

# Organisation and performance in renal anaemia management

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## Abstract

### Introduction

Performance in healthcare systems is under constant scrutiny, with particular focus on safety, quality and efficiency. The management of many long-term diseases involves complex patterns of care processes. However, the mechanisms by which this works are poorly understood, with care pathways reflecting pre-determined, linear processes.

Renal anaemia is a significant complication of chronic kidney disease that is expensive to treat and is associated with reduced quality of life and increased morbidity and mortality. There is wide variation between the clinical performance measures of centres for renal anaemia management, which researchers and practitioners have suggested is due to differences in organisation.

### Aims and objectives

This research explores the features of high and low performing renal anaemia management services to build evidence for their improvement.

### Methods

A multiple case studies approach examining anaemia management at eight renal centres with high and low performance was used. Data were collected using observation, interview and document sampling. The Unified Modelling Language was employed to define an abstract framework of the renal anaemia management service. A thematic analysis explored factors considered influential in the process and performance of renal anaemia management.

### Results

System latency and reliability, regular communication and trust between decision makers all appear significant in producing high performance. The group of activities and coordination mechanisms used to manage renal anaemia in haemodialysis patients in high performing centres reflect these features. The current tax regime encourages practice that has neither quality nor efficiency at its core.

### Discussion

The findings provide an important platform for performance improvement in renal anaemia management. In addition, the process modelling represents a departure from the major body of such work in healthcare, using a richer language to represent the complex and adaptive nature of healthcare systems. Therefore, the approach presented here may be a useful template for future work in this field.

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## List of abbreviations

%Hypo	Percentage of hypochromic red blood cells
AKI	Acute kidney injury
ANSA	Anaemia Nurse Specialist Association
ARF	Acute renal failure
BDN	Benefits Dependency Network
BNF	British National Formulary
BRS	British Renal Society
CAPD	Continuous automated peritoneal dialysis
CARI	Caring for Australasians with Renal Impairment
CCPM	Cosmos Clinical Process Model
CERA	Continuous erythropoiesis receptor activator
CfH	Connecting for Health
Chr	Content of haemoglobin in reticulocytes
CKD	Chronic kidney disease
CQC	Care Quality Commission
CQUIN	Commissioning for Quality and Innovation
CRF	Chronic renal failure
CRP	C-reactive protein
CSN	Canadian Society of Nephrology
DOaS	Do Once and Share
EBPG	European Best Practice Guidelines
eGFR	Estimated glomerular filtration rate
EHR	Electronic health record
EPO	Erythropoietin; Epoetin
ERF	Established renal failure
ESA	Erythropoiesis stimulating agent
ESRF	End stage renal failure
FBC	Full blood count
FP10(HP)	English secure prescription form (hospital prescription)
FTE	Full time equivalent
GDP	Gross domestic product
GFR	Glomerular filtration rate
GP	General practitioner
Hb	Haemoglobin
HCC	Healthcare Commission

Hct	Haematocrit
HD	Haemodialysis
HL7	Health Level 7
HM	Her Majesty's
IS	Information system
ISTC	Independent sector treatment centre
IT	Information technology
IU	International units
IV	Intravenous
JIT	Just in time
KDIGO	Kidney Disease: Improving Global Outcomes
KDOQI	Kidney Disease Outcomes Quality Initiative
Kt/V	Measure of dialysis adequacy ( $K - \text{clearance of urea} * t - \text{time} / V - \text{volume}$ )
Kuf	Ultra-filtration coefficient of a dialyser
LRA	Logical Record Architecture for health and social care
MCV	Mean cell volume
MDT	Multidisciplinary team (meeting)
MHRA	Medicines and Healthcare products Regulatory Agency
MIT	Massachusetts Institute of Technology
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NIHR	National Institute for Health Research
NKF	National Kidney Foundation
NSF	National Service Framework
OpenEHR	Open Electronic Health Record
PASA	Purchasing and Supplies Authority
PbR	Payment by Results
PC	Personal computer
PCT	Primary Care Trust
PD	Peritoneal dialysis
PGD	Patient group directive
pmp	Per million of population
QA	Quality assurance
QOF	Quality and Outcomes Framework
R&D	Research and development
RA	Renal Association
RCP	Royal College of Physicians

RRT	Renal replacement therapy
SC	Sub-cutaneous
SCr	Serum creatinine
SD	Standard deviation
SHA	Strategic Health Authority
StR	Specialty Registrar
TSAT	Transferrin saturation
UK	United Kingdom
UML	Unified Modelling Language
URR	Urea reduction ratio
US	United States (of America)
USA	United States of America
VAT	Value added tax
VBP	Variety and best practice
WHO	World Health Organisation

# Chapter 1

## Introduction

Within healthcare, there is increasing awareness of differences between organisations in policies, practice and outcomes for patients that are not explained by differences in their patients' diseases or preferences (Wennberg, 2002). The evidence-based healthcare movement seeks a better and wider understanding of existing knowledge along with the generation of new knowledge to reduce these and other problems with healthcare (Gray, 2001).

As a result of the systematic collection and analysis of patient data from United Kingdom (UK) renal centres it has become clear that there is a large and persistent variation between centres in achievement of clinical performance measures for correction of renal anaemia, among other things (Ansell et al., 2010). This variation in the UK and a similar situation in the United States of America (USA) have been analysed statistically, providing evidence that much of the difference cannot be accounted for by patient differences, resources and facilities, local social factors, treatment for anaemia and effectiveness of renal replacement therapy (Burton et al., 2000; Fink et al., 2007). This research therefore examines the management of renal anaemia in a selection of organisations with the aim of improving understanding of the different approaches taken and identifying good practices to enable improvements to its delivery.

## 1.1 Problem domain

The provision of healthcare in the UK consumed 9.6% of GDP in 2008-9 (Office of Health Economics, 2009) and is primarily provided by the government-owned National Health Service (NHS), which employs 1.43 million staff (NHS Information Centre for Health and Social Care, 2010), making it the largest employer in Europe (NHS, 2007). Despite being nationalised over 60 years ago, the NHS is still a set of largely decentralised organisations with central government attempting to effect changes through policy initiatives.

Pang et al (2006) consider modern healthcare to have seven ubiquitous problems:

- Errors and mistakes
- Poor quality healthcare
- Waste
- Unknowing variations in policy and practice
- Poor experience by patients
- Overenthusiastic adoption of interventions of low value
- Failure to get new evidence into practice

Exploring these issues within the USA, the Institute of Medicine has released two major reports, *To err is human* (2000) and *Crossing the quality chasm* (2001) examining the extent and reasons for the problems and how other industries manage them. They conclude that there are tens of thousands of deaths each year in the USA as a result of preventable errors in health care and call for a fundamental reinvention of the system, citing six challenges:

- Reengineered care processes
- Effective use of information technologies
- Knowledge and skills management
- Development of effective teams
- Longitudinal coordination of care across patient-conditions, services and sites of care
- Incorporating performance and outcome measurements for improvement and accountability

In the UK, the last ten years have seen unprecedented increases in healthcare funding, intended to improve the service provided. This has occurred in tandem with policies to invest in information systems (Department of Health, 1998, 2000), use performance targets, league tables and performance related payments (Department of Health, 2002, 2003, 2004b) and

encourage patient choice (Department of Health, 2004b, 2006a, 2008). While the investments have significantly improved access to care, the current and previous government believe the quality and efficiency of care can still improve dramatically (Department of Health, 2008, 2010).

There is a large variability in aggregate clinical performance indicators for renal anaemia between centres, which, the Renal Registry report suggests, could be reduced by studying high performing centres (Richardson et al., 2007). The severity of renal anaemia in patients undergoing dialysis is associated with co-morbidity, mortality and reduced quality of life (NICE, 2006a). The primary clinical performance indicator for the management of anaemia is haemoglobin level and, in the UK, the current recommendation is to maintain patients between 10.5 and 12.5 g/dl. The latest published figures show that renal centres have between 39% and 70% of haemodialysis patients within the target haemoglobin levels (Richardson, Ford, Gilg & Williams, 2010). Differences in performance in anaemia management have been analysed statistically and the conclusions of the authors were that a significant proportion were caused by differences in care processes and centre organisation (Burton et al., 2000; Fink et al., 2007).

## 1.2 Performance improvement

Efforts to improve performance in organisations typically focus upon the organisation's culture and technology (the knowledge, skills, tools and processes used). Arranging the appropriate culture and technology given an organisation's purpose and context are essential to high quality operations. The importance of process among these was given particular prominence by Business Process Reengineering (Hammer & Champy, 1993) which argued that in the light of new tools (information technology), organisations could be fundamentally reorganised away from functional silos into more responsive and efficient process-based organisations.

Total Quality Management (Oakland, 2003), Business Process Reengineering (Hammer & Champy, 1993), Continuous Quality Improvement, Six Sigma (Pande, Neumann & Cavanagh, 2000) and Lean (Womack, Jones & Roos, 1990) are all approaches to performance improvement that encourage local identification of new ways of working with the guidance of certain principles. These all came to prominence during the 1980s and 1990s and are seen by some as management fads (Ponzi & Koenig, 2002). They emphasise changes in technology and culture and often espouse fundamental redesign or iterative changes and tests to guide the process.

In contrast to these locally innovative approaches to performance improvement are best practice approaches such as benchmarking; the identification and adoption of existing practices superior to those currently in use (Camp, 1995); or the design of one-size-fits-all information systems (Swan, Newell & Robertson, 1999). These approaches focus on generic solutions to a problem and are often criticised for their insensitivity to the uniqueness of each context and how that will affect the superiority of the practice being transferred.

All of these approaches to performance improvement have been used in healthcare and the tools and language that they use have often been tailored accordingly. In addition, many of the features of these approaches have been combined as a breakthrough or improvement collaborative (Institute for Healthcare Improvement, 2003; Øvretveit, 2002). This involves a group of organisations focusing on improvements to a particular area, making and testing changes and communicating with each other about their successes and difficulties (Øvretveit, 2002). Within renal anaemia management a collaborative was launched at the British Renal Society conference (Renal Association, 2007), although without the funding for repeat meetings there was limited collaboration between centres and little evidence of improvement.

### 1.3 Process modelling

Process modelling is a key component of performance improvement efforts. It helps participants in the process understand the part they play, assists thinking about alternatives, helps to create shared understanding and gives an explicit representation to which one can refer. The formalisation of representations of purpose and activity has received a great deal of attention within the information systems and software engineering literature. While many such approaches have been created, the Unified Modelling Language (UML) (Object Management Group, 2009) is becoming established as the pre-eminent language due to its flexibility and wide range of perspectives. Recently, the NHS has begun using UML to build a set of data models for clinical domains called the Logical Record Architecture for Health and Social Care (LRA) (NHS Connecting for Health, 2010b). The intention is that the designers of health and social care information technology (IT) applications will use these models to support information sharing that is relevant to organisational processes.

Process models typically present a single process, rather than a categorisation of multiple processes, which limits their analytical power. King and Johnson (2006) have proposed the use of a toolkit of business process modelling techniques to capture variety and best practice in processes. This extends the ability to model and compare related processes by providing a framework with which to organise them.

Although process modelling is a key component of performance improvement, as was mentioned above, any aspect of an organisation, its context and the multiple relationships between these can affect performance. It is therefore important to recognise that different contexts, cultures and skill sets may fit best with different processes.

## 1.4 Thesis overview

This thesis explores how organisation affects performance in renal anaemia management. Chapter 2 examines how performance and good practice are viewed within healthcare before considering the nature of chronic care and the implications for efforts to model it. The context of UK healthcare, CKD and renal anaemia management are provided in chapter 3, which identifies current understanding of organisation in the problem domain and the performance variations that prompted the research. Chapter 4 describes the approach of multiple case studies, the methods used to gather data on the organisation of renal anaemia management and analyse its impact on performance. In chapter 5, a framework for renal anaemia management is described that provides an overview of the functions of anaemia management and the approaches to its delivery encountered in the course of the research. Chapter 6 examines whether performance is associated with three basic contextual features: the resource of the participating organisations, the size and the ethnic mix of their patient population. Chapter 7 examines a selection of factors that appear to affect performance in renal anaemia management including latency, coordination, roles, relationships, use of decision support and reliable drug supply and administration. Finally, chapter 8 synthesises the evidence from the previous chapters to provide a set of recommendations for practice improvement in renal anaemia management.

## Chapter 2

### Literature

The research aims to examine the impact of organisation on performance in renal anaemia management, in order to enable improvements. In the introduction, the problem of poor performance in healthcare was briefly outlined along with the essence of performance improvement approaches. Within healthcare, both innovative performance improvement approaches and those involving transfer of practice (spread of innovation) are in use, as well as those that combine these designs such as the breakthrough collaborative (Institute for Healthcare Improvement, 2003). In this thesis, the primary focus will be on the identification of existing practices that result in better performance because of the speculation that they exist in the problem domain (Burton et al., 2000; Fink et al., 2007; Richardson et al., 2007) and the relative tractability of such a problem for doctoral research. Therefore, this chapter examines the concept of good practice in healthcare, in the context of evidence-based medicine and good practice. The chapter then considers the nature of chronic care and how this may influence approaches to modelling it, before reviewing relevant approaches to process modelling, or the creation of care pathways – a regular feature of process improvement initiatives. However, first the concepts of performance and quality are explored in section 2.1.

The search for relevant literature has been an ongoing process and carried out using a variety of methods including keyword searching in a variety of databases, cited reference searching, tracing of citations and discussion with senior academics. In addition, to identify literature closely related to the proposed research, a systematic review of the literature was conducted in December 2007, which Appendix D describes and evaluates.

## 2.1 What is performance?

Performance is the behaviour of a system with respect to a purpose (S. Anderson et al., 2006). Within the operations management literature, organisational performance can be evaluated against five performance objectives; cost, speed, quality, dependability and flexibility (Slack, Chambers & Johnston, 2004). Here, quality relates to the excellence of the product/service while dependability is the reliability of access to or delivery of the expected product/service. Flexibility is the ability to cope with different output requirements (choice) and produce similar outputs given differing inputs.

The term quality appears to have become an alternative word for performance for some within healthcare, following the publication of the Institute of Medicine's (2001) report, *Crossing the quality chasm*, which named six aims for improvement: safe, effective, patient-centred, timely, efficient, and equitable. Many definitions of quality in healthcare now include efficiency or value for money (Raleigh & Foot, 2010), although the Darzi report, *High quality care for all* (Department of Health, 2008) gave quality the more limited scope of prevention of ill health, empowerment of patients to personalise care, effectiveness of treatment and safety. These are closer to the meaning of quality used in operations management, although there remain areas of overlap with other performance aspects such as safety with dependability.

## 2.2 Evidence based medicine and best practice

Evidence-based medicine is the predominant paradigm in Western-style healthcare and shares much in common with the concept of best practice from the management literature. These emphasise rationalist (quality of technology) rather than normative (culture of quality) approaches to performance improvement (see Barley & Kunda, 1992) and the replication or transferability of practice, rather than innovation as a means to performance improvement.

### 2.2.1 Evidence-based medicine

Evidence-based medicine is the application of the best available scientific evidence as part of the decision making and application of treatment to patients (Sackett et al., 1996). This is a centralised and top-down approach to the discovery and use of good practice involving large-scale research, systematic reviews and dissemination of knowledge through a variety of channels to inform national policies and local practice. The successionist experimental methods (e.g. randomised controlled trials) and resulting standardised and averaged evidence base appear at odds with the unique nature of the individual patient case, yet both perspectives are necessary for the delivery of high quality care (Plsek & Greenhalgh, 2001).

Evidence-based medicine is typically concerned with individual care, albeit in the abstract, although Gray has published a book regarding its application to system organisation (2001). This is described as “a scientific approach to healthcare management” (Gray, 2001) echoing the movement of *scientific management* (see section 2.2.2 Best practice, below). Gray recommends a nested set of strategies for organising patient care as: managed care, pathways and guidelines. Managed care is the systematic treatment provided as a set of services for a group of patients. Pathways, as discussed below, describe the local implementation of care and patient progress. Guidelines are supports for the decision-making process given a set of circumstances and are considered part of the promotion of best-practice in the NHS (Gray, 2001). Gray considers it essential that these guidelines are adapted to local circumstances with the involvement of all who will be providing care to increase local ownership and improve the fit. This softens the approach allowing abstract good practice to be appropriated and recognises some of the cultural issues involved in change management.

