support supplements the decision making in the idealist reality; its main use being when uncertainty exists in the decision maker's mind, the idealist reality, on what the decision should be. Where the decision maker has no uncertainty on the problem assessment or on course of action then they will not require decision support. Therefore, the ideal role for decision support is where it can offer advice to the decision maker who has a high degree of uncertainty on how to reach a decision. This may be due to inexperience of the decision maker, or high complexity of the problem. Both of these factors are relevant to the problems faced in clinical decision making.

How decision support can complement the decision making process is shown in figure 4.16. Again decision support is shown as a separate entity to the decision maker. Within the decision maker and the decision support figure 4.16 depicts the parallel operation of the model of decision making. Thus there is an active support of the decision making by the CDS system through the generation of a structured, patient specific, decision simulation. This is different from the support offered by a clinical information system merely containing medical knowledge, or data; this is acting as another knowledge source for the decision maker. In such a system the knowledge provided may or may not help the

decision making process, it may even increase the decision maker's confusion. The type of support provided by the clinical information system is more accurately labelled clinical knowledge support. Where the knowledge provide is either: state knowledge (patient data); knowledge of treatment techniques, or conceptual medical knowledge. The important distinction is that the knowledge provided by the information system is not applied in either solving or structuring the decision problem faced by the clinician.

Thus clinical decision support is the material patient specific simulation of the decision making process. The simulation provides a structuring of the process, and advice at any, or all, of the stages of the decision making process. Knowledge support can inform the decision process but it does not actively support the decision making process, its purpose is to increase the decision maker's knowledge.

8.5 CLINICAL PROBLEM ANALYSIS

Chapter five defines the material clinical problem to be addressed by the introduction of a clinical decision support system. The objectives of the chapter were:

i) To specify the clinical problem as presented by clinicians.

ii) To present the clinical domain knowledge required in the analysis of the clinical problem.

iii) To produce a systems analysis of the clinical problem.

Clinicians at the Mayday University Hospital identified two clinical problems with treating renal failure on a general intensive therapy unit (ITU) using continuous venovenous haemodialysis (CVVHD):

i) A large quantity of fluid is exchanged in patients undergoing CVVHD. Maintaining the fluid balance in these patients requires accurate fluid balance calculations. At present there is scope for inconsistencies in the fluid balance

calculations.

ii) An expert with experience in managing fluid and electrolyte balance will not be available 24 hours a day to offer advice to staff operating the CVVHD.

The epistemological analysis of the clinical problem was based on medical science concepts of physiology and pathophysiology of the kidney. Such an examination is necessary to build up an understanding of the vocabulary used to express knowledge in the field. Thus medical science formed the conceptual knowledge foundation for the problem system analysis and the knowledge elicitation during the analysis of the decision making.

8.5.1 Medical Domain Knowledge

The kidney plays a central role in the regulation of the cellular environment of the body. The kidney's functions are summarised in figure 4.7, and a more detailed description of these functions is given below:

i) The kidney excretes waste products of the metabolism by a combination of ultrafiltration and secretion.

ii) The blood pH is regulated by the control of the plasma concentration of free hydrogen ions.

iii) The effective circulating fluid volume is regulated by responding to control signals from the sympathetic nervous system and the hormone control system.

iv) Regulation of plasma osmolarity is achieved through the response of the hypothalamus to changes in the plasma osmolarity.

v) Control of plasma electrolyte levels is effected by the processes of ultrafiltration, secretion and reabsorption. Thus, the kidney exerts indirect control over the level of electrolytes in the other fluid compartments of the body.

vi) Regulation of the red blood cell mass is achieved by the excretion of erythropoietin which acts in the stem cells of the bone marrow, stimulating red blood cell production.

These kidney functions rely on the operation of the central functional unit of the kidney, the nephron. It is through the interaction of the nephron with the renal capillaries, the kidney's interstitial fluid space, and the collecting tubules, figure 5.8, that the kidney performs the above functions. During acute tubular necrosis (ATN) the nephrons of the impaired kidney cease to perform their function effectively. Loss of the functioning nephrons then needs to be compensated for by renal replacement therapy (RRT). Haemodialysis is an option for RRT which acts to compensate for the loss of functions (i) to (v).

A popular and efficacious treatment for replacing the vital renal functions described in the ITU is continuous venovenous haemodialysis (CVVHD). This removes excess fluid from the patients plasma by a process of ultrafiltration. While solutes such as urea, creatinine and potassium are removed by processes of diffusion and convection. Whilst a buffer in the dialysate diffuses into the patients plasma across the semi-permeable dialysis membrane to counteract the affects of metabolic acidosis.

8.5.2 Systems Analysis of the Clinical Domain

The aim of the systems analysis was to form clinically specific knowledge of the problem on top of the conceptual scientific medical knowledge reviewed above. The clinically specific knowledge built up during the systems analysis included a profile of the patient group, and of the management of their condition. Thus systems analysis is an important stage in formulating a solution to a clinical problem.

The patient group being considered in the project are ITU patients with two or more compromised organ functions, where the kidney is one of the organs in failure. The cause of the loss of the patient's renal function is ATN, and they will require renal replacement therapy (RRT). In the past the Mayday University Hospital, a district general hospital, has

had to send these patients requiring RRT to St Helier Hospital, where there is a renal unit to support the ITU. To overcome this problem Dr S Morgan set up the operation of the CVVHD service at the Mayday, thus reducing the need to transfer acutely ill patients. However, this has created the local difficulties described at the start of this section (8.5).

From the medical domain knowledge reviewed above it is apparent that haemodialysis essentially controls the fluid and biochemical balances of a patient's body. Therefore, to build up an understanding of the use of CVVHD on the ITU an analysis of a patient's fluid and biochemical flows is required. A flow diagram representing a patient receiving haemodialysis on the ITU is shown in figure 5.21. Between each of the boxes in the diagram flows a volume of fluid and a quantity of biochemical substances. Each of the flows represents a factor which can potentially change the patients fluid balance and their biochemistry. The problems with this process highlighted above are: accuracy in fluid data management, and a lack of constantly available expertise to manage the process.

Accurate fluid data management is particularly important for a patient receiving haemodialysis to keep the patient in a uvolaemic state and avoid complications of hypovolaemia or hypervolaemia. The fluid balance calculations performed involve the measurement of input and output fluid volumes, and estimation of insensible and sweat losses. At present the charting and estimates are produced manually. Typically this means performing approximately 15 hourly measurements and up to 10 repeated numerical calculations. Repeated manual calculations using many variables are prone to producing calculation errors. As was demonstrated in chapter 7 the automation of the process using computer technology can eradicate calculation errors, provide more sensitive estimates of insensible losses, and provide a planning aid for fluid delivery to the patient. Moreover, guidance can be given to produce controlled gradual changes in the patient's total body water when required.

8.5.2.1 Fluid loss estimates

During analysis of the fluid charting the need for a scientific analysis of insensible losses was highlighted by a review of estimates for daily amounts. These ranged from a daily total insensible losses of 500 ml to 1400 ml per day. In the worst case this represents a possible error of 900 ml per day in estimates of insensible loss. A possibility for producing estimates that are more sensitive to changes in patient and ambient conditions are the quantitative models of respiratory and transepidermal losses described in section 5.5.3. Thus, application of these models in a computer based fluid charting system will improve the sensitivity of the estimated insensible losses. However, no evidence has been found of the evaluation of the quantitative models for estimating insensible losses in the ITU setting. Therefore, further scientific study is required to establish the accuracy of these models when applied to calculating an ITU patient's insensible losses under varying conditions. It is anticipated that such a study will lead to an improvement in the accuracy of insensible loss estimates, and hence the fluid balance calculations. There is similar scope for a improvement in the accuracy of fluid charting for ITU patient's suffering from fever through further scientific investigation and modelling of cutaneous sweat losses.

8.6 DECISION MAKING FOR HAEMODIALYSIS MANAGEMENT

Chapter six produced a model of the decision making managing a patient's continuous venovenous haemodialysis treatment. The objectives were:

i) To apply the models of clinical decision making to the problem of clinical decision support in the management of renal failure in intensive care.

ii) To produce a protocol for making the CVVHD treatment decisions, and for qualitatively assessing the patient and treatment states.

The commonly used treatment compensating for a patient's loss of renal function in the ITU is CVVHD. Therefore, the decisions managing the CVVHD process are controlling the adverse affects of the ARF. The generic process model for analysing clinical decision

making is shown in figure 4.8. There are three levels of decision making in this model: patient assessment; treatment, and monitoring. For the case being considered here there is only one modality of treatment being considered, CVVHD. This simplifies the process to only having to model the treatment decision making, with inputs from an assessment of the patient. Within the treatment decision making process the options for the set up of the treatment are represented graphically by a decision tree.

The standard set up of the treatment equipment was analysed in the clinical problem assessment, section 5.3.4.2. This included an analysis of the equipment used and its configuration during treatment. Having established the fixed parameters of the treatment the next stage was to establish the options when implementing the treatment. As mentioned above the elicited treatment options are represented in a decision tree. The structure of each of the decision nodes in the tree was, a choice of two options with clinical knowledge in the form of rules defining when the options should be active (figure 4.9). For the decision state when both of the options were active a controlling logic function was specified to control the output of the decision node. In addition goals for each of the possible options represented in the tree were defined, to facilitate the pragmatic evaluation of the decisions made. The connection of the individual decision nodes is illustrated in figure 6.1. On level A the decisions represented by the tree include whether to begin renal replacement treatment or not, and on lower levels range to the more specific decisions such as whether to add potassium to the replacement fluid or not (D1).