### 2.2.2 Best practice

Best practice has a long history in the rationalist ideology of management literature, often traced to F.W. Taylor, an engineer who took a mechanistic perspective of organisations

and led the theory of scientific management at the turn of the 20th century, placing an emphasis on identification of a 'best method' (Taylor, 1911). Frank and Lillian Gilbreth were followers of Taylor and presented *Process charts: First steps in finding the one best way to do work* (Gilbreth & Gilbreth, 1921), to the American Society of Mechanical Engineers who would later adopt this early process modelling technique as a standard. Following the second world war, *systems rationalism* developed, inspired by British operational command and concepts from electronics and computers (Barley & Kunda, 1992). The change of approach was from a focus on the concrete minutiae (such as hand movements) in Taylorism to the abstract and general (such as whole departments and organisations) in systems rationalism. The focus in such approaches is on improvements in technology (including process) and latterly the social structure and 'interface' with the environment. Rationalism is criticised for its increasing specialisation that sacrifices flexibility which in turn hampers organisations' ability to adapt in the face of a changing environment (Barley & Kunda, 1992). In addition, the stark lack of interest in employees leaves it unable to deal with cultural issues and potentially blind to the impact of their recommendations.

Best practice is seen by some authors as an abstract concept and others as a concrete example. Reijers and Liman Mansar (2005) define the ideal best practice as the best way to solve a particular problem in *any* context, but suggest that in reality it is necessary to localise it appropriately. Szulanski (1996) defines transfer of best practice as the "replication of a ... practice that is ... deemed superior to internal alternate practices and known alternatives outside the company." Benchmarking is considered to be "finding and implementing best practices" (Camp & Tweek, 1994) and involves the comparison of performance indicators for processes with similar purposes, gaining knowledge about the chosen 'best' practices and ultimately their recreation. While Camp (1995) believes a selection of best practices should be synthesised and adapted to local conditions, Szulanski and Winter (2002) suggest that the attempt should be to replicate a concrete example perfectly, arguing that the best practice is already high performing and easier to introduce as a whole. If best practice is transferable it must be knowable in the abstract, but the degree of abstraction possible for a particular best practice may be very limited (as Szulanski (1996) suggests) or high (as discussed by Reijers and Liman Mansar (2005)).

An important concern with best practice is that the approach might stifle adaptation and improvement. However, the literature on organisational routines has challenged this recently, considering that the abstract conceptualisation of a process (ostensive) provides the reference to which each real act of a process (performative) can be contrasted to identify opportunities

for change, in turn modifying the ostensive (Feldman & Pentland, 2003; Pentland & Feldman, 2005). The theory of organisational routines has recently been applied to healthcare to understand what resourcing, technological, coordinating and cultural structures are necessary to embed routines for the use of interpreter services in general practice (Greenhalgh, Voisey & Robb, 2007).

### **2.2.3 Good and best practice in healthcare**

Good practice is a concept that is gaining currency as an alternative to best practice (e.g. Department of Health, 2004a, 2007a; Donaldson, 2001) and emphasises the potential for continuing improvement of the practice, the necessary link between context and practice, the potential for several equally good alternatives and the uncertainty of the practice's superiority given multiple dimensions of performance and confounding influences.

There are many existing examples of good practice within healthcare, for example within renal care, patients who are identified as being at risk of requiring haemodialysis should receive immunisation against blood-borne viruses so that they are likely to be protected when exposed to risk of infection (Department of Health, 2001a). However, Spurgeon (1998 cited in Holloway, Hinton, Francis & Mayle, 1999) criticised best practice studies in healthcare for not examining the generalisability of practices, the context, the importance of personalities, the criteria for judging what is best practice or the effects of local forces. These are good reasons for criticism and apply not just to healthcare, although these are all areas that a study can examine, even if only tentative answers can be given.

Practice differences in healthcare are often presented as inevitably bad (e.g. Dilts, 2005). However, deliberate variation can be a response to differences in context, patient condition or preference or an attempt at innovative improvement. James and Hammond (2000) argue that medical practice differences arise from a combination of factors including: the complexity and limitations of medical knowledge, ambiguity surrounding the identification of best practice, the autonomous status of the medical profession and decentralised nature of teaching, human error and the limits of human ability.

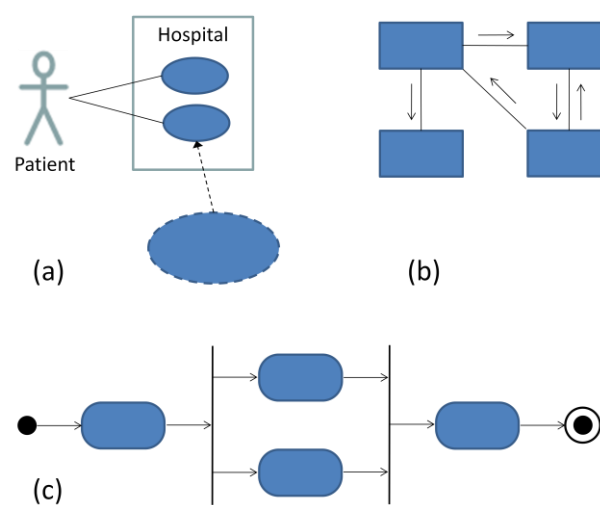
## 2.3 Care pathways for chronic care

Process modelling is an important aspect of understanding and sharing practice across many performance improvement approaches (Gilbreth & Gilbreth, 1921; Hammer & Champy, 1993) and is found in evidence-based medicine in the form of care pathways. A model is an explicit representation of an abstraction of reality. The National Library for Health (2005) defined care pathways as descriptions of sequences of healthcare for particular patients. Examples of care pathways for chronic care are contained in the National Service Frameworks for older people and renal services (Department of Health, 2001b, 2005) in the form of flowcharts. More recently, access to the Map of Medicine, “a visual representation of evidence-based, practice-informed pathways” (Map of Medicine, 2010b) has been purchased by the NHS and can be viewed online. Examples from the Map of Medicine such as the diabetes care pathway and the National Service Frameworks illustrate relatively linear processes like a production line or supply chain. As was suggested above, this will not always fit well with chronic care.

Within the academic literature, several studies using process modelling in healthcare have used common process modelling techniques, such as Soft Systems Methodology (Allam, Gray, McIntosh & Morrey, 2004) and the Unified Modelling Language (UML) (Knape et al., 2003; Kumarapeli, De Lusignan, Ellis & Jones, 2007; Liaw, Deveny, Morrison & Lewis, 2006; Lunn, Sixsmith, Lindsay & Vaarama, 2003). Of these, only one examined an existing process in detail, for which they used observation, data and document sampling and repeated revision of their models with interviews and group discussions with the local experts (Kumarapeli et al., 2007)

*e-Pathways* (de Luc & Todd, 2003) recommended the use of UML as an approach to formalise and standardise care pathway representations, something that is currently rare in practice (Crocker, Johnson & King, 2009). The UML (Booch, Rumbaugh & Jacobson, 2005; Object Management Group, 2009), a formalised and extensible collection of model types developed within the software engineering community, offers an approach that can describe more than just a linear view of activities. A process can be defined as a collection of activities that result in a transformation (S. Anderson et al., 2006) and are often considered in terms of activity, but the activity is only given purpose by reference to a desired transformation and can only be enacted by one or more entities collaborating. Although the activity models in UML are like flowcharts and therefore similar to many care pathways, there are other representations of behaviour in UML including use cases, communication diagrams, sequence

diagrams and collaborations (see figure 2.1). An actor is something with behaviour; in other words an entity or role that is more than just a static object or store of information, it is capable of performing processes. A use case is a class of scenarios that describes the interactions between a subject and the actors involved in a transaction or set of transactions. The use case relates to a user goal (a purpose that a user has for the subject). Communication diagrams represent the network of entities that collaborate in a particular case, collaboration diagrams emphasise who or what participates in some behaviour, while sequence diagrams emphasise the timing of interactions. Therefore, UML can represent various and multiple aspects as appropriate.



**Figure 2.1** Figurative examples of a selection of UML model types

(a) Use cases and collaborations. (b) Communication. (c) Activity.

### 2.3.1 Process types

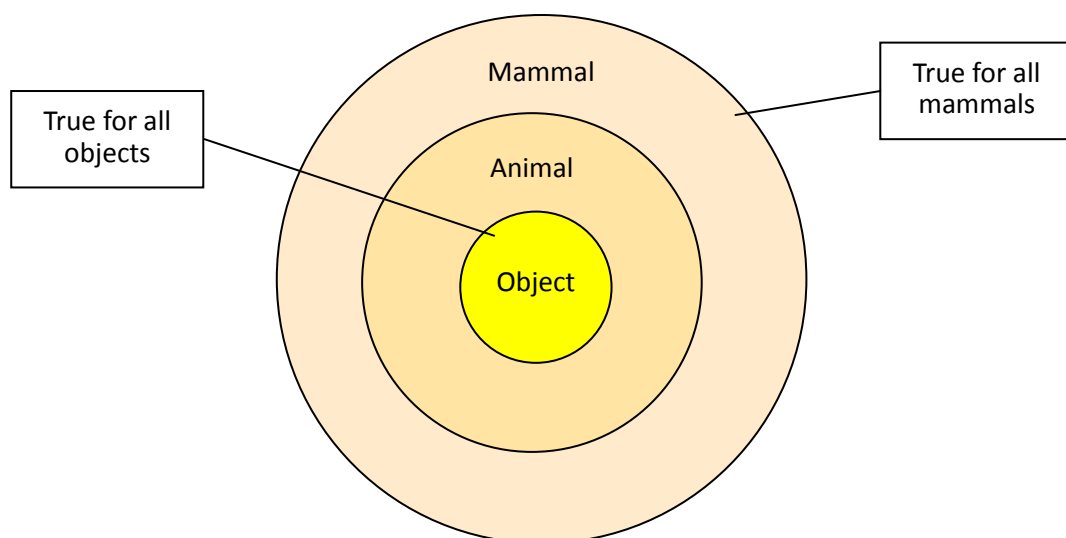
If process models are to be used in the abstract as a template for a new service or for comparison, it is necessary to consider what it means to generalise or specialise a process and how this may be done. While there are a host of methods available with which to model processes, until recently little attention has been paid to the organisation of such models. Therefore individual models stood alone and were not usually considered to be one of a type of activities. This is in contrast to models of objects and concepts, which are arranged and classified in an ontology to aid comparison of their similarities and differences.

Classification is used to obtain useful generalisations. Three different approaches to classification are classical categorisation, conceptual clustering and prototype theory (Booch, 1994). Classical categorisation identifies explicit properties that are shared; conceptual clustering is a related but fuzzier approach based upon qualitative similarities that are not

necessarily measurable; while prototype theory groups by degree of similarity to a specific example. Of these, conceptual clustering appears most appropriate to behavioural models.

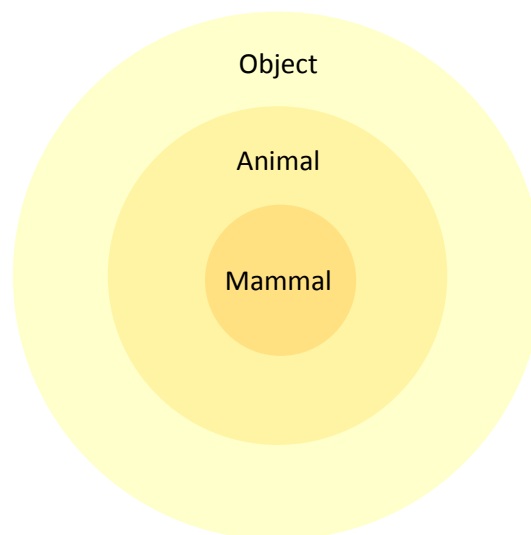
Within UML, use case and collaboration diagrams can use the generalise relationship but there is no consensus as to what specialising behaviour means (Cockburn, 2000). However, Malone, Crowston and Herman (2003) have presented a framework for organising a collection of processes using both generalisation and the more familiar notion of composition in *The MIT Process Handbook*. The method proposed is quite distinct from that in object-oriented analysis and design where a generalisation typically collects only the similar features of a group of concepts, a method termed minimal set semantics (Malone et al., 2003). Malone et al. propose maximal set semantics (specifically for processes, maximal execution set semantics) as a method for generalisation of processes, essentially collecting all possible (known) ways of conducting the process. A generalisation under maximal execution set semantics can be achieved through either increased abstraction of activity nodes or an increased set of possible activity edges. This is in part analogous to the declaration of an abstract class in an object-oriented language where specification of the activity used to produce an external behaviour is left to the specialised class and thus similar to Cockburn's (1998) recommendations for generalising use cases.

To explain further, in the standard minimal set approach of object-oriented programming, sub-types (specialisations) can only add features and the defined features of the sub-types are an increase upon those of their super-type as illustrated in Figure 2.2.



**Figure 2.2 Defined features of classes (minimal set semantics)**

To take an alternative perspective, the potential attributes of each class are only limited by what is defined about them. The more that is defined, the smaller the scope of the class as illustrated in Figure 2.3. *The MIT Process Handbook* approach is to attempt to record that potential with respect to processes, enabling a synthetic model of the many ways of executing a process to be displayed.



**Figure 2.3 Potential features of classes**

*VBP: An approach to modelling process variety and best practice* uses the notions of the MIT process handbook to organise a hierarchy of processes with the formal language elements of UML (King & Johnson, 2006). The approach uses use cases as the basic element of the typology, in order that the clustering concept is a specific purpose (rather than an activity sequence for example).

## 2.4 Summary

Within healthcare, care pathways are an important part of evidence-based medicine and good practice approaches. These approaches can be critiqued for their frequent lack of consideration for context in its broadest sense, transferability and uncertainty about what is good, but they need not be insensitive to these aspects. The complex and varied nature of chronic healthcare may not lend itself to the typical style of current care pathways, but in UML there appears to be an existing modelling language that would be appropriate to the needs of both chronic and acute care delivery. However, UML has not been used extensively within healthcare. There also exists an approach for combining process models to create an abstract model of service delivery.

## **Chapter 3**

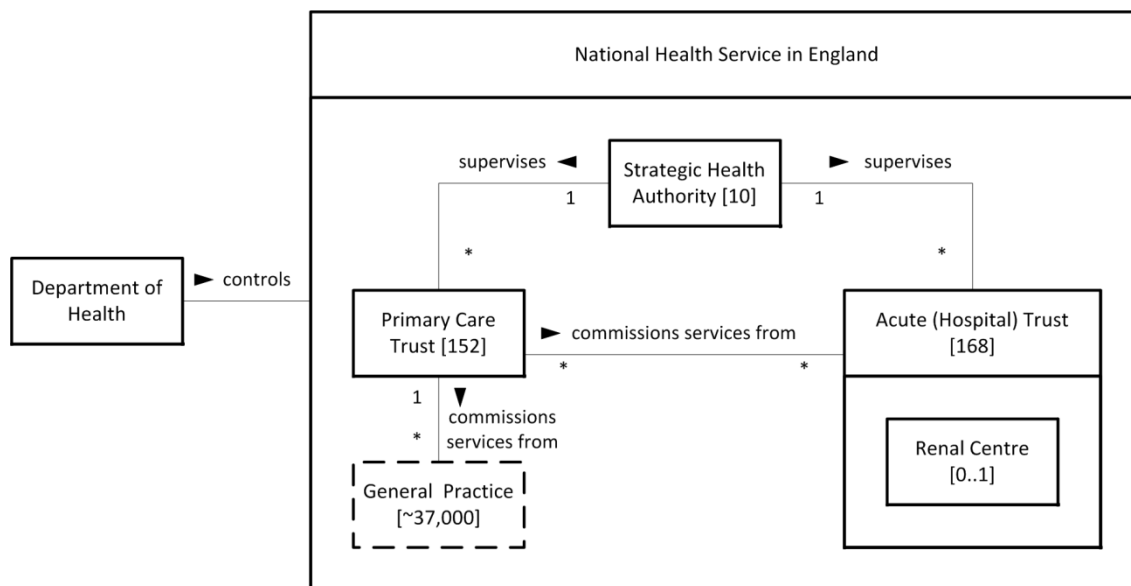
### **Context**

#### **3.1 UK healthcare organisation**

Within the United Kingdom (UK), most healthcare is provided free at the point of use by the publicly funded National Health Service (NHS), which consumed 8.3% of GDP in 2008/9 while private healthcare expenditure accounted for 1.3% (Office of Health Economics, 2009). The NHS employs 1.43 million staff (NHS Information Centre for Health and Social Care, 2010), making it the largest employer in Europe (NHS, 2007).

##### **3.1.1 NHS structure**

The NHS is composed of many legal entities, with funding flowing from central government to and between these entities (trusts) within a framework of rules. The NHS is organised differently in the constituent countries of the UK, now under the auspices of their devolved parliaments in Scotland, Wales and Northern Ireland. Within England the Department of Health controls the NHS whose service provision is broadly split between primary and secondary care, the main legal entities being Primary Care Trusts (PCTs) and Acute Trusts (see figure 3.1). 80% of funding goes to PCTs, which provide community services and commission services from privately owned General Practices and secondary services, mainly from the publicly owned Acute Trusts but also from the private sector and from Independent Sector Treatment Centres. This is overseen by 10 regional Strategic Health Authorities (SHAs), whose role is to ensure there is suitable and equitable provision of healthcare across their area. Some services, including dialysis and transplantation, are commissioned by specialised commissioning groups, based within SHAs and acting on behalf of PCTs. However, much of this is due to change under proposals set out in July 2010 (Department of Health) with the abolition of PCTs and SHAs and their replacement with GP commissioning consortia and an NHS commissioning board.



**Figure 3.1 Organisational overview of the NHS in 2010 and the position of renal centres within this structure (based on NHS, 2010)**

### 3.1.2 Policies

The latest reorganisation of the NHS (Department of Health, 2010) is just one in a series of Government-led changes, PCTs having themselves been established in 2002 and, along with SHAs, significantly reorganised in 2006 (House of Commons Health Committee, 2006). In addition to these changes to the higher organisational tiers of the NHS, a succession of policies attempt to direct or incentivise changes to the operation of the NHS. Current policies designed to improve the NHS include three payment schemes: Payment by Results (PbR), Quality and Outcomes Framework (QOF) and Commissioning for Quality and Innovation (CQUIN), although the latter of these was not in place during fieldwork and will not be described here.

PbR is a hospital funding mechanism designed to improve quality and efficiency, as well as enabling patient choice (Department of Health, 2002; King's Fund, 2007; Pate, 2009). The Department of Health introduced PbR in 2002, which sets out national, per patient, tariffs for most hospital procedures that PCTs pay for the services they have commissioned, changing the funding of hospitals away from local block contracts that were largely based on historical settlements and the skills of local negotiators. A mandatory national tariff has not been set for dialysis, transplantation, or other well-defined episodes within renal care, although the change to payment by procedure has occurred with the tariffs being negotiated locally.

PbR primarily incentivises hospitals to do more procedures where they are cheaper for the hospital than the national tariff. Therefore, hospitals have incentives to reduce the costs of their activities and increase the volume of those activities (Audit Commission, 2004). The

drivers for quality enabled by PbR are supposed to be patient choice and allowing commissioners to focus on what hospitals provide to the exclusion of cost. However, patient choice is limited in specialties such as nephrology where provision of care is centralised and the condition is chronic, because of the travel costs of choosing a different centre than the closest one. PbR is due to be replaced as part of the changes discussed above (Department of Health, 2010), although the precise form of the new system is unclear.

QOF is a voluntary incentive scheme for general practices designed to improve the quality of care they provide for their patients (Department of Health, 2003). Practices are rewarded based on achievement of a series of clinical performance indicators, for example the proportion of patients registered with Chronic Kidney Disease (CKD) whose blood pressure is 140/85 or less (NHS Employers & British Medical Association, 2009). However, this is described as “not about achieving targets or PCT performance management but rewarding contractors for good practice” (Department of Health, 2003). It has been reported that the introduction of the CKD section of QOF resulted in a 61% increase in referrals to one renal centre over 30 months (Phillips, 2009), meaning that many patients are now receiving appropriate specialist review, but also putting significant burden on renal centres.

### 3.1.3 Quality and performance

In addition to the bodies and incentive schemes described above, there are regulatory bodies in place to examine the care provided in hospitals. The Care Quality Commission (CQC) recently replaced the Healthcare Commission (HCC) (Great Britain, 2008) and is responsible for licensing and monitoring provision of care to ensure essential standards of quality are achieved (Care Quality Commission, 2010a). Hospital care is rated at a trust rather than departmental level, examining factors such as mortality rates, infection control and incident reporting (Care Quality Commission, 2010b).

There are a number of other bodies designed to assist in improving the care provided by the NHS by: funding research (National Institute for Health Research (NIHR) and the Medical Research Council (MRC)), producing clinical guidance (National Institute for Health and Clinical Excellence (NICE)), developing tools and techniques to enable organisational change (NHS Institute for Innovation and Improvement), and delivering “new computer systems and services” (NHS Connecting for Health, 2010a (NHS CfH)). Therefore, there is significant focus on performance improvement within the NHS, including organisational aspects of performance. In the section on renal anaemia management (3.3) the relevant work of NICE will be considered. Two models of the processes in renal care constructed under the auspices

of NHS CfH are discussed in the introduction to chapter 5, while the contribution of the NHS Institute to a renal anaemia improvement collaborative is noted in the introduction to chapter 7.

## 3.2 Chronic Kidney Disease

### 3.2.1 Diseases

Chronic Kidney Disease (CKD) describes the state of having significantly reduced kidney function or kidneys that are damaged or abnormal, for an extended period of time (Department of Health, 2005; Levey et al., 2005) and is often irreversible and progressive. Many underlying diseases can cause CKD but these produce a similar range of symptoms and have broadly similar treatment strategies. CKD is a global public health problem, and is associated with increased risks of kidney failure, cardiovascular disease, all-cause mortality and a wide range of comorbidities (Go et al., 2004; Weiner et al., 2004).

CKD is often categorised by degree of excretory kidney function into 5 stages, where 1 is normal excretory kidney function and 5 indicates the greatest extent of kidney disease and hence the lowest excretory kidney function (US National Kidney Foundation, 2002). These stages largely dictate the suite of care patients will be offered, with primary care typically managing patients in stages 1-3 and renal centres becoming increasingly involved through stages 3-5. At stage 5, renal replacement therapy (RRT) is often required for long-term survival, and this stage is known as Established or End Stage Renal Failure (ERF/ESRF).

It is estimated that at least 8.5% of the adult population of England and Wales have CKD stages 3-5, with proportions increasing with age and much greater proportions among women than men (Stevens et al., 2007). At the start of 2009 there were 47,525 adults in the UK receiving RRT, equivalent to 774 per million of population (pmp) (Tomson, 2010), a significant increase from approximately 30,000 in 2000 and not predicted to stabilise until at least 2025 (Roderick et al., 2004).

### 3.2.2 Treatment and services in the UK

Renal care is expensive and expanding, currently taking 2% of the NHS budget (Feest, 2007). Renal centres primarily exist to provide a wide range of specialist (secondary and tertiary) care to people with kidney related disorders. Within the NHS in England, these centres are part of acute trusts (see figure 3.1). Renal centres are located in hospitals but usually provide or coordinate services away from the main site. In England there are 52 renal centres serving estimated populations of between 0.29 and 2.20 million people (Ansell & Tomson, 2009). People typically access the care of a renal centre by referral from their GP;

although referrals also come from within the hospital sector, often because of an acute decline in kidney function associated with intercurrent illness.

Renal centres categorise their patients into 'modalities' according to their disease progression and the care they will provide for them (see figure 3.2 and figure 3.3). Patients who attend a clinic may receive advice and treatment and usually have a range of tests performed to assist in decision about their management. If a patient's prognosis indicates they are likely to reach CKD stage 5 within a year or two, they are usually provided with education and advice about the treatment options available, broadly termed renal replacement therapy (RRT) and conservative care. There are currently two methods for renal replacement therapy: either dialysis or kidney transplantation. There are several types of dialysis available, the main one in use being haemodialysis in a clinical setting, but also community based options of peritoneal dialysis (PD) and home haemodialysis (home HD) (see also figure 3.3). Conservative care management provides drug therapy to manage the symptoms of CKD stage 5 without the invasive impact of renal replacement therapy and may therefore be an appropriate choice among patients with limited life expectancy or those who otherwise make an informed choice not to undergo RRT (Murtagh et al., 2007). As an informed choice with specialist management it is a relatively new phenomenon, but increasing (Murtagh et al., 2006) following the publication of the National Service Framework for Renal Services (Department of Health, 2004a, 2005). There is significant preparatory work required for all forms of RRT, in particular surgical procedures to provide access for dialysis, identification of possible live kidney donors and medical assessment of operative and post-operative risk in the case of transplant, and counselling to achieve informed decision-making in all cases. For this reason, early identification of patients who are likely to progress to stage 5 assists with their transition.

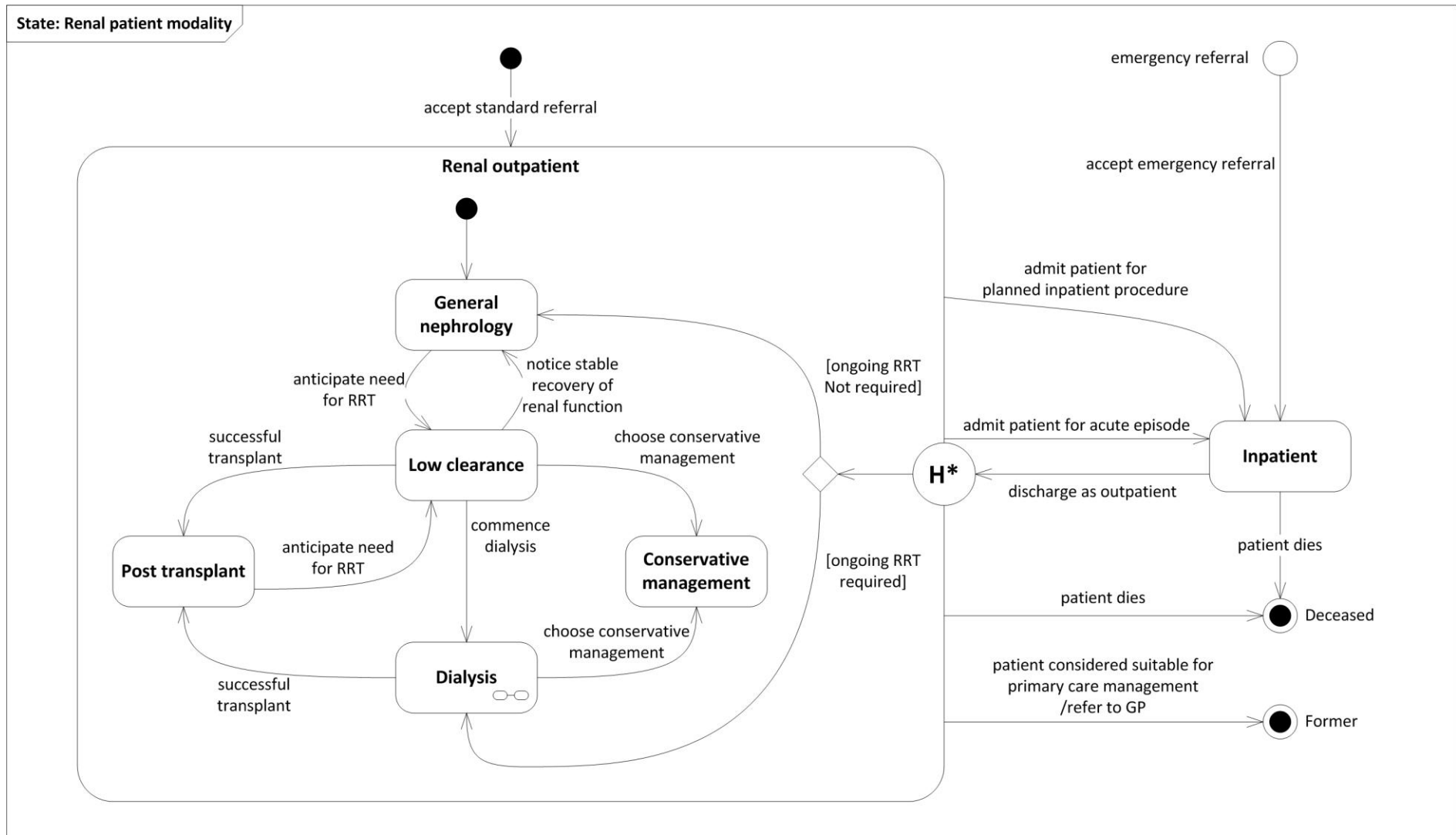
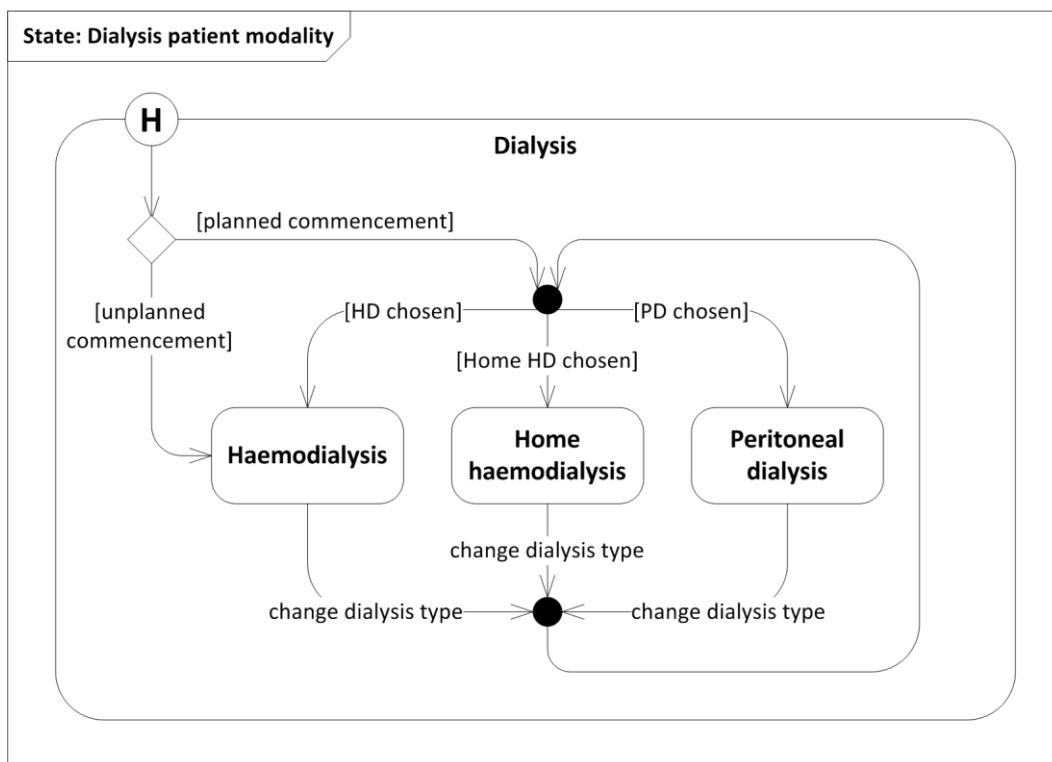


Figure 3.2 State diagram of renal patient modalities (based on the care pathway for renal replacement therapy, Department of Health, 2004a)



**Figure 3.3 State diagram of dialysis patient modalities (sub-state of dialysis in figure 3.2 above).**

### 3.2.3 Renal Registries

There are many national and international renal registries: organisations that collect datasets about renal patients, in particular RRT patients, and their care. The UK Renal Registry is a part of The Renal Association and collects standardised data quarterly from the information systems of all UK centres, including biochemical and haematological information, which makes it unique among registries (Hodsman, Feest, Ansell & Tomson, 2007). The Renal Registry publishes annual analyses based on this dataset that compare patient outcomes, treatment and demographics (e.g. Ansell et al., 2010). The Renal Registry primarily contains data on RRT patients, (see section 3.2.2) by far the largest subsection of which are HD patients. In addition, some data is held on other nephrology patients, in particular those in the process of being prepared for RRT, although this is less complete. Such a high quality clinical dataset is rare and provides great opportunities for research.

### 3.2.4 Variety in renal care and impact on outcomes

Within the UK renal community, the introduction of the Renal Registry report has drawn into focus persistent differences in performance across a range of measures between renal centres. Several studies across the world have examined such differences, attempted to

control for factors such as patient comorbidity, and concluded that a 'centre effect' remains (Fink et al., 2007; Khan et al., 1996; Schaubel, Blake & Fenton, 2001). However, a paper using artificial neural networks to examine survival on RRT in the UK found no evidence of a difference explained by the centres themselves (Tangri, Ansell & Naimark, 2006).

Multidisciplinary care in low clearance patients has been associated with reduced hospitalisation and improved survival time on dialysis in two studies (Curtis et al., 2005; Goldstein, Yassa, Dacouris & McFarlane, 2004). This involves access to a wide range of healthcare professionals (dietitians, pharmacists, nurse educators, etc.) rather than just nephrologists. Both studies were comparisons of patients attending the same centre and thus receiving otherwise comparable treatment. In addition, the patients receiving multidisciplinary care were significantly less anaemic at dialysis start and after 6 and 12 months (Curtis et al., 2005). Multidisciplinary care has also been associated with improved overall survival among elderly patients (Hemmelgarn et al., 2007). However, an earlier randomised controlled trial found no difference in any relevant marker between patients followed for five years (L. E. Harris et al., 1998) meaning that if a genuine effect existed in the other three studies the detail of the mechanisms or differences in context may be important.

Among HD patients, one study has examined the effect of multidisciplinary team meetings or sit-down rounds, a less frequent version of the ward walk round without the presence of a patient (Plantinga et al., 2004). The study compared 75 facilities and found a significant association between monthly or more frequent meetings and mortality after adjustment. In addition, a significant association was found with relation to high albumin (a general indicator of health) and to the total number of clinical performance indicators achieved, although no significant difference was found for the indicator for anaemia.