The source of clinical expertise used for deriving the decision options and knowledge for choosing between options was Dr S Morgan a nephrologist and ITU consultant. The clear intuitive arrangement of the decision tree helped to structure this process of knowledge elicitation.

From the model of clinical decision making (figure 4.13) the output of the decision tree depends on assessments of the patient's state and of the state of the treatment the patient is receiving. The patient and treatment assessments required were derived from the decision rules represented in the tree. The assessment of patient state is broken down into two main categories: static and dynamic. The static category represents the classification of a single

measurement of a variable, whilst the dynamic category is a classification of a change between measurements of a variable. Each category is split into a maximum of five levels based on the classification of patient variables used in the TANIT project (Uppsala University, 1993). For static patient assessment these are: critically high; high; in target range; low, and critically low. For dynamic patient assessment they are: rising acutely; rising; stable; falling, and falling acutely. The treatment assessment required includes the present state of the CVVHD treatment and of related treatment which affects the patients electrolyte, acid base and fluid balance. For example an assessment of the presence of insulin and dextrose therapy to reduce plasma potassium. A fuller description of the patient and treatment state assessments required is given in section 6.4 of the thesis.

The bases for testing the truth of the knowledge in the decision making model are the philosophical tests of truth: correspondence; coherence, and pragmatism. The knowledge in the decision goals was tested for coherence with knowledge from Willats (1987). These tests showed that the goals were reasonable and relevant for a patient suffering from ARF. In addition to the pathophysiological knowledge, knowledge of the CVVHD treatment supported the relevance of the actions to achieving the goals. Using the coherence test to explicitly evaluate and link knowledge in this way is the basis for validating and building justification into a knowledge based system. Further pragmatic testing of the knowledge base is required to show that the advice generated by the tree is effective, i.e. it satisfies the specified goals. Encapsulating the knowledge and applying it in a computer based decision simulation provides an opportunity for performing the pragmatic test on the knowledge base.

8.7 CDS TOOL DESIGN AND DEVELOPMENT

Chapter seven described the prototype computer system design and development, through satisfying the following objectives:

i) To specify the system requirements.

ii) To develop a system design for ITU patient management, incorporating the design

for a CVVHD decision support system.

iii) To design and develop a prototype information system for the management of an ITU patient's fluid balance.

iv) To specify the other modules required in the information system.

v) To assess the feasibility of designing a clinical decision support treatment advice system for continuous haemodialysis in the ITU.

vi) To program the clinical decision support function using the object oriented language C++, and to test its functionality.

The first stage of developing a computer based tool is to determine the system requirements. These were derived from the clinical problem assessment, hospital visits and references on requirements for clinical decision support systems. From the clinical problem assessment there is the need for:

i) A program for charting the fluids for patients receiving CVVHD, presenting numerical and graphical displays of hourly and cumulative patient fluid balance.

ii) A program which offers patient specific advice to the decision maker during the decision making process controlling the CVVHD treatment.

The potential user groups were derived from interviews at hospitals with, doctors, nurses, managers, a dietician and haemodialysis technicians. Four categories of user groups were identified: clinical; management; maintenance, and system evolution. The clinical requirements were the focus for the prototype system development, although for a system to be integrated with hospital management systems the requirements of other potential users will need to be taken into account in future system updates. The specific operational system requirements were derived from a mixture of hospital visits and from the general references on the requirements for CDS, many derived from the European INFORM project

(Hunter et al., 1991, and Ambroso et al., 1992). Thus the characteristics specified in the system requirements represent a review of both local opinion and wider published opinion. These requirements include specification of the importance of automatic data capture where ever possible, highlighting the importance of the user interface. Other requirements specified are the presentation of the data, operation of the knowledge base, and the administrative requirements for the system. An important requirement which has been identified in many sources is the need for an approach which integrates the decision support function with the information system.

The integrated approach was encapsulated in a modular system design (figure 5.3). The system design shows the modules of the renal replacement therapy management system (RRT) integrated with a total ITU patient data management system (PDMS). The RRT management system is one component of a total PDMS. Where, the total PDMS is concerned with the management of all patient data and information, and decision support for the patient as a whole. The other components of the PDMS will be concerned with other aspects of patient management, such as ventilator therapy. A fully integrated PDMS, like the one described, is required to give a holistic view to the ITU clinician of the patient and the treatment they are receiving. Using a single interface to this fully integrated PDMS will mean that the clinician will only have to use a single source to gather all relevant patient data and run the available decision support. This overcomes the potential complication of having multiple systems all with different bits of data on in multiple locations, and represents a considerable improvement over the existing disparate paper based system.

The separate modules in the system design are connected to each other and with the PDMS via a system manager. This controls information and data flows, manages the system operation, and acts as the interface for modules of the system to plug into. Connected to the system manager is the user interface, through which all user observed data enters the system, and all information is presented to the user. The data and information relevant to the management of ARF are stored in the RRT data and information system. The fourth module of the RRT system is the decision support sub-system, which will offer advice to the clinicians on the management of CVVHD.

8.7.1 Computer Based Fluid Charting

The RRT data and information system is further broken down into modules shown in figure 7.4. The primary function of the RRT data and information system focuses on patient specific clinical data and information. Thus the data and information stored must be identified with a specific patient. Part of the patient specific clinical data is in the computer based fluid charting system, which includes patient identifier and fluid volume data. The prototype computer based fluid charting system produced was based on the paper based system used at present. The prototype developed routinely performs calculations of fluid input, output and balance, in addition to offering graphical displays of all the fluid volume data. There is also a fluid planning capability for the physician to plan the fluid therapy for the next 12 or 24 hour treatment period, and linked to this a chart for calculating the volume of fluid to administer in the next hour. Thus a computer based fluid charting system has the advantages of offering automatic fluid balance calculations, graphical presentation of data, and presentation of fluid volume planning aids. These advantages of a computer based system have been demonstrated by the rapid production of the prototype fluid charting system described in section 7.5.1. Furthermore, the prototype provides the basis for the future development of an operational fluid charting system.

8.7.2 Clinical Decision Support System

The decision support system will operate on the basis of simulated decision making to offer advice to the clinical staff on the operational management of the patient's CVVHD treatment. The simulation is based on the model of the decision making controlling CVVHD developed in chapter 6. Applying this decision model the first stage of the decision process is to establish the current patient and treatment states, as defined in section 6.4. These state assessments then feed into the decision tree and treatment advice is generated according to rules defined in section 6.3. The goal of the advised therapy action is to bring the patient state variables into a defined target range within a defined time frame.

To test the potential effectiveness of the proposed action against the defined goals prior to it being recommended to the user the action will be simulated using a model of the material

domain. The prediction from the model based simulation is then compared to the goal state to evaluate the predicted effectiveness of the decision. The decision support module containing the models tests the chosen therapy settings through simulation of the patient state and the proposed treatment. The therapy settings tested by the simulation module could be those recommended by the CVVHD management system, or they could be chosen by the physician. Using simulation in this way offers the capability to predict the decision outcome before implementation, and thus the potential effectiveness of the chosen therapy settings can be evaluated prior to implementation. Taking the recommendation to begin renal treatment as an example a complete simulation model will need to predict the patient's: fluid volume change; plasma potassium; plasma phosphate; plasma urea; plasma creatinine, and base excess. In the complete model each of these goal variables are simulated and then depending on the evaluation and the users judgement an action will be performed. According the model of decision making in section 4.2.3 the action will be followed by a new problem assessment and an evaluation of the action outcome. During the evaluation the actions effectiveness and the accuracy of the action simulation are assessed.

To perform the simulation of treatment actions the simulation module needs to be able to simulate changes in the patient state and the treatment state. Section 7.4 reviewed existing models for utilisation in the simulation of patient and treatment state. None of the models proposed have been used in the intensive care setting, so use of any of the models would be experimental. The simplest and most established of the models is Sargent and Gotch's (1980) single compartment model of urea kinetics. For reasons of identifiability some of the more complex models would not be a suitable start point for building a simulation model. It is better to begin with the simple model of urea kinetics on an experimental basis to test the feasibility of using a quantitative model, and to assess the impact of its use in the ITU setting.

8.7.3 Encoding the Decision Tree

The main function of the CVVHD treatment advice module is to make treatment recommendations to the user. The basis for making the treatment recommendations is the

decision tree representing the treatment options and knowledge (section 6.3). Using the decision tree as the start point the intention is to build a decision simulation for CVVHD treatment.

The first issue to be addressed is how to encode the decision tree. Specifically the problem with the coding is to find a technique which can be used to naturally represent the decision tree, so that the program structure is a transparent representation of the model already developed. More generally the other qualities the implementation language should have are: it should be easy to update and maintain, and allow for integration with other applications. The language must be easy to update as clinical decision support is developed by iterative prototyping (Heathfield et al., 1991). Object-oriented design techniques seek to mimic the way that people form models of reality. Typically the reality referred to is a material one, and objects are thought of as material entities with attributes and behaviour in the material world. An object in a computer program is not a material object it is an expression of the abstract conceptual model of the object. An object can be more usefully thought of as a representation of the idealistic abstractions formed of reality, whether that reality is material or idealistic. Examples of models of material objects are obvious, such as the descriptive model of a car. The strength of object oriented programming applied in artificial intelligence is in the representation of models of idealist reality such as the model of a decision. So object oriented programming provides a transparent representation of the decision tree.

The advantages of object oriented programming over procedural languages include: encapsulation; inheritance, and polymorphism (Parsons, 1994). Encapsulation is the combining of object states and functions into a single file. This allows for easier maintenance than with procedural languages. Inheritance is the derivation of one class, the sub-class, from another class, the base class. Polymorphism is the ability of classes of object to respond to the same message in different, class specific ways. All of the mentioned characteristics of object oriented have the advantage of allowing for the reuse of code. Encapsulation of a class allows for the multiple creation of objects from the class. Inheritance allows sub-classes to re-use code in the base classes. While polymorphism is the reuse of symbols, operators and names, to apply to different object behaviours. It was

because of these reported advantages and the representational power of object oriented programming that it was selected to encode the decision tree.

The decision tree model can be viewed as a set of decision nodes, each one representing an option in the decision making process. Each of the decision nodes in the tree have similarities which can be represented in a base decision class, and differences which have to be represented in separate sub-classes. All decision nodes have a similar decision state structure, so they can be represented by the same structure in the program code. Moreover, the logic for determining the output state from the two mutually exclusive actions is common to all nodes. However, the functions or conditions which make the options active are unique to each decision node. Thus it is possible to define the object oriented hierarchy of the decision nodes using the generalised structure in figure 7.26. The general decision class at the top of the hierarchy consists of the generic decision state structure and the logical arbitration function. Below this are a number of sub-classes defining the conditions for activating the options of each decision node. For example decision node A1 has the file structure shown in figure 7.27. The decision rules are declared and defined in dec_a1.h and dec_a1-f.cpp respectively, whilst each of the functions has its own data type defined in classes a1_con1svar to a1_con01svar. The C++ code for the generic decision class and decision class A1 is in appendix D.

Each of the decision nodes of the decision tree (figure 6.1) have been coded in a similar manner to decision node A1. Using test files the functionality of all of the decision nodes has been validated (figures 7.29 to 7.40), and all were found to offer the correct advice for the test conditions set, thus proving the concept of modelling decisions as objects with states and decision functions. Moreover, it has been shown that object oriented programming techniques offer a coherent representation and implementation of models of the idealist reality. Thus the use of modelling and object oriented techniques in knowledge based systems has been demonstrated.

The next stage of development of the decision tree will include connecting together the decision nodes to produce a unified treatment advisor. The other required elements of the future development of the complete treatment advisor are: the advice justification

component; attachment of goals to the advice, and the meta control of the decision tree for controlling several decision cycles. Moreover, the integration of the decision tree with the data and information system will be required in an operational system.

8.8 SUMMARY

This chapter has discussed the main points relating to philosophy, methodology, method, technique, and tool application in the thesis. The aims, objectives and main points of each chapter have been considered individually. The following conclusions will consider how the aims of the thesis as a whole have been addressed, the contributions made to knowledge, and the possible directions for future work.

CHAPTER 9

CONCLUSION

9.1 MEETING THE OBJECTIVES

9.1.1 A Coherent Ontology and Epistemology for Clinical Decision Support

The central hypothesis of this thesis is that the paradigm for clinical decision support needs to shift from a technology centred paradigm to a coherent ontological-epistemological paradigm. In testing this hypothesis the first objective to be satisfied was the construction of a generic philosophical ontology and epistemology as an holistic analytical foundation for clinical decision support. This was done by systematically reviewing fundamental concepts of ontology and epistemology. From the systematic study generic analytical ontological and epistemological models were constructed. Following on from this the second objective was to apply these models in an analysis of clinical decision making and of clinical decision support. Application of the models produced an ontology and epistemology for decision making and decision support, and from these models process models of decision making and decision support were derived.

The third objective was to practically apply the ontological and epistemological framework to a clinical problem analysis; as the basis for the design of a clinical decision support tool. Applying the ontological model structured the analysis of the clinical problem into a model-based analysis of the material domain, followed by a model-based analysis of the idealist decision making domain. The epistemological models provided a basis for an analysis of the nature of knowledge and how it may be evaluated; in addition to providing a structure for building up knowledge in the analysis of the clinical problem.

9.1.2 Clinical Decision Support for the Management of Acute Renal Failure in the ITU

Objective four was to analyse and model the clinical problem of the management of acute renal failure (ARF) patients in the ITU. Analysis of this material clinical problem was based on conceptual knowledge of medical science. This knowledge was coupled with an analysis of the treatment of ARF in the ITU to construct a model of the material processes relevant to the management of ARF. Producing a decision making model for the management of CVVHD therapy was the fifth objective of the thesis. To meet this objective the analysis of clinical decision making was applied to produce a novel decision making model for the management of CVVHD therapy. Satisfying objectives four and five led to the sixth objective; designing and developing a prototype clinical decision support computer tool for continuous haemodialysis management. The prototype system developed demonstrated the capabilities of computer based fluid charting, and also demonstrated the use of object oriented programming to implement decision models of the idealist reality.

9.1.3 Insights from the Application of Ontology and Epistemology

Thus it has been shown that a coherent ontological and epistemological framework does provide insight into: clinical decision making; clinical decision support, and the development of an application specific system. Therefore, a coherent philosophy does provide clarity in the analysis for and design of clinical decision support tools, and it will be an aid in future CDS system analysis and design.

9.2 CONTRIBUTIONS TO KNOWLEDGE

9.2.1 Applied Ontology and Epistemology

At the philosophical level a novel formalism of a dualist ontology has been derived and used as an analytical tool in the thesis. There is also novelty in the explicit application of epistemology to CDS. This application has provided a new perspective of knowledge in the field of CDS in relation to its nature, source, scope, and validation. The nature of knowledge in epistemology is a justified true belief. The truth of a belief which

distinguishes it as knowledge is judged according to three philosophical criteria: correspondence; coherence, and pragmatism. The critical appraisal of any knowledge base relies on the application of these three criteria. Applying the classifications of knowledge shown in figure 3.6 to a clinical decision support system, the truth of the information in the system representing state and conceptual knowledge is tested according to: correspondence with an observation, and coherence with another knowledge base; whilst the know how in the CDS system is tested through the application of coherence, and pragmatism in the application of the know how to the fulfilment of a predefined purpose. The use of the pragmatic test for know how demands that the knowledge used is explicitly linked to a goal. Thus to evaluate a knowledge base pragmatically requires the linkage of decision goals and decision rules in the structure of a knowledge base. This requirement is reflected in the structure of the decision nodes of the CVVHD decision tree.

When applying the coherence test a major problem is that of selecting the other knowledge base to be used in the test. Through the consideration of phenomenology as the source of knowledge, using different sources of expertise has been argued to be an insufficient basis for coherence testing. The most reliable knowledge base available in the clinical domain is the medical science knowledge base. Therefore medical science should feature in the coherence testing of a clinical knowledge base. However, further work is required to better define the linkages in medical knowledge, and to more clearly define the clinical knowledge bases that should be applied in the coherence testing.

9.2.1 Clinical Decision Support

The insights and understanding of CDS gained from the application of ontological and epistemological concepts include the representation of decision making and the role of decision support. From this application, decision support is viewed as being offered where a problem-specific decision simulation is performed by the decision support tool, and decision advice is given to the user. This is contrasted with knowledge support which gives the user access to knowledge for use in the decision making process, but does not offer decision advice at any stage of the process.

Other contributions of the thesis relate to the novel clinical decision support problem of managing acute renal failure in the ITU. The analysis of the clinical problem has produced a novel model of the management of an ARF patient being treated with CVVHD on the ITU, and a new protocol for prescribing CVVHD treatment. During the clinical problem analysis a review of the published estimates for insensible and sweat losses produced significantly different values for these losses, and candidate quantitative models for calculating the insensible losses. The quantitative models show that insensible losses depend on variations in patient and ambient conditions, and using them would offer greater sensitivity to variations in these conditions than presently used estimates of the losses. However, the models have not yet been tested in the ITU setting and further scientific study is required before they can be implemented in an automatic fluid volume charting system.

From the development of the prototype decision support system the contributions include the systems requirements, and the conceptual integrated system design. The prototype fluid charting system developed has the advantages of offering: automatic fluid charting; graphical presentation of data, and fluid balance planning aids. The object-oriented programming of the decision tree nodes has shown that the concept of modelling decisions as objects with states and decision functions is functionally correct. Moreover, it has been shown that object-oriented programming techniques offer a coherent representation and implementation of models of the idealist reality. For the prognosis of a patient state following a proposed treatment action the use of quantitative models was investigated. However, to date quantitative simulation models have been applied to management of chronic renal failure but not in acute care; therefore the application of these models in the prediction of the effectiveness of actions requires further study.

9.3 THE WAY AHEAD

The future contributions of the work described in this thesis include further additions to the debate on the philosophical foundation for clinical decision support development. From such debate, and through further pragmatic application, the paradigm will be more fully developed. Through the application of the paradigm it is envisaged that there will be a change in the focus of the development of CDS from disparate tool development to

problem understanding based on a coherent philosophy and modelling approach. During the development of the paradigm a fundamental epistemological question to be answered in relation to testing newly formulated knowledge is: what established medical knowledge base is sufficiently proven to be used in coherence testing?

Clinically the protocol for CVVHD treatment still requires pragmatic testing to demonstrate its effectiveness. These tests could be effectively performed using a more fully developed decision support prototype system. The other future technological developments of the prototype system worth pursuing are the implementation and proving of the integrated decision support system design, and the completion of an implementable CVVHD decision support system. During the further development of the system the quantitative models of insensible loss, and patient state will require evaluation in the ITU setting. Then depending on the outcome of this evaluation the models will be incorporated into the CVVHD decision support system for a comprehensive evaluation in the ITU environment.