A recent report by the then president of the Renal Association, Professor Feehally (2007), describes his visits to every renal centre in the country in an attempt to examine similarities and differences in practice to assist the sharing of good practice and understand the reasons for the degree of variety. He considered the quality of care to be remarkable given levels of resource and found the variety was often intertwined with complex local and regional circumstances.

### 3.3 Renal anaemia management

Renal anaemia is a significant complication of CKD caused by a reduction in the production of erythropoietin and is increasingly common as kidney function declines (NICE, 2006a). It is associated with significant health costs, patient morbidity, heart disease and accelerated kidney damage. Healthy kidneys produce several hormones including erythropoietin, which stimulates red blood cell production. When haemoglobin (the protein that carries oxygen around the body) falls sufficiently the individual is considered anaemic. The condition is mainly treated using a combination of erythropoiesis-stimulating agents (ESAs) and iron with average drug costs alone estimated at £1600 per patient per year (Ansell, Brealey & Bell, 2007).

#### 3.3.1 Pathophysiology and prevalence of renal anaemia

In the general population at sea level, anaemia is defined as haemoglobin levels below 13 g/dl in men and 12 g/dl in non-pregnant women (World Health Organisation, 2001). Renal anaemia (anaemia caused primarily by reduced erythropoietin production) is associated with reduced quality of life; reduced activity, cognitive and sexual function; left ventricular hypertrophy and cardiac failure; increased hospitalisation and all-cause mortality (McMahon, 2008; NICE, 2006a). 90% of haemodialysis patients and 76% of peritoneal dialysis patients are treated for renal anaemia with ESAs in England, Wales and Northern Ireland (Richardson et al., 2010), approximating to 22,000 dialysis patients. In a survey of English GP databases, 81.5% ( $n = 4,443$ ) of people with stage 3-5 CKD had a haemoglobin record, of whom 15.3% were anaemic according to WHO criteria and 3.8% had Hb < 11 g/dl (de Lusignan et al., 2005), the point at which treatment should be initiated according to several guidelines (EBPG II working group, 2004; NICE, 2006a; US National Kidney Foundation, 2002). The latter figure was used by NICE (2006a) to estimate that 108,000 people in the UK may have anaemia and CKD. This potentially underestimates the total number requiring treatment, as it does not include those already successfully treated, although some will have anaemia due to other causes than CKD.

Red blood cells (also known as erythrocytes) deliver oxygen around the body. They make up approximately one quarter of the cells in the human body, normally being produced at a rate of 2 million per second and surviving for 100-120 days before being taken out of circulation and destroyed by the spleen (Pierigè, Serafini, Rossi & Magnani, 2008). This process normally maintains a stable mass of red blood cells, replacing them at the rate they are destroyed (Erslev & Besarab, 1997). They are produced and mature in bone marrow, a process

known as erythropoiesis that can take over a week; certain stem cells become responsive to erythropoietin and, in its presence, develop into erythroblasts, which then lose their nuclei and mature into erythrocytes (Elliott, Pham & Macdougall, 2008; Erslev & Besarab, 1997). However, in CKD patients there is often reduced erythropoietin production and, in HD patients, a typical reduction of 30-70% in erythrocyte lifespan (Ly, Marticorena & Donnelly, 2004). Erythrocytes are largely composed of haemoglobin, which contains iron and can bind to oxygen. The lifecycle of erythrocytes and the production process mean that changes in the rate of erythropoiesis do not cause instant changes in red cell number or haemoglobin concentration; it takes approximately one lifespan for a new steady state to be reached, which may be less than 30 or greater than 100 days in HD patients (Uehlinger, Gotch & Sheiner, 1992). In addition, an individual's change in erythrocyte production rate for a given change in erythropoietin vary significantly, with an estimated coefficient of variation of 45-50% (ibid) and the interaction of this with lifespan variation make projection of change in haemoglobin concentration difficult.

### **3.3.2 Treatment**

Modern treatment for renal anaemia mainly consists of a combination of iron and erythropoiesis stimulating agents (ESAs, often known as EPO), although blood transfusions may also be used and these were the standard treatment prior to the availability of ESAs during the 1980s. ESA tends to be favoured over transfusion because transfusion can reduce the chances of successful transplantation by causing sensitisation to tissue type antigens present on white blood cells, in addition to the risks of blood-borne infection (NICE, 2006a).

#### **3.3.2.1 ESA**

Erythropoiesis-stimulating agents (ESAs) act as a replacement for the hormone erythropoietin, which the kidney naturally produces. ESAs are injected, either intravenously (IV) or sub-cutaneously, and are suitable for self-administration by a trained patient. Several varieties of ESA are available with differing ranges of frequencies of administration, the exact frequency being dependent on dose and clinical choice (see table 3.1). There is no evidence that one ESA is more efficacious than another (NICE, 2006a). Epoetin alfa and epoetin beta (UK brand names Eprex and NeoRecormon respectively) are typically administered 3 times weekly, Darbepoetin alfa (brand name Aranesp) is typically administered weekly and methoxy polyethylene glycol-epoetin beta, a Continuous Erythropoiesis Receptor Activator (CERA, brand

name Mircera) is typically administered monthly. Other preparations are becoming available, but these were the ESAs typically in use in the UK at the time of the study.

**Table 3.1 Types and frequencies of ESA**

<i>Active ingredient</i>	Epoetin alfa	Epoetin beta	Darbepoetin alfa	Methoxy polyethylene glycol-epoetin beta
<b>Brand</b>	Eprex	neoRecormon	Aranesp	Mircera
<b>Frequency range</b>	1-3 x weekly	1-3 x weekly	Weekly-monthly	Fortnightly-monthly
<b>Typical frequency</b>	3 x weekly	3 x weekly	Weekly	Monthly
<b>BNF list cost<sup>1</sup> (6000 IU / 30 µg)</b>	£34.32	£44.94	£44.93	£44.94

<sup>1</sup> BNF = British National Formulary (British Medical Association & Royal Pharmaceutical Society, 2010). Prices correct at 1<sup>st</sup> June, 2010

### 3.3.2.2 IV Iron

Erythropoiesis uses iron and in CKD patients, in particular HD patients, IV iron supplementation is often required to achieve optimal response to ESA. Among HD patients, IV iron is often given as a regular treatment, while in other CKD patients single doses or short courses are typically prescribed. There are three UK brands of IV iron, each of which contains a different active ingredient. Iron sucrose (Venofer) is typically administered in 200 mg doses while iron dextran (CosmoFer) and ferric carboxymaltose (Ferinject) are typically administered in 1000 mg doses. Yet Venofer and Ferinject are typically administered as a slow IV injection while CosmoFer is typically administered as an IV infusion, taking much longer per dose than Venofer or Ferinject.

**Table 3.2 Types of IV iron**

<i>Active ingredient</i>	Iron sucrose	Iron dextran	Ferric carboxymaltose
<b>Brand</b>	Venofer	CosmoFer	Ferinject
<b>Typical HD schedule</b>	Weekly	Two-monthly	Two-monthly
<b>Typical non-HD schedule</b>	3-7 doses at 1 per week	1 dose	1 dose
<b>Time taken to administer</b>	5-30 minutes	3-4 hours	5-30 minutes
<b>BNF list cost<sup>1</sup> (1 g)</b>	£85.00	£79.70	£217.50

<sup>1</sup> BNF = British National Formulary (British Medical Association & Royal Pharmaceutical Society, 2010). Prices correct at 1<sup>st</sup> June, 2010

### 3.3.3 Assessment and evaluation of renal anaemia

Regular review of the haemoglobin of patients managed with ESA, at least monthly during the initiation phase and 1-3 monthly during a maintenance phase, are recommended (McMahon, 2008; NICE, 2006a; Renal Association, 2008). In the course of routine management of renal anaemia, several laboratory blood tests are used in combination with clinical observation. Laboratory investigations typically include: haemoglobin (Hb); one or two measures of iron status, typically serum ferritin and either transferrin saturation (TSATs) or percentage of Hypochromic red blood cells (%Hypo); and C-Reactive protein (CRP) which is a marker for inflammation, for instance caused by chronic infection. Additionally, glomerular filtration rate (GFR) or estimated GFR (eGFR), itself calculated from Serum Creatinine (SCr), are measures of kidney function.

To differentiate renal anaemia from other causes of anaemia, additional investigations may be used such as endoscopy and tests for Vitamin B12 and folate. Additional measures of iron include mean cell volume (MCV) and content of haemoglobin in reticulocytes (CHR). Haematocrit (Hct) is sometimes used in place of haemoglobin as a measure of the volume of red blood cells in a sample blood, rather than relative mass, although in the UK haemoglobin is predominantly used.

### 3.3.4 Service delivery

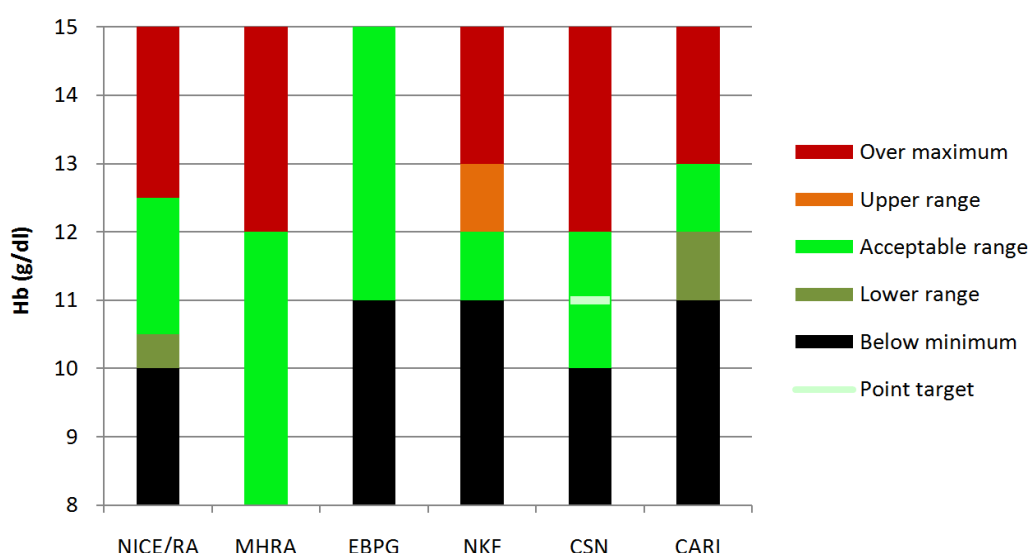
There are a range of reported approaches to service delivery in renal anaemia management (Anaemia Nurse Specialist Association & British Renal Society CKD forum, 2009; L. Bennett & Alonso, 2005). However, there are no detailed studies of the roles and responsibilities involved or the activities conducted to provide anaemia management as a whole.

Following the introduction of ESAs, many renal centres created the role of anaemia nurse or anaemia coordinator (Jenkins, 2004), with responsibility for maintenance of funding and provision of ESA, its optimal use and provision of statistics to commissioners (Sanders et al., 1999). ESA manufacturers often funded these posts in part or in full, at least initially. A survey of anaemia management practice in continental European countries in 2005 found wide variations in the split of responsibilities between doctors and nurses, although in general doctors were responsible for the initiation of treatment, while monitoring was varied and education was largely nurse-led (L. Bennett & Alonso, 2005). A role that combines prescribing, education, support and a single point of contact per patient is recommended in the implementation guide to the NICE guidelines (NICE, 2006b).

Flexibility around the place of drug delivery and administration was recommended by NICE (2006b), and a variety of options for community-based administration of IV iron have been developed (Anaemia Nurse Specialist Association & British Renal Society CKD forum, 2009; Bhandari & Naudeer, 2008; Peebles & Fenwick, 2008). However, such services are not available to patients attending most renal centres, and their implementation and the options available in each locality vary, with some providing home treatment and others providing treatment from community hospitals and clinics, or both.

### 3.3.5 Guidelines for renal anaemia management

A variety of organisations produce guidance on the treatment of renal anaemia and the use of ESAs. One of the key features of such guidance is typically a target haemoglobin range for those patients who are being treated with ESAs. Historically, concern was with ensuring adequate treatment and correction of anaemia, meaning targets were specified in terms of minimum haemoglobin. More recently, a series of studies have suggested that treatment with ESAs, in particular in high doses, may increase the risk of death (Besarab et al., 1998; Drüeke et al., 2006; Singh et al., 2006) or stroke (Pfeffer et al., 2009) and provide little improvement in quality of life balanced against greatly increased costs (NICE, 2006a). Because of these findings, newer guidelines for haemoglobin are typically given as ranges, maxima or both. The guidelines are described below and a graphical comparison is presented in figure 3.4, although this involves some assimilation due to differences in language and criteria between them.



**Figure 3.4 Comparison of guidelines for haemoglobin targets.**

Published by: National Institute for Healthcare and Clinical Excellence (NICE), Renal Association (RA), Medicines and Healthcare products Regulatory Agency (MHRA), European Best Practice Guidelines (EBPG), National Kidney Foundation (NKF), Canadian Society of Nephrology (CSN), Caring for Australasians with Renal Impairment (CARI).

The primary guidelines in England for renal anaemia management are from NICE (2006a). They recommend a treatment strategy to achieve haemoglobin levels between 10.5 and 12.5 g/dl, now incorporated in the Renal Association (2008) Clinical Practice Guidelines 4<sup>th</sup> edition. The National Service Framework for renal services (Department of Health, 2005) identified the treatment of anaemia for all patients with CKD in line with the then forthcoming guidelines as a marker of good practice, which are also endorsed by the Royal College of Physicians.

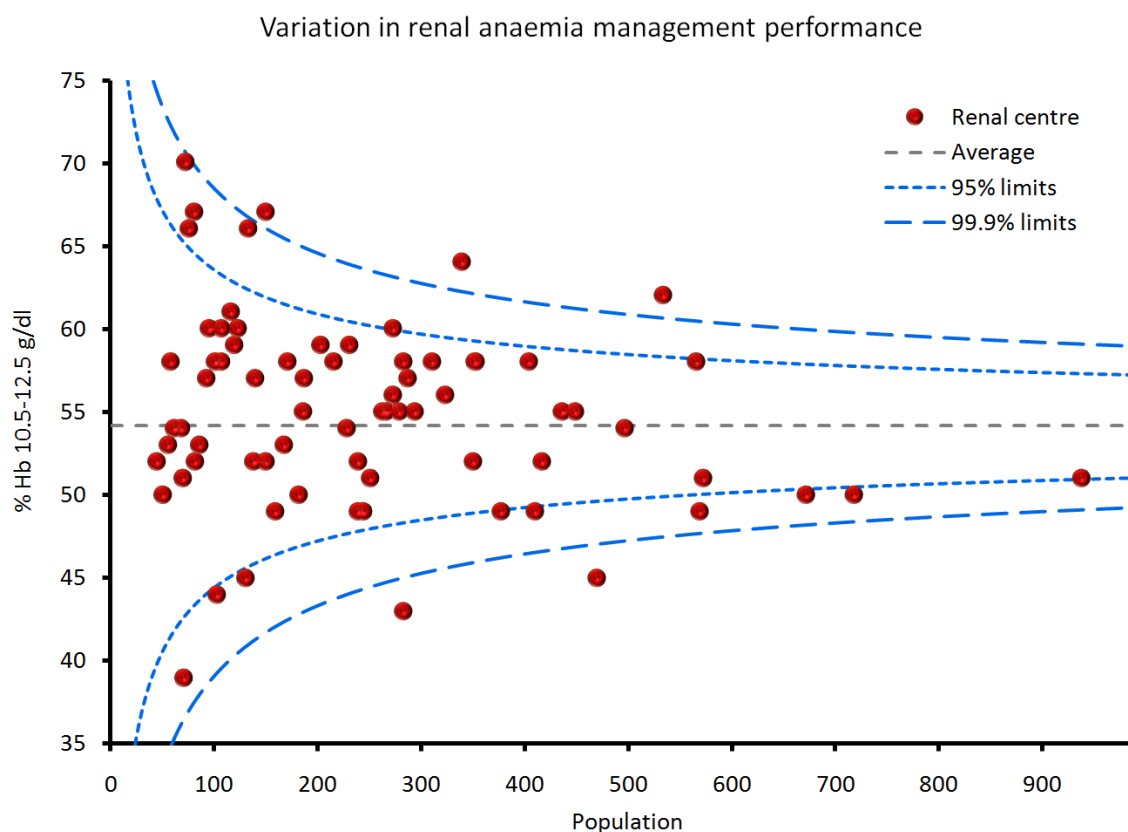
Additional guidance comes from the US National Kidney Foundation's (2006, 2007) KDOQI (Kidney Disease Outcomes Quality Initiative) guidelines for anaemia in CKD, who recommend a target of 11-12 g/dl, not exceeding 13 g/dl. The UK's Medicines and Healthcare products Regulatory Agency (2007) recommend treating to a maximum haemoglobin concentration of 12 g/dl. Similarly, the Canadian Society of Nephrology recommends targeting 11 g/dl, with 10-12 g/dl being acceptable. In contrast, the guidelines of CARI (Caring for Australasians with Renal Impairment) recommend a lower limit of 11 g/dl and a target of 12-13g/dl in patients at low risk of cardiovascular disease.

Previous recommendations for haemoglobin levels for British renal units were provided by the Renal Association standards 3<sup>rd</sup> edition (greater than 10 g/dl (Renal Association, 2002) and European Best Practice Guidelines 2<sup>nd</sup> edition (greater than 11 g/dl (EBPG II working group, 2004)). With no upper limit on haemoglobin in these prior guidelines, several units attempting to achieve compliance systematically treated their patients to much higher average haemoglobin values, with the perverse consequence that they now have some of the worst results when measured against the new guideline (see Richardson, Ford, Gilg & Williams, 2008; Richardson et al., 2007).

While there are some discrepancies between the different guidelines produced (see figure 3.4), with different weight being given to the conflicting evidence, there appears to be a broad consensus that both high and low haemoglobin levels are potentially harmful and all would be satisfied with a patient's haemoglobin remaining stable at 11.5 g/dl. However, less than 55% of HD patients in the UK had a haemoglobin within the 10.5-12.5 g/dl range (Richardson et al., 2010), while the MHRA have set a tighter maximum of 12 g/dl and KDOQI and CARI recommend a minimum of 11 g/dl. The mean and median haemoglobin for UK HD patients were 11.5 and 11.6 g/dl respectively, suggesting that there is broad consensus among practitioners that 11.5 g/dl is an appropriate haemoglobin level for these patients but that it is difficult to achieve this, or even the wider targets that guidelines have proposed.

### 3.3.6 Performance in renal anaemia management

There is a large and significant variation between renal centres in performance for renal anaemia management in the UK. In the latest Renal Registry report, centres attained between 39% and 70% of HD patients within the NICE guideline target range of Hb 10.5-12.5 g/dl (Richardson et al., 2010) and this is illustrated in figure 3.5. For the UK minimum standard of Hb  $\geq 10$  g/dl, centre performance ranged from 69% to 95% of HD patients (ibid). Standard deviation (SD) of haemoglobin, of particular importance if centres are to achieve a narrow spread of patients, also varied from 1.1 to 1.8 (ibid). The difficulty with this data is that it includes patients who are not treated with ESA and may have a naturally high haemoglobin level, although 90% of HD patients are treated with ESA at centres that submit prescribing data so the overall effect should be small.



**Figure 3.5** Funnel plot of percentage of HD patients with Hb 10.5-12.5 g/dl by renal centre (constructed from data in Richardson et al., 2010).

This variation is similar to the overall picture three years ago at the start of this research, when there was a range of centres with between 35% and 69% of HD patients in the target Hb 10.5-12.5 g/dl and 69% to 98% of HD patients with Hb  $\geq 10$  g/dl (Richardson et al., 2007). There has been some improvement, with 55% of patients within Hb 10.5-12.5 g/dl at the end of 2008 (Richardson et al., 2010) compared with 49% three years earlier (Richardson et al.,

2007). However, there has not been a dramatic change in other summary statistics. However, significant improvements have been made since 1997 in achievement of the UK minimum standard of  $Hb \geq 10$  g/dl (from 65% to 86% of prevalent HD patients) (ibid). The report recognised that to perform well against the new NICE guidelines, centres would have to achieve narrower distributions of haemoglobin, that certain centres had been consistently better at doing this and attempts should be made to learn from them (ibid).

### 3.3.7 Protocols, algorithms and decision support systems

In order to provide the appropriate dose of iron and ESA to patients, a range of protocols, algorithms and computer-assisted decision support systems have been proposed and evaluated in practice. They have also been used to attempt to standardise management in research trials (e.g. Pfeffer et al., 2009). Typically, these recommend stepwise adjustment of dose based on current iron and haemoglobin levels (see Brimble et al., 2003, p. 2655, figure 1; or NICE, 2006a, p. 23, figure 3.3, for examples).

The NICE (2006a) guidelines included a set of algorithms or flowcharts to guide decision making with respect to individual patients. To achieve the target haemoglobin of 10.5-12.5 g/dl, the intervention thresholds (haemoglobin at which the ESA dose is changed) are at 11 and 12 g/dl, increasing the dose for patients with  $Hb < 11$  g/dl and decreasing the dose where  $Hb > 12$  g/dl. They recognise that the algorithms are based on common sense strategies rather than an evidence base and recommend an observational study of their use to suggest amendments. A different published 'algorithm' also involves changes in dose based on current haemoglobin in 1 g/dl steps, which the information system recommends, although in this case the absolute doses at each step can be altered on a per-patient basis by the reviewing clinician (Benton, 2008).

A series of articles from Leeds St James's renal centre describe the impact of their computer-aided algorithm on average haemoglobin and the percentage of patients achieving guideline values, as well as demonstrating that by changing the intervention thresholds they could systematically move their patient population to higher or lower haemoglobin levels (Richardson et al., 1999; Richardson, Bartlett & Will, 2000, 2001).

Recently, an article compared the haemoglobin levels of two groups of patients, one of which was always treated according to a protocol, and found significant association between the use of the protocol and a patient being 'on target' (Chan, Moran, Hlatky & Lafayette, 2009). Patients were not randomly assigned to either category but were using the protocol unless their clinician chose to manage them differently. The authors conclude that "Adherence to

anemia protocols, as practiced in the dialysis units included in this cohort, may improve hemodialysis patients' ability to achieve target hemoglobin levels" (Chan et al., 2009, p. 1956). An alternative explanation for this finding is that clinicians are unlikely to alter current management for a patient whose haemoglobin is within the guideline. However, for a patient not achieving a desired haemoglobin they may well adjust their management in a manner contrary to the guideline because of circumstances that the guideline does not account for; yet the patient may still not achieve a desired haemoglobin level because their haemoglobin is difficult to control.

An evaluation of the prescribing for, and haemoglobin levels of, patients at centres across Europe assigned to use of a computerised decision support tool based upon EBPG guidelines compared with a control group found no difference in haematological targets (Locatelli et al., 2009). In a similar vein to the article by Chan et al. (2009), they also evaluated the haemoglobin level of 'adherers' to the EBPG guidelines and find that more adherers achieve their target, in both intervention and control groups. They conclude that adherence improves attainment but that a computerised decision support system made no difference to anaemia management (Locatelli et al., 2009). Apart from a series of analytical problems (e.g. clustering not taken into consideration) and ambiguity over whether centres were matched before randomisation or not, it is unclear what exactly the intervention (or control) was: if the tool was translated into local languages, what rules it used, how it was received by clinicians or fitted with practice. What the study did tell us was that this system, in the manner it was introduced, made no impact on the likelihood of decisions agreeing with their operationalisation of the EBPG guidelines. This is unsurprising as there is no evidence that there was any desire for or belief in the system or that it was appropriate to the many contexts in which it was placed.

There has been one randomised controlled trial of a protocol, which found no difference between the protocol and control groups, although attainment of target haemoglobin increased substantially in both groups during the study (Brimble et al., 2003). However, the group assigned to the protocol did end up with significantly reduced ESA use by comparison with the control group suggesting there may be economic benefits to protocol use.

It is clear that where algorithms are used to manage a patient population, the haemoglobin levels of that group can be systematically adjusted within limits. The one randomised controlled trial of a protocol has suggested that they offer no improvement in standards of care, although a possible financial benefit. However, currently published approaches are relatively simplistic, often based on current haematological values and dose

alone and do not automatically tailor their response to individual patients who respond differently to treatment. This may make them unsuitable for some patients without the manual adjustment described by Benton (2008). For this reason or others there may also be some resistance to their use, at least in their current formats.

### 3.3.8 Haemoglobin variability and cycling

In addition to the inter-patient differences in response to ESA and in absolute haemoglobin levels, significant interest has recently developed in intra-patient haemoglobin variability or *haemoglobin cycling*. Lacson, Ofsthun and Lazarus (2003) identified a median within-patient SD of 0.7 g/dl, nearly half of the UK average centre SD of 1.5 g/dl (Richardson et al., 2010). Studies of large databases have shown associations between haemoglobin variability and morbidity or mortality (Ebben, Gilbertson, Foley & Collins, 2006; Yang et al., 2007). It is likely that these associations are at least partly because intercurrent illness causes both haemoglobin variability (by altering responsiveness to ESA) and increased mortality (Regidor et al., 2006). However, some authors have also proposed that some of the association may be the result of a direct causal chain from frequent dose adjustments to variable haemoglobin levels, and variable haemoglobin levels causing increased mortality (Fishbane & Berns, 2007). Frequent dose adjustments have also been attributed to dose-adjustment algorithms that depend on absolute haemoglobin levels rather than trends over time (ibid).

The use of CERA (see the section about ESA, 3.3.2.1), which has an extended half-life and longer dosing intervals has been proposed by some to reduce haemoglobin variability (Besarab et al., 2007; Locatelli et al., 2007). However, these claims are based on comparisons of data from different contexts, both in time and in location, in both cases with an analysis of epoetin alfa use between 1998 and 2003 (Fishbane & Berns, 2005). In two controlled studies to examine the relative efficacy of CERA in haemodialysis (Sulowicz et al., 2007) and non-dialysis (Kessler et al., 2010) patients by comparison with epoetin alfa and darbepoetin respectively, no significant difference was found between groups for within-patient haemoglobin variability.

### 3.3.9 Evidence of a centre effect in renal anaemia management

Several studies have examined whether a 'centre effect' exists for renal anaemia, with all reporting a significant or even dominant contribution to patient haemoglobin, although predominantly in the US. In the UK, one study of anaemia in dialysis patients has examined differences between renal centres (Burton et al., 2000). After adjustment for the association between haemoglobin and age, gender, total time on dialysis and diagnosis, there was little

change in the difference between centres, suggesting that differences in management accounted for the differences in patient haemoglobin.

Three studies have investigated the relationship between organisation and quality indicators for renal anaemia management in the US using statistical methods. Reddan et al. (2003) examined differences between 18 renal networks (providers of dialysis at multiple centres) and found in a regression that significant differences were associated with two of those networks, in each case associated with higher haemoglobin while taking into account age, gender, 3 laboratory variables, ESA dose and dialysis dose. More recently an examination of differences in the performance of US renal centres controlling for factors including dosing, patient factors, centre size and local environmental variables such as socioeconomic status and health access found there was still a significant difference that they attributed to centre processes and recommended further work to investigate these (Fink et al., 2007). Finally, a study of renal centres in North California, all of which belonged to one network with the same algorithms for many aspects of care found that the centre was highly significant, explaining more of the difference in haemoglobin than patient characteristics (Chan et al., 2008). While there were geographic differences between these centres (e.g. urban-rural) and wide variation in size of centre (unanalysed), the scale of the effect suggests management processes contribute significantly to patient haemoglobin.

An investigation of process, clinical indicators and outcomes in the European clinics of a private renal dialysis provider, Fresenius Medical Care, examined differences across four countries and over a four-year period (Richards et al., 2007). Measures of process were provided relative to the targets established in the European Best Practice Guidelines (EBPG II working group, 2004; , 2002). The statistics suggest improvements in many process and clinical indicators over the four years (e.g. percentage of patients receiving IV iron) but wide variety in the way care is provided across countries and little evidence of correlation with outcomes (ibid). The clear improvements demonstrated against best practice guidelines and ambiguous trends in outcome measures highlight the difficulty in evaluating process using a small number of variables and the associated difficulties of determining 'best' practice through quantitative means.

### 3.4 Discussion

It appears that there are significant differences between both patients and centres for attainment of clinical performance indicators for anaemia management and that among centres this is partly explained by their processes for patient management. Given the high proportion of HD patients who are not within guideline ranges and the variability of the haemoglobin of many individual patients, it is clear that managing a population to within a narrow band of haemoglobin is difficult. This is despite the apparent efforts of clinicians, the extensive research, attempts to develop and employ protocols and computerised decision support. However, some centres are achieving significantly better results than others with respect to the measures available and aspects of their organisation may be transferrable depending on individuals and context.

While existing observational comparisons of performance have been powerful at detecting differences statistically associated with the centres, they have been limited in explanatory power by a lack of detail about the organisational differences between the centres. In the study limited to one provider in North California (Chan et al., 2008), differences at an organisational level appeared to be ruled out because algorithms for management were consistent across sites. While some very plausible explanations for the differences (e.g. use of transfusions, socio-economic status and dialysis access care) were discussed, the focus on individual patient management in general and algorithms to standardise decision making seemed to be at the expense of considering broader organisational factors.

Although there are some reports of practice in renal anaemia management, there is no framework by which providers can categorise themselves or consider alternatives to their existing practice. Nor has there been any detailed comparison of the practice of renal anaemia management at different locales. Because the variation in performance in this important area of healthcare is believed to be partly related to organisational factors, a detailed investigation of the organisation of renal anaemia management is appropriate. To attempt to identify whether differences in organisation are relevant, a comparison of organisations is appropriate. In particular, it would be useful to identify if there are particularly good or bad practices and understand the contextual constraints and enablers for these.

## **Chapter 4**

### **Methodology**

This chapter presents the philosophy, methodology and design that guided this research. This research has been designed with the aim of understanding how the organisation of renal anaemia management influences its performance, with the purpose of enabling improvements to be made. The following objectives were outlined:

- 1) Produce a framework for the management of renal anaemia
- 2) Examine processes and contexts with respect to the performance of centres against guidelines for patient indicators
- 3) Produce a set of recommendations for the future organisation of the management of renal anaemia

Currently, there is not an explicit model describing renal anaemia management. To be able to compare existing services requires some form of reference model or framework. Such a framework will also assist with the design of new services for renal anaemia management and therefore chapter 5 addresses objective 1. As was established in chapter 3, there appears to be differences at the renal centre level in renal anaemia management outcomes that are believed to relate to organisational differences. Therefore, chapter 6 and chapter 7 identify differences in context and approach to renal anaemia management and examine their relation to performance. This is supported by Appendix A, where case narratives are provided to offer a description of the case and their unique contexts. Objective 3 brings together the evidence and theory generated in objectives 1 and 2 and identifies recommendations for practitioners and policy makers. This is described in the discussion (chapter 8).

## 4.1 Summary of the methodology

The research used a prospective case study design at eight sites employing a range of methods designed to identify and present processes associated with good practice in the management of renal anaemia. The focus of the study was the set of primary and supporting processes for managing renal anaemia within a renal centre. Eight renal centres with extremely high or low performance indicators for anaemia management were recruited for comparative purposes. Methods of data collection included observer-as-participant observation, semi-structured interview and document sampling. The data collection began with a relatively wide scope and later focused in on areas indicated by the ongoing analysis. The analysis followed a general inductive approach including data-driven development of a set of themes, analytical coding of the data using these themes and extensive use of data displays, in particular process modelling.

## 4.2 Research philosophy

The researcher's personal philosophy is a pragmatist perspective (Ritchie & Lewis, 2005); that different approaches can offer different insights to a research question. This fits with a critical realist ontology and epistemology for scientific research (Blaikie, 2007). A realist ontology assumes that there is a metaphysically objective world but that it is only ever experienced in a subjective manner (Patton, 2002; Pawson & Tilley, 1997b). Realism allows a researcher to examine the metaphysically objective and subjective and attempt to make epistemologically objective statements about them. In other words, both the external real world and individual interpretations can be important and can be the subject of study. Furthermore, realism rejects the notion that scientific progress can be made solely through deduction and embraces inductive research (Hunt, 2005).

According to Pawson and Tilley (1997b), realistic evaluation stresses the importance of examining the mechanism and context which explain the regularity or outcome pattern. Instead of concentrating solely on whether a particular programme achieves an outcome, one should investigate why.