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Appendix A

Artificial Intelligence Systems in Routine Clinical Use

Appendix B

Respiratory Water Loss Theory

RESPIRATORY WATER LOSS THEORY

1. Mass flow of air, m_a

m_a = (minute volume, V_m, x density of dry air, d_a x 60 minutes)

$= V_m \times d_a \times 60 \text{ g h}^{-1}$ (B1.1)

From the American Institute of Physics handbook d_a at 20°C and 1 atmosphere is 1,204 g m^{-3}

V_m = Respiratory Rate x Tidal Volume

$= f_{RR} \times V_T \text{ m}^3 \text{ min}^{-1}$ (B1.2)

The respiratory rate, f_{RR}, and the tidal volume, V_T, are defined in Wilson (1992), page 366.

$m_a = 72{,}204 \times f_{RR} \times V_T \text{ g h}^{-1}$ (B1.3)

2. Absolute Humidity, Y (Treybal, 1968)

Y= mass of water vapour in grams in 1 gram of dry air

$$= \frac{\text{partial pressure of water vapour}}{\text{partial pressure of air}} \times \frac{\text{molecular weight water}}{\text{molecular weight air}}$$

$$= \frac{p_w}{p_a} \times \frac{M_w}{M_a} = \frac{p_w}{P_T - p_w} \times \frac{M_w}{M_a} \quad \text{(B2.1)}$$

where P_T = total pressure of the gas and vapour mixture.

3. Relative Humidity, RH (Treybal, 1968)

$$RH = \frac{\text{partial pressure of water vapour}}{\text{vapour pressure of water}} \times 100\%$$

$$= \frac{p_w}{p_{vp}} \times 100\% \qquad \text{(B3.1)}$$

(Note: Relative Humidity is not the same measure of humidity as percentage saturation).

4. Vapour Pressure, p_{vp} (Treybal, 1968)

The vapour pressure of a liquid is the equilibrium pressure it exerts on the gas above it. Vapour pressure varies with temperature. At the normal boiling point of the liquid, water 100°C, the vapour pressure of the liquid equals the pressure of the atmosphere acting on it.

There are tables that give values of the vapour pressure of water across a range of temperatures. However, in a computational model it is more convenient to use an equation such as the Antoine vapour pressure equation, (Reid, 1987) :

$$\log_{10}(\text{Vapour Pressure}) = A - \frac{B}{T + C} \qquad \text{(B4.1)}$$

Where T is in degrees celsius, and the constants A, B and C vary with the temperature range being considered and the identity of the liquid. Reid states that the Antoine equation gives accurate results provided it is used over a limited temperature range and within the pressure range 7.6 to 1520 mmHg.

Ultman (1987) derived the following equation from the values for A, B and C given in Foust et al. (1980):

$$\log_{10}(p_{vp}) = 7.09161 - \frac{1668.21}{228 + T} \qquad \text{(B4.2)}$$

where the vapour pressure is express in kPa.

Unfortunately Foust does not state a range of temperatures which these constants are valid for. When the calculated values of vapour pressure at 0°C and 100°C are compared to tabulated values, errors of -2.60% and -0,003% are found. Vapour pressures outside this range of temperatures will not have to be calculated. Therefore, the quantitative significance of errors in the calculated value of vapour pressure is negligible.

5. Absolute humidity, Y, in terms of relative humidity, RH

From the definition of RH

$$p_w = \frac{RH \times p_{vp}}{100} \qquad \text{(B5.1)}$$

& $$Y = \frac{p_w}{P_T - p_w} \times \frac{M_w}{M_a} \qquad \text{(B5.2)}$$

From Treybal (1968, page 188) $\frac{M_w}{M_a} = 0.622$

and substituting for p_w in equation B5.2

$$Y = \frac{0.622 \times RH \times p_{vp}}{100P_T - RH \times p_{vp}} \qquad \text{(B5.3)}$$

6. Conversion of Fahrenheit, t_F to Celsius, T_c

$$t_F = \frac{9}{5}T_c + 32 \qquad \text{(B6.1)}$$

7. Mass of water vapour per unit volume, MV

MV = density of dry gas x Absolute humidity

$$= d_A \times Y \qquad \text{(B7.1)}$$

$$Y = \frac{0.622.RH \times p_{vp}}{100P_T - RHp_{vp}} \; ; \; d_A = 1.204 g/dm^3$$

Therefore,

$$MV = \frac{0.749RH \times p_{vp}}{100P_T - RHp_{vp}} \qquad \text{(B7.2)}$$

8. Density of water

From tables at 0°C the density of water is 0.999 g ml^{-1} and at 100°C it is 0.958 g ml^{-1}. Therefore an approximation of 1 g ml^{-1} will be used for the density of water.

Appendix C

Transepidermal Water Loss Theory

THEORY FOR TEWL

1. Fick's law

$$\text{Flux} = - \text{Diffusivity} \left(\frac{\text{Concentration gradient}}{\text{Change in distance}} \right) \qquad \text{(C1.1)}$$

The negative sign indicates that the direction of flux flow is in the direction of a decreasing concentration gradient. The diffusivity is a measure of the ability of the molecules to diffuse in the medium being considered. This ability is determined by the size of all the molecules in the system, the density of the molecules in the system and the velocity of the molecules whose diffusivity is being measured. The dimensions of diffusivity are unit area squared per unit time.

If in the above expression the concentration is measured in moles per metre cubed the S.I. units of flux are :

$$\text{Flux} = \text{moles } m^{-2} s^{-1}$$

This can be thought of as the number of moles of molecules of A passing through a unit area in a second.

To convert a molar flux into a mass flux the expression is multiplied by the molecular mass M_A.

therefore

$$\text{Mass} = -M_A.D.\frac{dc}{dx} = -D.\frac{dd}{dx} \qquad \text{(C1.2)}$$

where d = density

Now,

$$d = \frac{Mp}{RT} \qquad \text{(C1.3)}$$

where, M = molecular mass

p = partial pressure

R = universal gas constant (8.205×10^{-2} m^3 atm/kmol °K)

T = temperature in degrees kelvin

Therefore,

$$\text{Mass flow} = -\frac{M_A D.dp}{RT\ dx} \qquad \text{(C1.4)}$$

Applying this formula to the stratum corneum, where its thickness is denoted by l, and the partial pressure gradient is the difference between the partial pressure of water in the subcutaneous layer and at the skin surface. Subcutaneous partial pressure is approximately equal to the vapour pressure at the perfusion temperature, then

$$TEWL = \frac{M_w D_w (p_{vp}(T_p) - p_s)}{RT_a l} \qquad \text{(C1.5)}$$

where $p_s < p_{vp}(T_p)$ and TEWL is expressed in $g.m^{-2}.s^{-1}$.

2. Body Surface Area (BSA)

The original formula quoted by DuBois and DuBois (1916) was:

$$BSA = 71.85 \times W^{0.425} \times H^{0.725} \qquad (C2.1)$$

where W = weight (kg)

H = height (cm)

BSA = body surface area (cm^2)

For units of metres and kilograms the expression is:

$$BSA = 0.2025\ W^{0.425}\ H^{0.725} \qquad (C2.2)$$

Appendix D
C++ Code for Generic Decision Class and for Decision Number A1

```
//=============================================================================
//
//FILENAME:                 state.h
//FILE TYPE:                C++ header class for STATE
//COMPILER USED:            Borland C++ version 4.5
//AUTHOR:                   David Murley, City University
//DATE CREATED:  24 July 1995
//
//_____________________________________________________________________________
//
//DESCRIPTION: Class STATE represents the data type which is a component
//             part of the structure of a decision node.  Hence, state is a
//             component class of the DECISION class.
//
//BASE CLASSES: None
//DERIVED CLASSES: None
//COMPONENT CLASSES: None
//CONTAINS CLASSES: None
//
//USAGE: The basis for the attributes of the decisions in the decision tree
//
//KNOWN BUGS: None
//_____________________________________________________________________________
//
//MODIFICATION HISTORY
//DATE:
//AUTHOR:
//DESCRIPTION:
//_____________________________________________________________________________

//----------PRE-PROCESSOR MACROS-----------------------------------------------

#ifndef STATE
#define STATE

//-----------------------------------------------------------------------------
//                                          DECLARATION OF CLASS STATE
//
//-----------------------------------------------------------------------------

class state
{
        public:
                char *thestate;//the character string defining the decision output, or state
```

```
                unsigned int begin:1;//defines the state of the begin action conditions
                unsigned int nbegin:1;//defines the state of the do not begin action
conditions
                unsigned int bt:1; //defines the decision state which is a function of the states
of //          begin and nbegin
                state(char* astate,unsigned int a,unsigned int b, unsigned int c);//constructor
                ~state();//destructor
};

//----------------constructor definition-------------------------------------

inline state::state(char*astate=0 , unsigned int a=0, unsigned int b=0, unsigned int c=0 )
: thestate(astate), begin(a), nbegin(b), bt(c)//inline intialisation of the state constructor
                {
        #if DEBUG
                cout<< "\n Creating object of type state\n";
        #endif
                }

//----------------destructor definition--------------------------------------

inline state::~state()//inline definition of the state destructor
                {
        #if DEBUG1
                cout<< " Inside the state destructor \n";
        #endif
                }

//-------END OF STATE DECLARATION-----------------------------------------------


#endif
```

```
//=============================================================================
//
//FILENAME:                 decision.h
//FILE TYPE:                C++ header class for DECISION
//COMPILER USED:            Borland C++ version 4.5
//AUTHOR:                   David Murley, City University
//DATE CREATED:  24 July 1995
//
//_____________________________________________________________________________
//
//DESCRIPTION: Class DECISION represents the attributes of the decision nodes
//              in the decision tree.  In addition to declaring the functions
//              which are common to all the sub-classes.
//
//              The attributes are defined in the data structure defined by the
//              component state class.
//
//              Sets the DEBUG condition to true for testing files during development.
//
//BASE CLASSES: None
//DERIVED CLASSES: None
//COMPONENT CLASSES: STATE
//CONTAINS CLASSES: None
//
//USAGE: The decision class forms the structure of all the decision nodes
//
//KNOWN BUGS: None
//_____________________________________________________________________________
//
//MODIFICATION HISTORY
//DATE:
//AUTHOR:
//DESCRIPTION:
//_____________________________________________________________________________

//----------PRE-PROCESSOR MACROS-----------------------------------------------


#ifndef DECISION
#define DECISION
#define DEBUG 0
#include <iostream.h>
#include "state.h"
```

```
//---------------------------------------------------------------------------
//                                  DECLARATION FOR DECISION CLASS
//
//
//---------------------------------------------------------------------------
class state;//pre-declaration of class state, because data type state used in
                                //decision class.  (For the benefit of the compiler)

class decision
{
        protected:
                state &dec_state;//decision attributes
        public:
                virtual unsigned int action(decision & );//function for giving action choice
- //             contains logic
                decision(state& a_state);//constructor
                virtual ~decision();//destructor

};

//----------------constructor definition-------------------------------------

inline decision::decision(state& a_state):dec_state(a_state)//inline definition of the dec_a1
constructor
                {
        #if DEBUG
                cout<< "Creating object of type decision \n";
        #endif
                }

//----------------destructor definition--------------------------------------


inline decision::~decision()//inline definition of the dec_a1 destructor
                {
        #if DEBUG
                cout<< " Inside the decision destructor \n";
        #endif
                }

//---------definition of action function containing logic for action choice----

inline unsigned int decision::action(decision &)
        {

        if (dec_state.begin && (!dec_state.nbegin))//if there are reasons for starting
treatment and //        no reasons not to then begin CVVHD
                {
```

```
                dec_state.bt=1;
                }


        if ((!dec_state.begin && !dec_state.nbegin)|| dec_state.nbegin)//if there are reasons
 to not start treatment then the advice is not to start
                {
                dec_state.bt=0;
                }
        return dec_state.bt;
        }

#endif
//-------END OF DECISION DECLARATION----------------------------------------
```

```
//=============================================================================
==============
//
//FILENAME:                dec_a1.h
//FILE TYPE:               C++ header class for DEC_A1
//COMPILER USED:           Borland C++ version 4.5
//AUTHOR:                  David Murley, City University
//DATE CREATED:  24 July 1995
//
//_____________________________________________________________________________
_________
//
//DESCRIPTION: Class DEC_A1 represents the knowledge base used to decide which
//             action to take at point A1 in the decision tree.  This class
//             contains only the functions for making the decision, its
//             attributes are derived from its base class DECISION.
//
//             The functions firstly set the begin, or nbegin, to be true or
//             false.  The state of these two is then tested to decide on
//             whether to begin treatment or not.  If any of the conditions
//             to not begin treatment are satisfied then the advice offered
//             will be to not begin treatment.
//
//BASE CLASSES: DECISION, in file decision.h
//DERIVED CLASSES: None
//COMPONENT CLASSES: None
//CONTAINS CLASSES: A1_CON1SVAR, A1_CON2SVAR, A1_CON1DVAR,
A1_CON2DVAR,
//                                        A1_CON3DVAR, A1_CON01SVAR.
//
//USAGE: The data objects (contained classes) are used to feed in the classified
//                    patient and treatment state assessments, into the decision functions.
//
//KNOWN BUGS: None
//_____________________________________________________________________________
_________
//
//MODIFICATION HISTORY
//DATE:
//AUTHOR:
//DESCRIPTION:
//_____________________________________________________________________________
_________

//----------PRE-PROCESSOR MACROS----------------------------------------------

#ifndef DEC_A1 //macro if condition to prevent multiple definitions of dec_a1
#define DEC_A1//action to be taken if DEC_A1 not defined
```

```
#include "decision.h"// file containing the decision and state declaration
#include "a1c1svar.h"// file containing data object a1_con1svar declaration
#include "a1c2svar.h"// file containing data object a1_con2svar declaration
#include "a1c1dvar.h"// file containing data object a1_con1dvar declaration
#include "a1c2dvar.h"// file containing data object a1_con2dvar declaration
#include "a1c3dvar.h"// file containing data object a1_con3dvar declaration
#include "a1c01sva.h"//file containing data object a1_con01svar declaration

//-------------------------------------------------------------------------
//              DECLARATION FOR DECISION A1 CLASS
//
//_____________________________________________________________________________
_____________

class dec_a1:public decision//the decision structure attributes are inherited
{
                public:
//----------condition statements for begin treatment set begina1----------------

                unsigned int condition1s(const a1_con1svar &);//memeber function
containing the rules
                unsigned int condition2s(const a1_con2svar &);//memeber function
containing the rules
                unsigned int condition1d(const a1_con1dvar &);//memeber function
containing the rules
                unsigned int condition2d(const a1_con2dvar &);//memeber function
containing the rules
                unsigned int condition3d(const a1_con3dvar &);//memeber function
containing the rules

//------------condition statements for  not begin treatment set nbegina1--------

                unsigned int condition01s(const a1_con01svar &);//memeber function
containing the rules

//------------------protoype for set the state string function------------------

                char* advice(decision &);// member function which sets advice statement

//---------dec_a1 constructor and destructor protoypes-------------------------

                dec_a1(state& a_state);//constructor for the class dec_a1
                ~dec_a1();//destructor for the class dec_a1
};

//-----------------constructor definition-------------------------------------

        inline dec_a1::dec_a1(state &a_state):decision(a_state)//inline definition of the
```

```
dec_a1 constructor
                {
        #if DEBUG//only when DEBUG is = 1 will these be printed onto the screen.
DEBUG defined in the decision base class
                cout<< " Creating object of type dec_a1\n";
        #endif
        #if DEBUG1
                cout << "State_a1 in dec_a1 constructor = " << a_state.thestate<<"\n";
                cout << "Begina1 in dec_a1 constructor = " << a_state.begin<<"\n";
                cout << "nBegina1 in dec_a1 constructor = " << a_state.nbegin<<"\n";
        #endif

                }

//-----------------destructor definition----------------------------------------

                inline dec_a1::~dec_a1()//inline definition of the dec_a1 destructor
                {
        #if DEBUG1
                cout<< " Inside the dec_a1 destructor \n";