This mechanism-based model of causality fits with object-oriented analysis and design concepts, where it is the behaviour of collections of objects that produces change (Booch, 1994) and can be expressed in the Unified Modelling Language (UML). Policy makers initiate programmes because they wish to transform an outcome pattern from  $x$  to  $y$  (see figure 4.1). When evaluating a programme, as well as examining whether this change occurred (see figure 4.2), it is important to consider the effects of different contexts and the mechanism that realises the transformation (see figure 4.3 to figure 4.5) so that an understanding of why a particular instance of a programme worked (or otherwise) is developed. The model of causality is generative (caused by a mechanism i.e. figure 4.4 and figure 4.5) rather than successionist (caused by an object or attribute i.e. caused by the presence of the programme in figure 4.3). Pawson and Tilley (1997b) state this in terms of a formula:  $\text{mechanism} + \text{context} = \text{outcome}$ . However, given the (probably) nonlinear and interactive effects of mechanism and context, the formula may be better stated as:  $f(\text{mechanism}, \text{context}) = \text{outcome}$

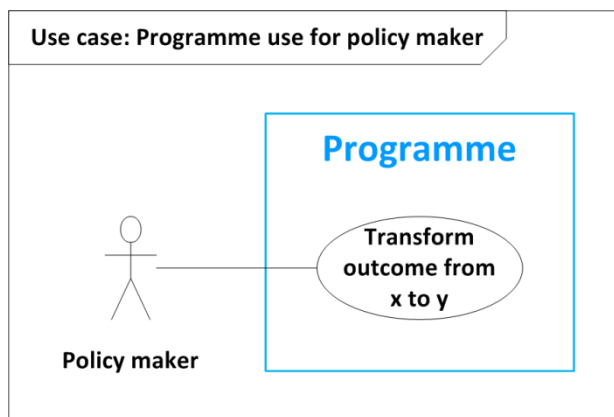


Figure 4.1 Use case for social programme

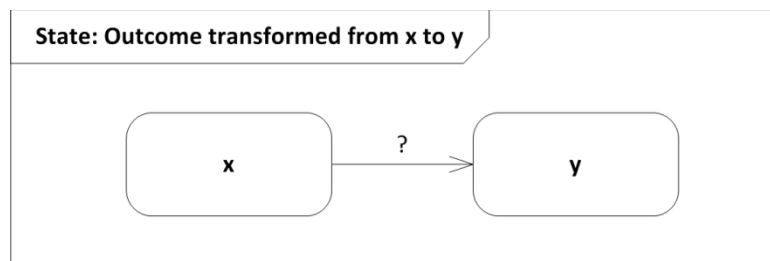


Figure 4.2 State diagram of transformation from x to y

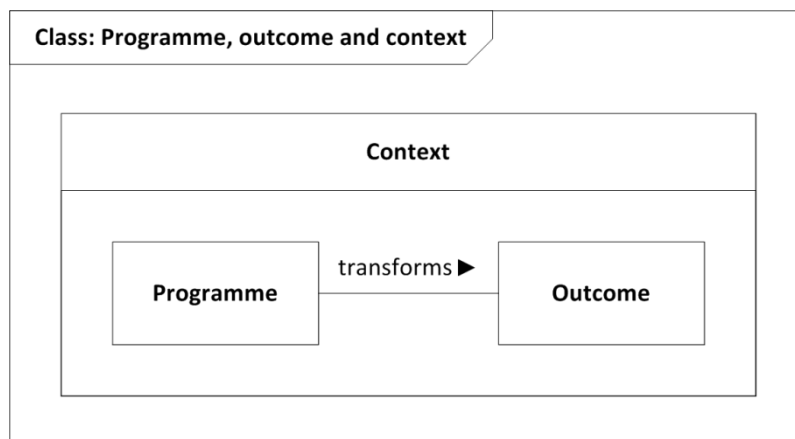


Figure 4.3 Class diagram showing the intended relationship between a programme, an outcome and their context.

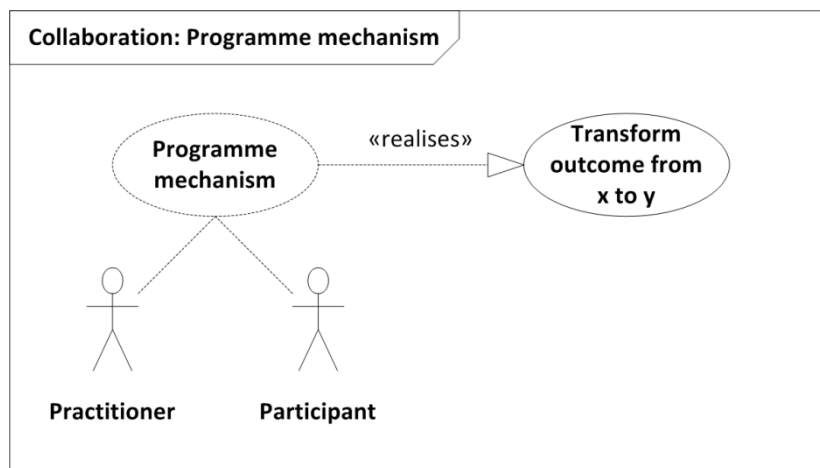


Figure 4.4 The collaboration between a practitioner and participant to enact the programme mechanism that realises the change in outcome.

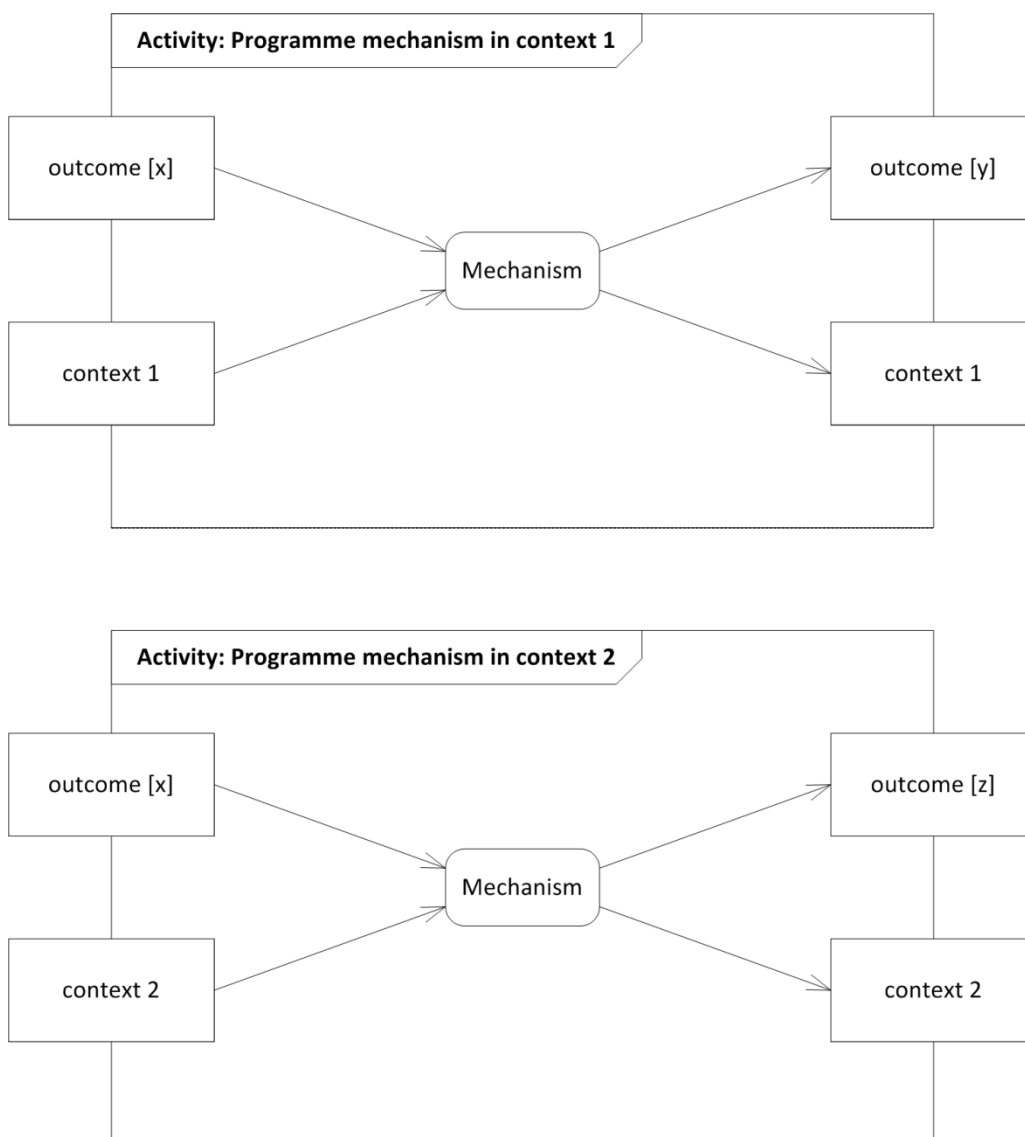


Figure 4.5 The same mechanism transforming an outcome in different contexts can produce different results.

## 4.3 Research design

### 4.3.1 Strategy

The research was performed with the aim of understanding how the organisation of renal anaemia management influences its performance, with the purpose of enabling improvements to be made. Therefore the research had both a contextual and evaluative function (Ritchie & Lewis, 2005). The contextual function of the research required a naturalistic enquiry (Miles & Huberman, 1994), aiming for a holistic understanding of the real setting, rather than an experimental or quasi-experimental strategy. Because of the evaluative function of the research, it was useful to examine more than one setting. To satisfy these functions, the research adopted a multiple case studies approach (Patton, 2002; Yin, 2003), a type of organisational study considered particularly useful for developing theory (Ferlie, 2001). However, the object of investigation was a set of processes, rather than the typical departmental or organisational approach. Process research involves an explicit focus on the actions, events and agents which make up processes; the patterns they form, their prerequisites and causes (Pentland, 1999). The research primarily used qualitative data, which is particularly appropriate for studies of processes, which cannot be fairly summarised with a few variables (Patton, 2002). The approach enabled a large set of possible influences on unit performance to be assessed, many of which would not be particularly meaningful if quantified. Due to the qualitative nature of the inquiry and the small sample size, the sampling strategy was purposive (Keen, 2006; Miles & Huberman, 1994), and an extreme case selection (*ibid*), focusing upon units with the best and worst performance indicators to identify the associated patterns of practice and enable comparisons to be drawn. The collection and analysis of data occurred alongside one another, with analysis informing data collection as the research progressed. This is a typical strategy in qualitative research (Denscombe, 2003).

### 4.3.2 The cases

#### 4.3.2.1 Case boundary

The case boundary for empirical data collection was set as the collection of processes for managing renal anaemia, and those that support them, within a renal centre. The case was limited to renal anaemia related activity to allow the research to focus on those aspects most likely to affect renal anaemia outcomes. It was limited to the renal centre because the selection was made using performance data for the management of haemodialysis patients

(see section 4.3.2.2 below), for whom the testing and decision making processes are always performed by the renal centre. In addition, based on my experience in Leeds and York renal centres (see section 4.6 below, pilot study and training), I believed that the delivery and administration of medicine for haemodialysis patients was also always performed by the renal centre (something I discovered to not be true during my fieldwork). Limiting the case to the renal centre made securing participation and site access easier, requiring agreement of only one organisation in each case. It also assisted in providing the researcher with a longer period of contact with each organisation, increasing the depth of the data collection and the closeness of the researcher to the research setting.

#### **4.3.2.2 Site selection**

The criteria for selection were those units whose clinical performance indicators were extremely high or low to understand which factors may influence patient indicators/outcomes. Selection approaches in qualitative studies and case studies should be purposive: designed to maximise the information relevant to the question gathered from each case, rather than provide a sample whose statistical attributes are generalisable to a wider population (Patton, 2002; Yin, 2003). Given the purpose of identifying organisational differences related to performance and recommending particular practices, it was reasonable to focus on the highest performing units. Similarly, to provide contrast the lowest performing units were an appropriate group to study. Therefore, an extreme case selection was chosen so that the highest and lowest performers against the current quality criteria for renal anaemia management would be chosen, in the same manner as Hoffenberg et al (2001) for their study of length of stay in emergency departments. Ranked lists were drawn up for each group based solely on quality criteria, as discussed below, and units approached in the order shown on the list. To ensure the anonymity of participants, the participating sites cannot be identified and therefore the exact procedure for ranking cannot either, to avoid replication of the result. Eight units were approached including four from each category. The choice of eight units was designed to provide a sufficiently large sample to see repeated patterns emerging and draw distinctions between groups of units.

The sample was limited to centres in England. The NHS in England has a separate management structure than the other countries of the United Kingdom (UK) and therefore the operating environment for these centres is more homogeneous than for the whole of the UK. The NICE (2006a) guideline and Renal Association guideline 4<sup>th</sup> ed. for haemoglobin (Cassidy, Richardson & Jones, 2007) (Hb 10.5-12.5 g/dl), which is the primary clinical performance

measure for renal anaemia management in the UK, was used as the primary selection criterion. In all cases, the selection was based on performance among the haemodialysis population, as they are the largest group for which performance data are published and the group in greatest need of medication for anaemia management. The highest and lowest performing units were selected in order, taking standard deviation from the mean based on the population size of each unit into account. The Renal Registry dataset was from December 2006, but as the NICE guideline had only been published in September of 2006 and the 4<sup>th</sup> edition of the Renal Association guideline was unpublished, data based on the previous main UK guideline for haemoglobin, the 3<sup>rd</sup> edition of the Renal Association's clinical practice guidelines (Cameron, 2002) ( $Hb \geq 10$  g/dl) was taken into consideration. Centres that were high performing based on the NICE guideline were also required to be above the mean on the Renal Association 3<sup>rd</sup> edition guideline. Units that were low performing on the NICE guidelines were selected in two categories: those that were above the mean and those that were below the mean on the Renal Association 3<sup>rd</sup> edition guideline. The list for recruitment was based solely on these criteria and not a convenience strategy. The groups are summarised below in table 4.1.

**Table 4.1 Selection criteria for groups in the study**

	<b>Group 1</b>	<b>Group 2</b>	<b>Group 3</b>
<b>Number of cases</b>	4	2	2
<b>Performance based on NICE (2006a) guideline</b>	High	Low	Low
<b>Performance based on Renal Association guideline 3<sup>rd</sup> ed. (Cameron, 2002)</b>	Above the mean	Above the mean	Below the mean

Therefore, four high performing and four low performing cases were selected based on the NICE (2006a) guideline; six centres above the mean and two centres below the mean were selected based on the Renal Association guideline 3rd ed. (Cameron, 2002).

Additional factors that were considered were centre population and geographic dispersal. To identify processes with relevance to large centres it was important that the sample was not only of small centres and vice versa. The inclusion of standard deviation from the mean in the criteria guarded against the former and the final eight centres included three below the mean and median for renal centre dialysis populations and five above. Geographic dispersal was also strong with centres sited in England's North East, North West, South East, South West and Midlands and included both relatively rural locations and large population centres with varying degrees of ethnic population and deprivation (see also table 4.2).

### 4.3.2.3 Renal centre recruitment results

In March 2008, the eight centres at the top of their respective lists (i.e. the top four from group 1, two from group 2 and two from group 3) were requested to participate by both email and formal letter (provided in Appendix E) addressed to the clinical director. The recruitment was followed up with phone calls and emails in an attempt to establish the centre's willingness to participate, the appointment of a local collaborator and a submission to the trust's R&D department for study approval. In June, when only three centres had agreed to participate, requests for expressions of interest were sent to the next two sites on each list.

In total, ten centres were asked to participate in order to recruit the eight centres that were desired. Two centres therefore did not take part: one centre decided not to participate as they believed it would not be beneficial to them and one centre did not respond to eighteen requests to participate over a two-month period. Given the limited resources and time-scale for the study, it was felt necessary to pursue an alternative centre at this stage. In each case, when a new centre was approached it was selected based on the order given in the list. In mid-September of 2008, the eighth unit agreed to participate.

**Table 4.2 Basic features of participating renal centres**

Centre	Performance group Hb 10.5-12.5 <sup>a</sup>	Performance group Hb $\geq$ 10 <sup>b</sup>	Number of consultant nephrologists	Number of satellite units	Size (scale 1-5) <sup>c</sup>	Ethnicity (scale 1-5) <sup>d</sup>
A	Low	Low	11	6	5	5
B	High	High	5	2	3	2
C	Low	High	5	2	3	5
D	High	High	4	2	2	3
E	Low	Low	13	5	5	5
F	High	High	4	2	2	2
G	Low	High	9	3	4	2
H	High	High	7	2	4	4

<sup>a</sup> Group based upon percentage of HD patients with haemoglobin between 10.5 and 12.5 g/dl, 2006. (calculated from data in Richardson et al., 2008)

<sup>b</sup> Group based upon percentage of HD patients with haemoglobin greater than or equal to 10 g/dl, 2006. (calculated from data in Richardson et al., 2008)

<sup>c</sup> Size measured by number of prevalent dialysis patients on 31/12/07 in English centres split into quintiles where 1 is the quintile of smallest centres and 5 relates to the largest. (calculated from data in Farrington et al., 2009)

<sup>d</sup> Percentage of black prevalent dialysis patients on 31/12/07 in English centres split into quintiles where 1 is the quintile of centres with the smallest percentage population of Black patients and 5 relates to the largest. (calculated from data in Farrington et al., 2009)

One known aspect of renal anaemia management that differs between these eight sites and some other renal centres is the employment of an anaemia nurse; all units in the sample have at least one, but at other centres the responsibilities of this role are integrated in others.

#### **4.3.2.4 Timing and order of visits**

The fieldwork was split into two phases with a period of analysis in between (although additional analysis was ongoing throughout fieldwork). Phase one occurred between the 11<sup>th</sup> August, 2008 and 14<sup>th</sup> January, 2009; phase two occurred between the 13<sup>th</sup> July and 25<sup>th</sup> September, 2009. Each phase involved a visit to each site for one working week, resulting in ten days total contact time with each site. The order of visiting sites in the first phase was largely opportunistic and based upon when access was authorised and dates that were suitable for both parties were available. Where possible the week that was selected was one in which a review of haemodialysis blood test results would occur. However, this was not always possible because the centre did not necessarily know when this would occur or because of clashes between availability. In the second phase of visits, clearance had already been obtained and the intended order for visiting sites was randomised using random number generation in Microsoft Excel 2007. The final order altered slightly to fit in with the needs of sites and to ensure the required data were collected.