                cout << "dec_state.thestate in dec_a1 destructor = " <<
dec_state.thestate<<"\n";
                cout << "dec_state.begin in dec_a1 destructor = " << dec_state.begin<<"\n";
                cout << "dec_state.nbegin in dec_a1 denstructor = " <<
dec_state.nbegin<<"\n";
        #endif
                }

#include "dec_a1-f.cpp" //include the definitions of the condition member functions



#endif// endif statement for the ifndef at the top of the file.

//-------End of DEC_A1 class file-------------------------------------------
```

```
//=============================================================================
//
//FILENAME:                dec_a1-f.cpp
//FILE TYPE:               C++ function definition file for DEC_A1
//COMPILER USED:           Borland C++ version 4.5
//AUTHOR:                  David Murley, City University
//DATE CREATED:  24 July 1995
//
//_____________________________________________________________________________
//
//DESCRIPTION: Class DEC_A1 represents the knowledge base used to decide which
//             action to take at point A1 in the decision tree. This class
//             contains only the functions for making the decision, its
//             attributes are derived from its base class DECISION.
//
//             The functions firstly set the begin, or nbegin, to be true or
//             false. The state of these two is then tested to decide on
//             whether to begin treatment or not. If any of the conditions
//             to not begin treatment are satisfied then the advice offered
//             will be to not begin treatment.
//
//BASE CLASSES: DECISION, in file decision.h
//DERIVED CLASSES: None
//COMPONENT CLASSES: None
//CONTAINS CLASSES: A1_CON1SVAR, A1_CON2SVAR, A1_CON1DVAR,
A1_CON2DVAR,
//                                        A1_CON3DVAR, A1_CON01SVAR.
//
//USAGE: The data objects (contained classes) are used to feed in the classified
//                    patient and treatment state assessments, into the decision functions.
//
//KNOWN BUGS: None
//_____________________________________________________________________________
//
//MODIFICATION HISTORY
//DATE:
//AUTHOR:
//DESCRIPTION:
//_____________________________________________________________________________


//--------SET OF FUNCTIONS WHICH TEST THE BEGIN TREATMENT
RULES----------
```

```
//FUNCTION CONDITION1S DEFINES RULES FOR FIRST STATIC DATA
CONDITI0N

unsigned int dec_a1::condition1s(const a1_con1svar & var)
{
        if (var.urest ==4 && var.crtst==4 && var.hydst >=3 && var.ivfst >=3)//using
integars to represent the classification gap
        {
        dec_state.begin= 1;//begin a1 conditions satisfied, needs to be set before test for
state_a1 output
        }
        else //if none of these condions are satisfied then do not begin
        {
        dec_state.begin= 0;// begin a1 conditions not satisfied
        }
#if DEBUG1
        cout << "\n The state of dec_state_begina1 in the function is " << dec_state.begin
<<"\n";
#endif
        return dec_state.begin;
}

//FUNCTION CONDITION2S DEFINES RULES FOR SECOND STATIC DATA
CONDITI0N

unsigned int dec_a1::condition2s(const a1_con2svar & var)
{
        if (var.potst ==5 && var.idtst==1 && var.acbst<=2 && var.abtst==1)//using
integars to represent the classification gap
        {
        dec_state.begin= 1;//begin a1 conditions satisfied, needs to be set before test for
state_a1 output
        }
        else //if none of these condions are satisfied then do not begin
        {
        dec_state.begin= 0;// begin a1 conditions not satisfied
        }
        return dec_state.begin;
}

//FUNCTION CONDITION1D DEFINES RULES FOR FIRST DYNAMIC DATA
CONDITI0N

unsigned int dec_a1::condition1d(const a1_con1dvar & var)
{
        if (var.crtdy ==4 && var.uredy==4 && var.time>=48)//using integars to represent
the classification gap
        {
```

```
        dec_state.begin= 1;//begin a1 conditions satisfied, needs to be set before test for
 state_a1 output
        }
        else //if none of these condions are satisfied then do not begin
        {
        dec_state.begin= 0;// begin a1 conditions not satisfied
        }
        return dec_state.begin;
}

//FUNCTION CONDITION2D DEFINES RULES FOR SECOND DYNAMIC DATA
CONDITI0N

unsigned int dec_a1::condition2d(const a1_con2dvar & var)
{
        if (var.potdy ==5 && var.time>=6)//using integars to represent the classification
gap
        {
         dec_state.begin= 1;//begin a1 conditions satisfied, needs to be set before test for
state_a1 output
        }
        else //if none of these condions are satisfied then do not begin
        {
        dec_state.begin= 0;// begin a1 conditions not satisfied
        }
        return dec_state.begin;
}

//FUNCTION CONDITION3D DEFINES RULES FOR THIRD DYNAMIC DATA
CONDITI0N

unsigned int dec_a1::condition3d(const a1_con3dvar & var)
{
        if (var.hydst ==4 && var.pulst ==1 && var.urvdy<=1 && var.time>=48)//using
integars to represent the classification gap
        {
        dec_state.begin= 1;//begin a1 conditions satisfied, needs to be set before test for
state_a1 output
        }
        else //if none of these condions are satisfied then do not begin
        {
        dec_state.begin= 0;// begin a1 conditions not satisfied
        }
        return dec_state.begin;
}

//--------SET OF FUNCTIONS WHICH TEST THE DO NOT BEGIN TREATMENT
RULES----------
```

```
//FUNCTION CONDITION1S DEFINES RULES FOR FIRST STATIC DATA CONDITI0N

unsigned int dec_a1::condition01s(const a1_con01svar & var)
{
        if ((var.blpst <=2 && var.bptst==1) || var.bldst ==1 )//using integars to represent the classification gap
        {
        dec_state.nbegin= 1;//begin a1 conditions satisfied, needs to be set before test for state_a1 output
        }
        else //if none of these condions are satisfied then do not begin
        {
        dec_state.nbegin= 0;// begin a1 conditions not satisfied
        }
        return dec_state.nbegin;
}


//----------------FUNCTION FOR DECIDING ON WHAT ADVICE TO GIVE TO USER----------


char* dec_a1::advice(decision & a1_1)
        {
        action(a1_1 );
        if (dec_state.bt==1)//if there are reasons for starting treatment and no reasons not to then begin CVVHD
                {
                dec_state.thestate = "Begin Renal Replacement Therapy";
                }


        if(dec_state.bt==0)//if there are reasons to not start treatment then the advice is not to start
                {
                dec_state.thestate = "Do not begin Renal Replacement Therapy";
                }

        #if DEBUG1
        cout << "\n Inside the function call The decision state for decision a1 is: " << dec_state.thestate << "\n";
        #endif

        return dec_state.thestate;
        }
```

```
//=============================================================================
//
//FILENAME:                a1c1svar.h
//FILE TYPE:               C++ header class for A1_CON1SVAR
//COMPILER USED:           Borland C++ version 4.5
//AUTHOR:                  David Murley, City University
//DATE CREATED:  24 July 1995
//
//_____________________________________________________________________________
//
//DESCRIPTION: Class A1_CON1SVAR represents the data struture and the data
//             interface for function condition1s in class DEC_A1.
//
//             The data items represent those used in the function to set
//             begin for decision A1.  The functions form the interface to
//             the test functions and the patient and treatment state
//             assessment.
//
//BASE CLASSES: None
//DERIVED CLASSES: None
//COMPONENT CLASSES: None
//CONTAINS CLASSES: None
//
//USAGE: Data interface for the treatment prescription knowledge base.
//
//KNOWN BUGS: None
//_____________________________________________________________________________
//
//MODIFICATION HISTORY
//DATE:
//AUTHOR:
//DESCRIPTION:
//_____________________________________________________________________________

//----------PRE-PROCESSOR MACROS-----------------------------------------------

#ifndef A1_CON1SVAR //macro if condition to prevent multiple definitions
#define A1_CON1SVAR
#include "test_a1.h"

class dec_a1;//pre-definition of class dec_a1

//-----------------------------------------------------------------------------
//          DECLARATION FOR A1_CON1SVAR CLASS
```

```
//
//_____________________________________________________________________
_________


class a1_con1svar
{

//--------------------DATA STRUCTURE-----------------------------------------
        private:
        int urest;
        int crtst;
        int hydst;
        int ivfst;

//------------------INTERFACE FUNCTIONS-------------------------------------
        public:
        friend dec_a1;
        a1_con1svar(int ,       int ,     int ,     int );
        void iniat_var(int *, a1_con1svar *);
};

//-----------------constructor definition-----------------------------------

inline a1_con1svar::a1_con1svar(int a=0,     int b=0,          int c=0,          intd=0):urest(a),
                                             crtst(b),hydst(c),ivfst(d)
        {
        #if DEBUG1
                cout<< " Inside the a1_con1svar constructor \n";
        #endif
        };


//-----------------test conditions------------------------------------------

void a1_con1svar::iniat_var(int *arr, a1_con1svar *vars)
        {
        vars->urest=0;
        vars->crtst=0;
        vars->hydst=0;
        vars->ivfst=0;
  if (arr[0]==1)
                {
                vars->urest=4;
                vars->crtst=4;
                vars->hydst=3;
                vars->ivfst=3;
        #if DEBUG
```

```
            cout<< " Condition number 1s is set to active \n";
        #endif
        }
        else
        {
        #if DEBUG
            cout<< " Condition number 1s is set to inactive \n";
        #endif
        }
            return;
        }

#endif

//-------End of a1_con1svar class file-----------------------------------------
```

```
//=============================================================================
==============
//
//FILENAME:                a1c2svar.h
//FILE TYPE:               C++ header class for A1_CON2SVAR
//COMPILER USED:           Borland C++ version 4.5
//AUTHOR:                  David Murley, City University
//DATE CREATED:  24 July 1995
//
//_____________________________________________________________________________
_________
//
//DESCRIPTION: Class A1_CON2SVAR represents the data struture and the data
//             interface for function condition2s in class DEC_A1.
//
//             The data items represent those used in the function to set
//             begin for decision A1.  The functions form the interface to
//             the test functions and the patient and treatment state
//             assessment.
//
//BASE CLASSES: None
//DERIVED CLASSES: None
//COMPONENT CLASSES: None
//CONTAINS CLASSES: None
//
//USAGE: Data interface for the treatment prescription knowledge base.
//
//KNOWN BUGS: None
//_____________________________________________________________________________
_________
//
//MODIFICATION HISTORY
//DATE:
//AUTHOR:
//DESCRIPTION:
//_____________________________________________________________________________
_________

//----------PRE-PROCESSOR MACROS----------------------------------------------


#ifndef A1_CON2SVAR //macro if condition to prevent multiple definitions of dec_a1
#define A1_CON2SVAR
#include "test_a1.h"

class dec_a1;class dec_a1;//pre-definition of class dec_a1

//-----------------------------------------------------------------------------
```

```
//          DECLARATION FOR A1_CON2SVAR CLASS
//
//_____________________________________________________________________
_________

class a1_con2svar
{

//--------------------DATA STRUCTURE-----------------------------------------
        private:
        int potst;
        int idtst;
        int acbst;
        int abtst;

//------------------INTERFACE FUNCTIONS-------------------------------------
        public:
        friend dec_a1;
        a1_con2svar(int ,      int ,    int ,    int );
        void iniat_var(int *, a1_con2svar *);
};

//-----------------constructor definition-----------------------------------

inline a1_con2svar::a1_con2svar(int a=0,    int b=0,        int c=0,        intd=0):potst(a),
idtst(b), acbst(c), abtst(d)
        {};


//-----------------test conditions-----------------------------------------

void a1_con2svar::iniat_var(int *arr, a1_con2svar *vars)
        {
        vars->potst=0;
        vars->idtst=0;
        vars->acbst=0;
        vars->abtst=0;
        if (arr[1]==1)
                {
                vars->potst=5;
                vars->idtst=1;
                vars->acbst=2;
                vars->abtst=1;
  #if DEBUG
                cout<< " Condition number 2s is set to active \n";
        #endif
        }
```

```
        else
        {
        #if DEBUG
                cout<< " Condition number 2s is set to inactive \n";
        #endif
        }
        return;
        }

#endif

//-------End of file----------------------------------------------------------
```

```
//=============================================================================
==============
//
//FILENAME:                a1c1dvar.h
//FILE TYPE:               C++ header class for A1_CON1DVAR
//COMPILER USED:           Borland C++ version 4.5
//AUTHOR:                  David Murley, City University
//DATE CREATED:  24 July 1995
//
//_____________________________________________________________________________
_________
//
//DESCRIPTION: Class A1_CON1DVAR represents the data struture and the data
//             interface for function condition1d in class DEC_A1.
//
//             The data items represent those used in the function to set
//             begin for decision A1. The functions form the interface to
//             the test functions and the patient and treatment state
//             assessment.
//
//BASE CLASSES: None
//DERIVED CLASSES: None
//COMPONENT CLASSES: None
//CONTAINS CLASSES: None
//
//USAGE: Data interface for the treatment prescription knowledge base.
//
//KNOWN BUGS: None
//_____________________________________________________________________________
_________
//
//MODIFICATION HISTORY
//DATE:
//AUTHOR:
//DESCRIPTION:
//_____________________________________________________________________________
_________

//----------PRE-PROCESSOR MACROS-----------------------------------------------


#ifndef A1_CON1DVAR //macro if condition to prevent multiple definitions
#define A1_CON1DVAR
#include "test_a1.h"//test file which sets the test conditions for dec_a1

class dec_a1;//pre-definition of class dec_a1

//-----------------------------------------------------------------------------
```

```
//          DECLARATION FOR A1_CON1DVAR CLASS
//
//_____________________________________________________________________
_________


class a1_con1dvar
{
//--------------------DATA STRUCTURE-----------------------------------------
        private:
        int crtdy;
        int uredy;
        int time;

//------------------INTERFACE FUNCTIONS-----------------------------------------
        public:
        friend dec_a1;
        a1_con1dvar(int ,      int ,     int );
        void iniat_var(int *, a1_con1dvar *);
};

//-----------------constructor definition-----------------------------------

inline a1_con1dvar::a1_con1dvar(int a=0,    int b=0,         int  c=0):crtdy(a),  uredy(b),
time(c)
        {};

//-----------------test conditions-----------------------------------------

void a1_con1dvar::iniat_var(int *arr, a1_con1dvar *vars)
        {
        vars->crtdy=0;
        vars->uredy=0;
        vars->time=0;
        if (arr[2]==1)
                {
                vars->crtdy=4;
                vars->uredy=4;
                vars->time=48;
        #if DEBUG
                cout<< " Condition number 1d is set to active \n";
        #endif
        }
        else
        {
        #if DEBUG
                cout<< " Condition number 1d is set to inactive \n";
        #endif
```

```
            }
        return;
        }

#endif

//-------End of a1_con1dvar class file-----------------------------------------
```

```
//=============================================================================
==============
//
//FILENAME:                a1c2dvar.h
//FILE TYPE:               C++ header class for A1_CON2DVAR
//COMPILER USED:           Borland C++ version 4.5
//AUTHOR:                  David Murley, City University
//DATE CREATED:  24 July 1995
//
//_____________________________________________________________________________
_________
//
//DESCRIPTION: Class A1_CON2DVAR represents the data struture and the data
//             interface for function condition2d in class DEC_A1.
//
//             The data items represent those used in the function to set
//             begin for decision A1.  The functions form the interface to
//             the test functions and the patient and treatment state
//             assessment.
//
//BASE CLASSES: None
//DERIVED CLASSES: None
//COMPONENT CLASSES: None
//CONTAINS CLASSES: None
//
//USAGE: Data interface for the treatment prescription knowledge base.
//
//KNOWN BUGS: None
//_____________________________________________________________________________
_________
//
//MODIFICATION HISTORY
//DATE:
//AUTHOR:
//DESCRIPTION:
//_____________________________________________________________________________
_________

//----------PRE-PROCESSOR MACROS-----------------------------------------------

#ifndef A1_CON2DVAR //macro if condition to prevent multiple definitions of dec_a1
#define A1_CON2DVAR
#include "test_a1.h"

class dec_a1;//pre-definition of class dec_a1

//-----------------------------------------------------------------------------
//             DECLARATION FOR A1_CON2DVAR CLASS
```

```
//
//_____________________________________________________________________
_________

class a1_con2dvar
{

//--------------------DATA STRUCTURE-----------------------------------------
        private:
        int potdy;
        int time;

//------------------INTERFACE FUNCTIONS-------------------------------------
        public:
        friend dec_a1;
        a1_con2dvar(int ,       int );
        void iniat_var(int *, a1_con2dvar *);
};

//-----------------constructor definition-----------------------------------

inline a1_con2dvar::a1_con2dvar(int a=0,     int b=0):potdy(a), time(b)
        {};

//-----------------test conditions-----------------------------------------
void a1_con2dvar::iniat_var(int *arr, a1_con2dvar *vars)
        {
        vars->potdy=0;
        vars->time=0;
        if (arr[3]==1)
                {
                vars->potdy=5;
                vars->time=6;
  #if DEBUG
                cout<< " Condition number 2d is set to active \n";
        #endif
        }
        else
        {
        #if DEBUG
                cout<< " Condition number 2d is set to inactive \n";
        #endif
                }
        return;
        }
#endif

//-------End of a1_con2dvar class file-----------------------------------------
```

```
//=============================================================================
===============
//
//FILENAME:                a1c3dvar.h
//FILE TYPE:               C++ header class for A1_CON3DVAR
//COMPILER USED:           Borland C++ version 4.5
//AUTHOR:                  David Murley, City University
//DATE CREATED:  24 July 1995
//
//_____________________________________________________________________________
_________
//
//DESCRIPTION: Class A1_CON3DVAR represents the data struture and the data
//             interface for function condition3d in class DEC_A1.
//
//             The data items represent those used in the function to set
//             begin for decision A1. The functions form the interface to
//             the test functions and the patient and treatment state
//             assessment.
//
//BASE CLASSES: None
//DERIVED CLASSES: None
//COMPONENT CLASSES: None
//CONTAINS CLASSES: None
//
//USAGE: Data interface for the treatment prescription knowledge base.
//
//KNOWN BUGS: None
//_____________________________________________________________________________
_________
//
//MODIFICATION HISTORY
//DATE:
//AUTHOR:
//DESCRIPTION:
//_____________________________________________________________________________
_________

//----------PRE-PROCESSOR MACROS----------------------------------------------

#ifndef A1_CON3DVAR //macro if condition to prevent multiple definitions of dec_a1
#define A1_CON3DVAR
#include "test_a1.h"

class dec_a1;//pre-definition of class dec_a1

//-----------------------------------------------------------------------------
```

```
//          DECLARATION FOR A1_CON3DVAR CLASS
//
//_____________________________________________________________________
_________

class a1_con3dvar
{

//--------------------DATA STRUCTURE-----------------------------------------
        private:
        int hydst;
        int pulst;
        int urvdy;
        int time;

//------------------INTERFACE FUNCTIONS-------------------------------------
        public:
  friend dec_a1;
        a1_con3dvar(int ,       int , int , int );
        void iniat_var(int *, a1_con3dvar *);
};

//-----------------constructor definition-----------------------------------

inline a1_con3dvar::a1_con3dvar(int a=0,    int b=0, int c=0, int d=0):hydst(a), pulst(b),
urvdy(a), time(b)
        {};

//-----------------test conditions------------------------------------------

void a1_con3dvar::iniat_var(int *arr, a1_con3dvar *vars)
        {
        vars->hydst=0;
        vars->pulst=0;
        vars->urvdy=0;
        vars->time=0;
        if (arr[4]==1)
                {
                vars->hydst=4;
                vars->pulst=1;
                vars->urvdy=1;
                vars->time=48;
  #if DEBUG
                cout<< " Condition number 3d is set to active \n";
        #endif
        }
        else
```

```
        {
        #if DEBUG
                cout<< " Condition number 3d is set to inactive \n";
        #endif
                }
        return;
        }
#endif

//-------End of file----------------------------------------------------------
```

```
//=============================================================================
==============
//
//FILENAME:                a1c01sva.h
//FILE TYPE:               C++ header class for A1_CON01SVAR
//COMPILER USED:           Borland C++ version 4.5
//AUTHOR:                  David Murley, City University
//DATE CREATED:  24 July 1995
//