#### **4.3.2.5 Participant selection and recruitment**

Participants within each site were invited to participate before or during the fieldwork. A list of participant types to be recruited by the anaemia nurse and local collaborator were requested prior to arrival, containing at least anaemia nurse, consultant, haemodialysis nurse, peritoneal dialysis nurse and supplemented based on discussions with them. The recruitment of participants continued on-site based on snowballing (recommendations or arising during interviews with participants) and as a result of observations. All potential participants received a participant information sheet (provided in Appendix E) to guide their decision at least 24 hours prior to consenting to participate.

## 4.4 Data collection

The methods of data collection used included observer-as-participant observation (L. Anderson, 2008), semi-structured interview and document sampling. These standard methods for field-based qualitative research provide different types of data to help a researcher identify what is occurring and understand why (Shortell, 1999). They also enable data triangulation between methods, where data from multiple methods overlap (Patton, 1999).

### 4.4.1 Focus

The initial scope of the data collection was wide, later focusing in on specific areas. Initial data collection was guided by the plan for observation (presented in section 4.4.2.1), a collection of concepts (Appendix E) and the interview topic guide (Appendix G).

### 4.4.2 Observation

Observer-as-participant observation (L. Anderson, 2008) was used routinely with anaemia nurses, during meetings and occasionally with other members of staff. This type of observation involves the researcher interacting with the participants, for example asking questions and being involved in discussion, but not becoming embedded within an existing role in the organisation. This form of participant observation is often necessary in studies of specialist healthcare where few researchers would have the skills and qualifications necessary to fully participate in activities, as discussed by Wind (2008) who proposed the alternative name, negotiated interactive observation, to clarify the nature of the observation in comparison with the typical ethnographic practice of participant-as-observer observation. While recognising the appropriateness of this alternative name for this fieldwork, the research will continue to use the more familiar term, observer-as-participant observation.

During the course of observations differing degrees of interaction occurred depending upon the familiarity of the observer with the activities taking place, the focus of the observations and the circumstances (for example, during meetings I did not interject, but would speak when spoken to). In several sites, I was able to provide information systems support, assisting with formulae and macros in spreadsheets, manipulation of objects in presentations and even helping to unearth functionality of a pathology results information system that was unknown to the participant.

Observations were recorded at the time as field notes that were written up into full notes, stored electronically, on the night of the same day or, where possible, during the day. Notes were always written as concretely as possible, leaving generalisation to the analysis. Initial field notes were made both on paper and (more usually) on a tablet PC, either handwriting or typing into Microsoft OneNote (2007). The use of a PC for capturing field notes has been considered it to create a barrier. However, having started by taking notes on paper and then switching to handwriting on the tablet PC and finally typing I did not consider that it changed the relationship with the participant(s) in observation. These participants routinely use computers as part of their jobs and may therefore not consider it unusual or distracting as others might. It may be that this is an evolving area as use of and familiarity with computers becomes increasingly widespread.

#### **4.4.2.1 Observation plan**

Although observation began with a relatively open focus, a broad plan of areas to be covered during the first week of investigation was drawn up to assist with developing a comprehensive overview of the centre's management of renal anaemia, based upon the experiences of the pilot study (section 4.6). The generic plan was further developed, both in the light of data collected as the project progressed and for each centre as a result of pre-visit discussions with the local collaborator and anaemia nurses.

The plan involved preliminary observation and discussion with the anaemia team to outline what routines exist and the processes for anaemia management. The decision making process for renal anaemia management of HD and PD patients was to be observed, as was the issuing of prescriptions and their organisation in the HD unit. The equivalent processes for PD and any communications with primary care were to be observed. The delivery of treatment to patients, taking of bloods and notification of test results were to be discussed with the relevant staff.

For each process observed, consideration was given to: who is responsible, who are the stakeholders/actors and what are their interests, what is the trigger, how long does it take, what inputs are required, what resources (capital, labour, information and their ownership) are involved, what outputs are created, where do they come from / go to, how long does that take (delay), what are the exceptions, what is the expected volume (throughput)?

In addition to the processes that were anticipated to be observed, guidance for general observation included the following questions: what is the physical space like? What are the

feelings? What are the power relationships (formal and informal)? What is the culture? What is the social structure?

### 4.4.3 Interview

At least one semi-structured interview was conducted with each participant in which open-ended questions related to the context, management and operations were asked, allowing the participant to identify the issues they consider important. The interviews were used to gain further insight into the reasons for the current situation, explore possible theories and test the investigator's understanding and models.

A topic guide for the interviews was drawn up (Appendix G), focusing on the process, performance and problems of renal anaemia management, structure and culture of the trust and unit and changes in renal anaemia management. The specific questions asked were tailored to the circumstances, based on the participant's role, the answers they gave and my existing knowledge (or lack) of the centre. The topic guide also developed in response to data gathered over the first round of visits.

In the second round of visits, interviews focused in on areas of interest and exposed some of the developing theories to the participants in the manner of a realist interview (Pawson & Tilley, 1997a). The questions that were developed (Appendix H) either supplemented the existing questions for a new participant or formed the complete interview for an existing participant. Again, these questions were localised and individualised to maximise the information drawn from the interview. In addition, process models of the management of renal anaemia developed from the data gathered during the first round of visits were discussed with nurses to help identify flaws in the models or areas that had been missed (see also section 4.5.2.3). This type of respondent validation allowed the researcher to check the fit between the theory that was being developed and participants' beliefs. Where disagreements arose, they could be discussed and existing data reviewed to help establish the validity of the claims being made.

Interviews were mainly captured as digital audio where agreed to by participants, although for the first five visits of the first round of fieldwork this was limited to interviews with consultants as funding for transcription had not been secured. These recordings were reviewed by the researcher, anonymised (identifiable names were blanked from the recording but recorded in a linked document) and then transcribed externally. In the early visits and when participants declined to be recorded, notes were taken during the interview and written up afterwards.

On several occasions, interviews took place with two people at the same time. This changed the dynamic of the interview and the likelihood of contradictory accounts or opinions. This was only done at the request of participants and appeared to have a positive effect on gathering information about the routines that they perform, with each able to clarify the other's statements. However, in some cases it appeared to be restricting the willingness of participants to discuss problems and difficulties. The title of transcripts always made it clear where an interview had more than one respondent, allowing that to be considered during analysis.

## **4.5 Data management and analysis**

### **4.5.1 Data management**

Collected data was mainly held electronically, with the exceptions of: paper field notes, the fully written field notes of which were electronic; sampled documents, for which document summaries were produced; and the book of participant details, a pseudonymised version of which was created electronically. All participants were assigned a pseudonym that was used to identify them in relation to records of interviews and observations. The interview transcripts, field notes and reflections were entered into NVivo, and were case coded (tagged as relating to a case) at both the participant and case level.

### **4.5.2 Analysis**

The analysis took a variety of forms depending on the question being asked of the data. However, overall a general inductive approach (Thomas, 2006) was taken, involving data-driven or bottom-up descriptive coding, analytical coding and memoing and the use of data displays, in particular process models.

#### **4.5.2.1 Descriptive coding**

A thematic analysis was carried out with all field notes and interview transcripts, with closed coding (tagging data with reference to a scheme) performed in NVivo 7 initially and later NVivo 8. The coding scheme was developed using a process of open coding (tagging data without reference to any scheme) on paper print-outs of the available data at the time (field notes from the first three visits) which were then cut into snippets (photocopying as necessary where multiple codes applied) and physically arranged to produce eight broad themes. The themes were influenced by the focus of inquiry as well as the broad descriptive categorisations of both object-oriented modelling and Spradley (1980); these were: activities; entities; structure and interaction; strategy, policy, rules and definitions; performance factors; finance; clinical factors; and change in management (local). The broad themes were then structured via the same process, this time producing more subject specific codes. As closed coding progressed using this scheme, minor changes (addition, deletion, merging and splitting) were made to the codes but the overall structure and majority of codes were retained. The amount of data coded in any one chunk varied in both open and closed coding from part of a sentence

to paragraphs and even an entire source, although multiple codes were often applied to the data.

The approach to coding described above followed an attempt to code based on the framework developed prior to fieldwork which did not fit suitably with the data and then an attempt to free code from within NVivo, considered by the author to be cumbersome and difficult to reorganise.

#### **4.5.2.2 Analytical coding and memoing**

In addition to the analytical themes from the a priori framework, themes were noted during the course of descriptive coding and arose because participants regularly mentioned them or they stood out as unexpected or interesting to the researcher as a result of observation. In chapter 7, the reason for discussing each theme is outlined. Some of the codes used in the scheme described in 4.5.2.1 above were of an analytical nature or described the building blocks for analytical codes. In other cases, the themes cut across a set of codes.

Analysis proceeded in an iterative fashion, with theory building and testing at its core. Therefore, as data contradicted one explanation, alternative explanations would be sought, questions posed and the data examined to see what answers they could give and what further questions they prompted. During the course of the analysis, certain themes merged as it became apparent that a phenomenon of interest was actually a subset of a wider theme.

The analysis used the descriptive coding to retrieve relevant data to the questions being posed with the assistance of NVivo's query facilities. The resulting data was then examined with respect to the question and abstracted into memos, with hyperlinks (known as 'See also links' in NVivo) to the source data, which could then be reviewed in their context.

#### **4.5.2.3 Data displays**

Throughout the analysis and alongside coding and memoing, extensive use was made of data displays, graphical presentations of aspects of the data to assist with comprehension (as with graphs and tables in quantitative analysis) and the explication of theory development (see Miles & Huberman, 1994). The primary type of data display used were models of process and structure rendered in the Unified Modelling Language (UML) (Object Management Group, 2009). In addition, data tables, causal networks and similar diagrams were developed.

UML was used to develop use case, class, state, collaboration, communication, interaction and activity diagrams of renal anaemia management. As was described in chapter

2, UML has become the de facto modelling language for software engineering (Booch et al., 2005) and, as recommended in *e-Pathways* (de Luc & Todd, 2003), is being used for describing processes in healthcare (e.g. Kumarapeli et al., 2007), perhaps most notably in the development of the Logical Record Architecture for Health and Social Care by NHS Connecting for Health (2010b). One of the benefits of using UML is that it provides a range of diagram types for describing different aspects of a system, but also some limits on what can be shown in any one aspect and well-defined meanings for what is displayed. A key to UML diagrams is provided in Appendix I.

Modelling was occasionally conducted in the field but usually it was carried out as deskwork referring back to fieldnotes and interview transcripts. As described in section 4.4.3 above, a preliminary set of models were brought back to the field for member checking or respondent validation, which led to a number of changes being made to them. Models were developed using Microsoft Visio initially but later transferred to Visual Paradigm, to ease model management by providing a repository of entities and the relationships between them, rather than just diagrams.

To organise the models and identify the variety between them, they were drawn together in a hierarchy of types as outlined in the Variety and Best Practice approach (King & Johnson, 2006) and the MIT process handbook (Malone et al., 2003). Modelling was carried out at both the case and abstract levels in an iterative and non-linear fashion with models being altered in the light of each other. Process models were developed to the level of elementary business processes (Hammer & Champy, 1993) and deeper when deemed particularly relevant.

#### **4.5.2.4 Case narratives**

To assist with considering how in each case the context, organisation and approach to renal anaemia management fit together, case narratives were produced. The narratives were structured according to features that are common to each organisation and by features of particular interest to the individual organisation. In doing so, the uniqueness of each case was retained but the format also enabled a degree of comparison between cases.

## 4.6 Pilot study and training

To ensure the researcher was practiced at process modelling, two small-scale projects took place in the first half of 2007. The projects both took place in the NHS, one in a physiotherapy unit and one examining the anaemia management process at York hospital. In each case, the observations lasted a day, during which initial models were produced and discussed with participants. These models were then expanded and checked before being returned to the participants involved for checking. Positive responses were received from the participants regarding the accuracy and utility of the models, although one participant found that the key to the models was unclear. Participants reported no inaccuracies and although no deliberate errors had been introduced, the researcher considered it unlikely that entirely accurate models had been produced following such short site exposure. Therefore, during the fieldwork for this study, the developed models were explained and discussed directly with key participants and key processes re-observed. To ensure the researcher's understanding of process modelling was comparable with current industry standards the researcher attended courses and took exams in Business Analysis Essentials and Business Process Modelling with the Information Systems Examination Board.

The second project mentioned above, which examined the management of renal anaemia in haemodialysis patients provided initial exposure to the practice of renal anaemia management. This, in addition to an MSc dissertation project (Crocker, 2005) based in Leeds St James's renal centre and the review of literature, in particular the National Service Framework for renal services and NICE guidance for renal anaemia management helped to sensitise the author prior to fieldwork and helped in the formation of an initial framework of concepts to assist early fieldwork (Appendix F).

## 4.7 Methodological roots

The methodology described above is drawn from a range of disciplines that may not appear to sit easily alongside each other. Here the roots of these are identified and an explanation given for how they fit together.

In the social sciences, qualitative research has a long tradition that has developed rigorous methods for data collection and analysis. Observational methods have been used by anthropologists and ethnographers in conjunction with interviews and surveys to provide an understanding of how a society or organisation works for over a century (Pope & Mays, 2006). Case studies have also been used widely for organisational research. Over that time there has been much written about the technique of writing field-notes, the impact of being embedded in a social group on the group and the research, reflexivity to encourage an objective stance, consideration of the value of researcher and methods triangulation, methods for data management and analysis along with a host of other topics.

The software engineering, operations management, operations research and benchmarking communities use process modelling as a problem structuring method, i.e. to make an explicit representation of the problem to aid debate and analysis. Within software engineering, particular effort has been put into codifying the meaning of process models as part of wider work on object-oriented modelling methods. Initially developed for describing the behaviour of software, the same methods were advocated for business modelling as a preliminary task to software design. However, the methodology has largely been developed by practitioners rather than researchers and methods for data collection, management and analysis are not afforded the same coverage as they are in social sciences qualitative research more generally. For example, in *Object-oriented systems analysis and design using UML* (S. Bennett, McRobb & Farmer, 2005), unusual among software engineering texts in mentioning such methods, the chapter on requirements capture discusses questionnaires, interviews, document sampling and provides a brief description of the advantages and disadvantages of observation. However, the only advice offered consists of carrying a stopwatch and that observation may be structured or unstructured. There is then no advice for how to develop the materials gathered into UML models, apart from a description of the use and meanings of these models. In addition, the further reading section offers no literature on data collection or analysis. Other texts and training programmes include some advice for analysis, for example highlighting nouns and verbs to identify objects and activities. This shares some similarities with open coding at a descriptive level, with a focus on aspects that would be modelled.

However, they do not typically provide techniques for managing large datasets, examining contradictions or linking the data to the models.

Within the broader field of qualitative analysis in the social sciences, data displays have been used to assist both researcher and reader in comparing cases, comprehending complex concepts and webs of relationships, as is described extensively by Miles and Huberman (1994). Werner (1992), noting the absence of suitable process modelling techniques within ethnography describes an activity on arrow method for process modelling called Verbal Action Plan and illustrates its use for the routine of a Navajo male getting up in the morning. The technique is elegant in its portrayal of activity composition but only works for linear routines without decision-making or alternative routes. Decision trees and taxonomies (Bernard, 2006) have also been used within ethnography but lack integration with activity models and models of organisational structure. By using UML as a modelling language within a qualitative research approach, we add useful techniques to the analytical toolkit that are in keeping with existing approaches.

## **4.8 Impact of the researcher on the case, data and analysis**

One of the key issues in qualitative research is the impact of the researcher on data collection and analysis. The researcher's presence and behaviour will alter the behaviour of research participants in a manner that is somewhat unpredictable and unique to each participant. The observations they make will always be selective and incorporate a degree of interpretation as they make sense of the world around them, although this sense making is also the researcher's forte and the reason for selecting them as the primary instrument for data collection. Their field notes and analysis should attempt to identify the impact they may have had on the situations they study in order that the analysis can consider and include this information. However, to provide the reader with a better ability to judge the extent to which the researcher's prior beliefs, background and personality affected the findings of the research, a short biography is presented in Appendix B. In addition, reflections on the evolution of the study, data collection and analysis are presented in Appendix C.

## 4.9 Ethics

To ensure that the research did not treat participants unfairly, was sufficiently important to merit any inconvenience or risk and to comply with regulations the research was required to undergo a formal review of ethics. The Cambridgeshire 1 Research Ethics Committee of the NHS Research Ethics Service performed this and, following a request for further information, granted approval for the study (reference 08/H0304/30) on the 30<sup>th</sup> of April, 2008.