//_____________________________________________________________________________
_________
//
//DESCRIPTION: Class A1_CON01SVAR represents the data struture and the data
//             interface for function condition01s in class DEC_A1.
//
//             The data items represent those used in the function to set
//             nbegin for decision A1. The functions form the interface to
//             the test functions and the patient and treatment state
//             assessment.
//
//BASE CLASSES: None
//DERIVED CLASSES: None
//COMPONENT CLASSES: None
//CONTAINS CLASSES: None
//
//USAGE: Data interface for the treatment prescription knowledge base.
//
//KNOWN BUGS: None
//_____________________________________________________________________________
_________
//
//MODIFICATION HISTORY
//DATE:
//AUTHOR:
//DESCRIPTION:
//_____________________________________________________________________________
_________

//----------PRE-PROCESSOR MACROS-----------------------------------------------


#ifndef A1_CON01SVAR //macro if condition to prevent multiple definitions
#define A1_CON01SVAR
#include "test_a1.h"//test file which sets the test conditions for dec_a1

class dec_a1;//pre-definition of class dec_a1

//-----------------------------------------------------------------------------
```

```
//          DECLARATION FOR A1-CON01SVAR CLASS
//
//_____________________________________________________________________
_________


class a1_con01svar
{
//--------------------DATA STRUCTURE-----------------------------------------
        private:
        int blpst;
        int bptst;
        int bldst;

//------------------INTERFACE FUNCTIONS-------------------------------------
        public:
        friend dec_a1;
        a1_con01svar(int , int , int );
        void iniat_var(int *, a1_con01svar *);
};

//-----------------constructor definition-----------------------------------

inline a1_con01svar::a1_con01svar(int a=0, int b=0, int c=0 ):blpst(a), bptst(b), bldst(c)
        {};

//-----------------test conditions------------------------------------------

void a1_con01svar::iniat_var(int *arr, a1_con01svar *vars)
        {
        vars->blpst=3;
        vars->bptst=0;
        vars->bldst=0;
        if (arr[5]==1)
                {
                vars->blpst=2;
                vars->bptst=1;
                vars->bldst=1;
  #if DEBUG
                cout<< " Condition number 01sis set to active \n";
        #endif
        }
        else
        {
        #if DEBUG
                cout<< " Condition number 01s is set to inactive \n";
        #endif
  }
```

```
        return;
        }

#endif

//-------END OF a1_con01svar class file----------------------------------------
```

```
//=============================================================================
==============
//
//FILENAME:                main-da1.h
//FILE TYPE:               C++ main function for testing DEC_A1
//COMPILER USED:           Borland C++ version 4.5
//AUTHOR:                  David Murley, City University
//DATE CREATED:  24 July 1995
//
//_____________________________________________________________________________
_________
//
//DESCRIPTION: This program sets the test conditions for the decision A1.  It
//             uses all the files of the decision hierarchy, and the test file
//             test_a1.h to select one of seven test conditions.  Test
//             numbers 1 to 6 make the conditions individually active/true,
//             test number 7 makes all the conditoins active.  Tests 1 to 6
//             are used to test the operation of the individual conditions. Test
//             7 is used to ensure that when nbegin is true then the advice is
//             to not begin treatment.
//
//
//BASE CLASSES: None
//DERIVED CLASSES: None
//COMPONENT CLASSES: None
//CONTAINS CLASSES: None
//
//USAGE: the process control program for decision A1
//
//KNOWN BUGS: None
//_____________________________________________________________________________
_________
//
//MODIFICATION HISTORY
//DATE:
//AUTHOR:
//DESCRIPTION:
//_____________________________________________________________________________
_________

//----------PRE-PROCESSOR MACROS-----------------------------------------------

#define TEST 1

#include "dec_a1.h"


void main ()//should keep to a absolute minimum what is defined in main()
```

```
{
        cout << "FUNCTIONAL TEST RESULTS FOR DECISION A1\n";

int i;
for(i=1;i<9;i++)
{
        state state1("hello",0,0);
        dec_a1 run1(state1);//defines run1 as an instant of the the decision a1 intialises the
argument state-a1 to 0
        int beginact=0;
        int nbeginact=0;
        char* state_a1=0;

#if TEST
        test_a1 test1(0);
        int a=0;
        int * arrptr;
        arrptr=new int[6];
        test1.testset(a,arrptr);
#endif

#if TEST
        a1_con1svar vars10;
        a1_con1svar *vars1;
        vars1=new a1_con1svar;
        vars10.iniat_var( arrptr, vars1);
#endif

//put the start condition into function condition1s and do the same for all other functions
        if (beginact ==0)
                {
                beginact = run1.condition1s(*vars1);
                }
#if DEBUG
        cout << "The state of option A after running condition 1s " << beginact <<"\n";
#endif

#if TEST
        delete vars1;

#endif

#if TEST
        a1_con2svar vars20;
        a1_con2svar *vars2;
        vars2=new a1_con2svar;
        vars20.iniat_var( arrptr, vars2);
```

```
#endif
        if (beginact ==0)
                {
                beginact = run1.condition2s(*vars2);
                }
#if DEBUG
        cout << "The state of option A after running condition 2s " << beginact <<"\n";
#endif

#if TEST
        delete vars2;

        a1_con1dvar varsd10;
        a1_con1dvar *varsd1;
        varsd1=new a1_con1dvar;
        varsd10.iniat_var( arrptr, varsd1);
#endif

        if (beginact ==0)
        {
        beginact = run1.condition1d(*varsd1);
        }

#if DEBUG
        cout << "The state of option A after running condition 1d " << beginact <<"\n";
#endif

#if TEST
        delete varsd1;

        a1_con2dvar varsd20;
        a1_con2dvar *varsd2;
        varsd2=new a1_con2dvar;
        varsd20.iniat_var( arrptr, varsd2);
#endif

        if (beginact ==0)
                {
                beginact = run1.condition2d(*varsd2);
                }

#if DEBUG
        cout << "The state of option A after running condition 2d " << beginact <<"\n";
#endif

#if TEST
        delete varsd2;
```

```
        a1_con3dvar varsd30;
        a1_con3dvar *varsd3;
        varsd3=new a1_con3dvar;
        varsd30.iniat_var( arrptr, varsd3);
#endif

                if (beginact ==0)
                {
                beginact = run1.condition3d(*varsd3);
                }


#if DEBUG
        cout << "The state of option A after running condition 3d " << beginact <<"\n";
#endif

#if TEST
        delete varsd3;

        a1_con01svar varsd010;
        a1_con01svar *vars01;
        vars01=new a1_con01svar;
        varsd010.iniat_var( arrptr, vars01);
#endif

        if (nbeginact ==0)
                {
                nbeginact = run1.condition01s(*vars01);
                }

#if DEBUG
        cout << "The state of option B after running condition 01s " << nbeginact <<"\n";
#endif



#if DEBUG1
        cout << "\n The state of nbegina1 just before the 'if' query is " << nbeginact <<"\n";
        cout << "\n The state of begina1 just before the 'if' query is " << beginact <<"\n";
#endif

#if TEST
        delete vars01;
#endif

        state_a1=run1.advice(run1);//the if control structure used to set the
        cout << "The decision advice from running decision A1 is:\n " << state_a1 << "\n";
```

```
#if TEST
        delete arrptr;
#endif

 }
 return;
}
```

```
//=============================================================================
==============
//
//FILENAME:                test_a1.h
//FILE TYPE:               C++ test function for testing DEC_A1
//COMPILER USED:           Borland C++ version 4.5
//AUTHOR:                  David Murley, City University
//DATE CREATED:            2 August 1995
//
//_____________________________________________________________________________
_________
//
//DESCRIPTION: This program declares the test functions for setting the test
//             values for checking the functioning of the decision A1.  The
//             values depend on the configuration of a six element test array.
//             The configuration of the test array is set according to a number
//             entered by the user running main-da1.h.
//
//
//BASE CLASSES: None
//DERIVED CLASSES: None
//COMPONENT CLASSES: None
//CONTAINS CLASSES: None
//
//USAGE: to set the test states for decision A1
//
//KNOWN BUGS: None
//_____________________________________________________________________________
_________
//
//MODIFICATION HISTORY
//DATE:
//AUTHOR:
//DESCRIPTION:
//_____________________________________________________________________________
_________

//----------PRE-PROCESSOR MACROS-----------------------------------------------


# include <iostream.h>
#ifndef TEST_A1 //macro if condition to prevent multiple definitions of dec_a1
        #define TEST_A1


class test_a1
{
        private:
```

```
        int testset_no;
        public:
        test_a1(int);
        void testset(int & ,int *);
};

inline test_a1::test_a1(int testno)
        {
        testset_no=testno;
        }

#include "test_a1f.cpp" // the file defining the the test functions

#endif
```

```
//=================================================================
==============
//
//FILENAME:                test_a1f.h
//FILE TYPE:               C++ test functions for testing DEC_A1
//COMPILER USED:           Borland C++ version 4.5
//AUTHOR:                  David Murley, City University
//DATE CREATED:  2 August 1995
//
//_________________________________________________________________
_________
//
//DESCRIPTION: This program defines the test functions for setting the test
//             values for checking the functioning of the decision A1.  The
//             configuration of the test array is set by the function testset().
//
//
//BASE CLASSES: None
//DERIVED CLASSES: None
//COMPONENT CLASSES: None
//CONTAINS CLASSES: None
//
//USAGE: to set the test states for decision A1
//
//KNOWN BUGS: None
//_________________________________________________________________
_________
//
//MODIFICATION HISTORY
//DATE:
//AUTHOR:
//DESCRIPTION:
//_________________________________________________________________
_________


void test_a1::testset(int & testno, int *aptr)
        {
        testno=0;
        cout << "Input the number of the test set \n";
        cin >> testno;
        int con[6]={0,0,0,0,0,0};
        if (testno ==1)
                {
                con[0]=1;
                }
        if (testno ==2)
                {
```

```
        con[1]=1;
        }
if (testno ==3)
        {
        con[2]=1;
        }
if (testno ==4)
        {
        con[3]=1;
        }
 if (testno ==5)
        {
        con[4]=1;
        }
  if (testno ==6)
        {
        con[5]=1;
        }
   if (testno ==7)
        {
        con[0]=1;
        con[1]=1;
        con[2]=1;
        con[3]=1;
        con[4]=1;
        con[5]=1;
        }
    int i;
    for (i=0; i<6 ; i++)
        aptr[i]=con[i];
    return;
    }
```