The most important ethical considerations were around the presentation of data and conduct of the researcher to ensure anonymity of the individuals involved. In addition was the fair and pseudonymous reporting of results, the handling of personal data and not placing an undue burden upon the research sites. To ensure individuals did not feel pressured into participation by their peers, the researcher offered potential participants the right to a mock interview and observation, the results of which would be destroyed. However, no participant exercised this right during the study. To ensure the anonymity of participants, even where they had given consent for the use of quotations, these were not to be linked with individual centres. This is particularly to ensure that others within the centre cannot identify the participants. In addition, care was to be taken with the reporting of any data about centres that are public knowledge, in particular statistics from publication.

Local approval was gained from the research and development department of each participating trust who assessed the fitness of the site to cope with the researcher's presence. For each site a local collaborator (a consultant ( $n = 6$ ) or anaemia nurse ( $n = 2$ )) was appointed.

## 4.10 Critical review of the methodology

The current trend in healthcare is to identify care pathways that cover the complete patient journey while this research only focuses on one aspect of a patient's care. Other aspects do impact upon both the care received and the value of patient indicators and hence there would be an advantage in examining a wider care pathway. However, the greater the scope of each case study, the lesser the detail on each case or fewer the number of cases that can be considered with the given resources.

Similar criticism could be made of the number of cases in the study, and a similar defence can be made. While the maximum amount of information would be gathered from examining every renal centre in the country, this is neither practical nor desirable for the centres involved. The sample was designed to be large enough to gather sufficient data for the purpose, rather than wasting the resources of the renal centres in gathering excessive data.

The study is taking its evidence from units at the top and bottom of performance leagues and there may be valuable practices in units not included in the research. While this is true, by focusing on either end of the performance spectrum it is more likely that good practice will be identified given that a limited number of units will be sampled. The selection could have matched centres on a set of factors and stratified them on performance to attempt to control for those other factors but the ability to examine the top centres would have been limited by the relatively small total number of centres to match with and may have produced results that are less transferrable.

The measures used to identify units' performance (targets based on patient indicators) are not ideal as they record a proxy for limited aspects of performance. They give some indication of quality and reliability but no information about cost, timeliness or flexibility. Ideally, measures for these and other measures of quality and reliability would have been incorporated although the lack of access to such information and complication of calculating a combined index based on them resulted in only the patient indicators being used.

The study could also be criticised for not taking an action research approach. The study will present recommendations based upon the analysis but will not be actively engaging in helping units to enact those recommendations. While action research is an exciting field and may have resulted in greater worth for the units involved, it can be harder to identify the end of the study (Denscombe, 2003). That ability is particularly important in doctoral research.

Observation can be criticised for the impact of the investigator on the system under investigation as was discussed above in section 4.8. While concerns may be expressed about the Hawthorne effect, whether or not one actually existed in the Hawthorne studies (see Jones, 1992), these may be counteracted by the type of evidence to be gathered and the length of time spent in the field. After a period of investigation, one may expect that participants' guards may lower and routine patterns of behaviour will emerge. It would take significant coordination for multiple participants to enact or report the same, conspired routines. While quantitative changes may occur (e.g. working faster), and some qualitative changes may occur (e.g. not taking breaks), it seems unlikely that the whole pattern of work was altered for a study that was investigative rather than auditing in nature.

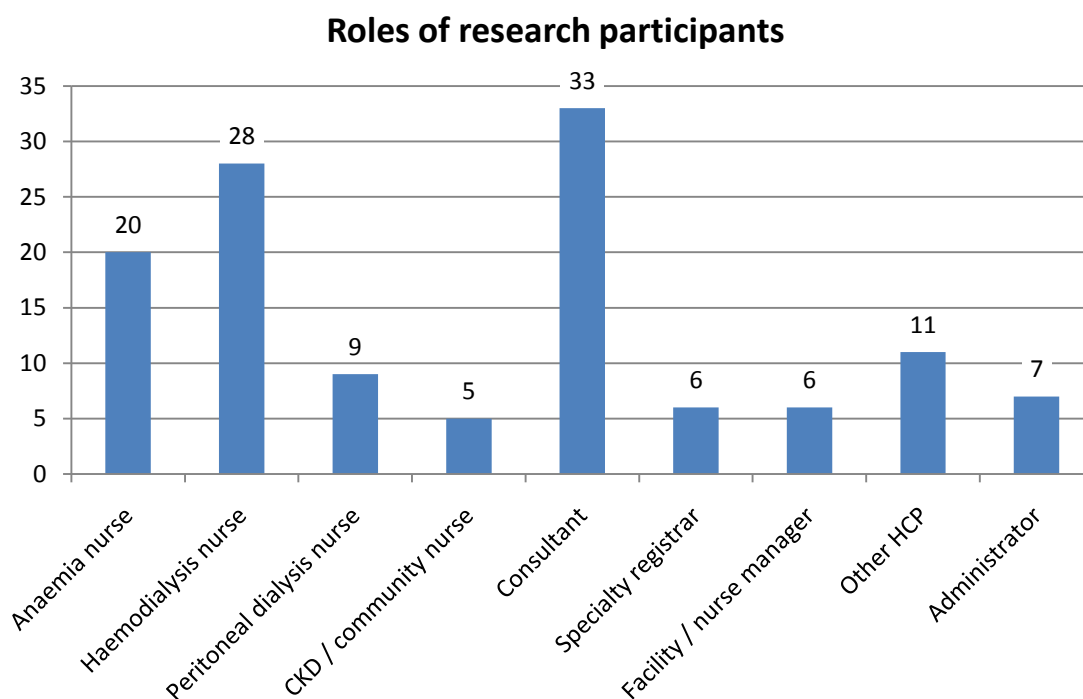
One data collection technique that could have been useful is the focus group. This could have provided a setting for more rapid process modelling, model checking and problem exploration. The difficulties with a focus group would be the elicitation of individual and contrary opinions, as well as the amount of participants' time required by comparison with their contributions. What were in effect mini focus groups took place when two participants were interviewed together (see section 4.4.3 above).

The study produced models of processes over a range of time. Different parts of the process were observed at different times, as were different centres. Processes were changing over time and this was not reflected in the process models. Instead, models of the process at the time that the performance data were collected were used, based on observations of the current process and descriptions of differences based on the interviews. If the observations had taken place during a period of unusual activity for the unit this should have been noticed during repeat visits, participant checking and interviews. The purpose was not to create a model that is cast in stone and will always represent the process at a particular centre. Indeed the modelling is intended to inspire change in the process. What was important was that a sufficiently accurate representation of the process that influences the patient indicators was captured between the model and the description.

One approach to improving the analytical rigour of qualitative studies not used in this research involves the use of multiple researchers (Shortell, 1999). The intention is that with multiple individuals examining the evidence the interpretation is less likely to be based on individual interests and selective examination of the relevant data. However, to do so appropriately requires that the multiple researchers are familiar with the study problem situation and coding scheme and this was, as part of a doctoral programme, a single researcher study.

## 4.11 Outline of participants and data collected

In total, 125 participants were recruited to the study, averaging 15 participants per site (range 10-20). Figure 4.6 shows the roles of the recruited participants. In addition, one individual declined to participate in the study and seven agreed in principle but were unavailable. Over 462 thousand words of field notes and interview transcripts were collected in 324 source documents. This included the transcripts of 78 recordings totalling 38 hours and 28 minutes.



**Figure 4.6** Roles of research participants

## 4.12 Summary

In this research, the study used data from Renal Registry reports about the degree to which units achieve the targets for haemoglobin as the outcome pattern. That was compared with empirical evidence of the processes, structures and context in each study unit to attempt to understand how the outcomes are caused.

The study methodology was appropriate as a useful strategy to investigate current practice to assist understanding, information sharing and generate theories of new ways of working. The use of observation, interview and document sampling enabled a good understanding of current practice to be triangulated that could not have been gained from survey or other methods alone. By examining two groups of units that had high and low performance measures, the patterns that emerged were not merely particular to any one unit but had confirmed repetition across multiple sites.

The results of the analysis are presented in chapter 5, chapter 6 and chapter 7, beginning with an analysis of the approaches to service delivery before presenting analyses of the organisational differences that may influence performance.

## Chapter 5

### A framework for renal anaemia management

In previous chapters it has been shown that there is large variation in performance for management of renal anaemia. It is known that renal anaemia is associated with significant comorbidity and reduced quality of life and that its management is costly (see section 3.3). Differences in performance are believed to be partially explained by the organisational processes involved. However, the reasons are not well understood and although there is a large body of clinical advice, there is much less information about organisation for service delivery in renal anaemia management.

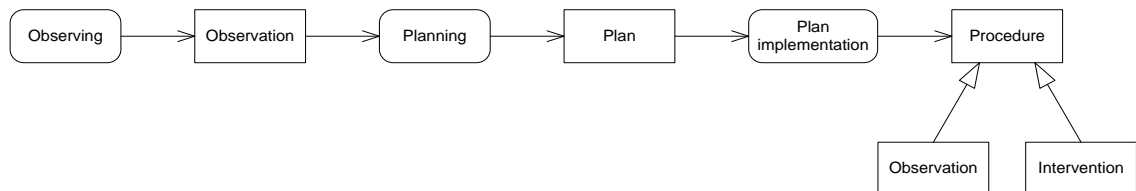
Currently there is no framework for the provision of renal anaemia management against which individual services can be examined, categorised or compared. In the methods chapter the objective of creating such a model was outlined and in this chapter the results of this will be presented. By providing a detailed description of how renal anaemia management is delivered it forms a framework for future research to analyse the performance of different approaches.

#### 5.1.1 Existing knowledge

Within health care, several notable frameworks for describing the concepts within the domain have been developed each with a specific focus on enabling IT development: the Cosmos Clinical Process Model (CCPM) (Cairns et al., 1992), Health Level 7 (HL7, 2010) and OpenEHR (OpenEHR, 2010). The CCPM project described the medical record as a collection of abstract objects (Fowler & Cairns, 1992), was sponsored by the UK NHS to and led by two clinicians and a modeller (M. Fowler); the latter of whom used it as a source for one of the key software patterns books *Analysis Patterns* (Fowler, 1997). HL7 is a widely used electronic messaging protocol for healthcare and includes a reference information model of data types (e.g. act, role) (HL7, 2010). OpenEHR is an organisation that develops open specifications and open source software to enable improved use of IT in healthcare. These three frameworks provide useful language and patterns from which more specific models can be developed. However, they are mainly object models rather than models of process.

Within the CCPM and OpenEHR there are abstractions of the complete clinical process that appear to include the same concepts and also match with a model proposed by Coiera

(2003, and personal communication, 24 March, 2009). In each there is a three-step pattern: measure, model, manage (Coiera); observing, planning, implementing (CCPM, see also figure 5.1); observing, evaluating, intervening (OpenEHR (Beale & Heard, 2007)). Because of the focus on object-oriented ontologies rather than the form of the clinical process, little more is made of these models than a basis for classifying the information that is used in, or can be recorded about, the clinical process.



**Figure 5.1 The Cosmos Clinical Process Model's overview of the clinical process (adapted from Cairns et al., 1992).**

Within the renal domain in England a modelling effort was undertaken to describe the renal patient pathway (Stribling, 2005), which was part of a wider programme called 'Do Once and Share' (Connecting for Health, 2006) that was initiated by NHS connecting for Health as an exercise in clinical engagement. Those involved in the production of Do Once and Share pathways were not specifically trained in a notation, language or approach for process modelling (Prof. Sir Muir Gray, personal communication, March 27, 2006) and in the case of the renal patient pathway this resulted in an attempt to show everything on one diagram and the mixing of many types and levels of concepts. This produced a rich but potentially confusing diagram that required significant knowledge of the domain to interpret it.

The Logical Record Architecture for Health and Social Care (LRA) is a modelling effort recently established by NHS Connecting for Health and the NHS Information Centre for Health and Social Care to standardise the terminology and relationships between the classes of data in health records and link that to their use (NHS Connecting for Health, 2010b). Therefore, business models are to be developed of specific domains, from which data models are derived and linked to an existing set of data element definitions where possible. As a demonstration of the approach, two domains, renal and maternity, are being modelled and incomplete results have been published. The LRA uses UML use case models, class diagrams and activity diagrams to describe the renal care domain and process. However, the data on which the renal example is based are not drawn from observation but from workshops (S. Bentley, personal communication, 28 September, 2010) with the renal information exchange group (a UK-wide group with interest in renal IT). This has resulted in quite linear activity models (allowing less variety than might be expected). The models provide a useful starting point for understanding

some areas of the renal domain, although they currently do not describe anaemia management processes. There are also problems with the way models have been constructed and inaccuracies within them. The stakeholder business view model, an overview of the processes in the domain has been reproduced in Appendix M.

Other nationally developed models of the renal patient pathway include figure one of the National Service Framework for renal services (Department of Health, 2004a, 2005) and the Map of Medicine's (2010a) chronic kidney disease pathway, although renal anaemia does not feature prominently in either of these. The NICE (2006a, 2006b) guideline for anaemia management in chronic kidney disease provides recommended algorithms for managing renal anaemia. However, here the focus is on decision making rather than service delivery. Recommendations for service delivery include appointing a single point of contact (anaemia nurse) for the coordination of patient prescribing, support and education; and considering patient choice and flexibility in the means of drug provision and administration, while taking account of continuity and cost of supply.

Significant effort therefore has been poured into attempts to model renal care, designed to support clinical decision making, service design and information system architecture. However, none of the existing models of renal care provides significant detail on renal anaemia management with the exception of the NICE guideline. However, the focus of this is largely on the decision making process rather than the delivery of care.

The models of the renal domain described above were rarely presented using a documented or consistent modelling language and this seems to be near ubiquitous across healthcare (Crocker et al., 2009). However, the models produced recently for the LRA do use UML.

Modelling activities across healthcare often appear to have been based on relatively little observation or the experience of a single centre. However, it is typically difficult to know as methods are rarely reported. The renal do once and share pathways (Stribling, 2005) are an important exception to this, where they describe how they took their models to a series of workshops with representatives from multiple centres to broaden the base of the modelling.

### 5.1.2 Aim

This chapter aims to provide an overview of how the management of renal anaemia is organised in England. A framework will be presented, providing abstractions of the structures and processes in place to provide such a service based on the experience of eight locations.

### **5.1.3 Organisation of the chapter**

The remainder of the chapter describes the methods used to develop the framework that describes renal anaemia management services. This is followed by a description of the framework and selected parts of the model, first describing the overall patient journey in renal and renal anaemia (the status of the patient from the perspective of the health service) an overview of the anaemia management service, the organisations that provide it and then the activities involved in parts of the service. The strengths and weaknesses of the research are discussed followed by a comparison of the results with existing literature.

## 5.2 Methods

The research reported in this chapter uses data collected and analysed as part of the wider research project as reported in chapter 4. In brief, this was a multiple case studies approach involving 8 cases and 16 weeks of fieldwork, data collection included interview and observation while analysis included descriptive and analytical coding, memoing and the extensive use of data displays, in particular UML models. Additional detail is given here of the modelling work performed.

### 5.2.1 Model development

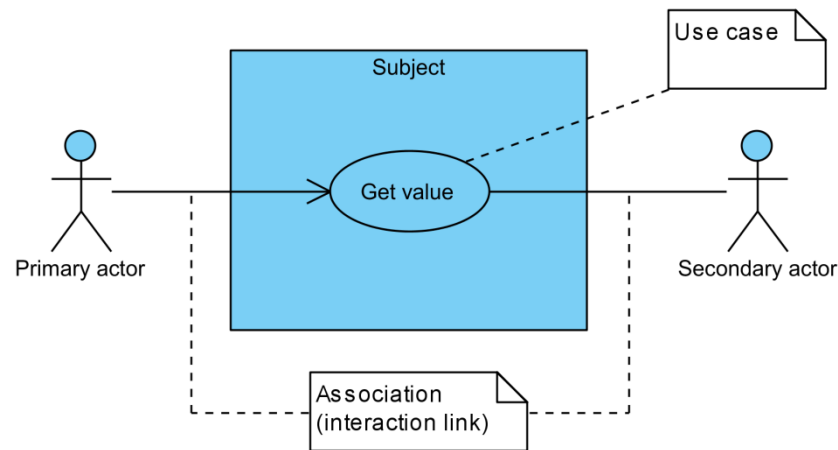
The processes and structure were primarily modelled using a combination of the elements available from the Unified Modelling Language 2.2 (Booch et al., 2005; Object Management Group, 2009). UML was chosen because of its pre-eminence as a modelling language. UML 2 introduced significantly greater functionality to activity models compared with its predecessors (Bock, 2003) and UML 2.2 is its latest version, making minor corrections to the version 2 specification. It is also the modelling language and version used for modelling in the LRA, meaning that the models developed here should be comparable with those of the LRA. Where UML could not elegantly express a relationship that was only needed for figurative purposes, alternatives such as a Venn diagram were employed.

Many different types of UML model were employed depending upon the feature and purpose. For structure this was class diagrams, for process primarily use case diagrams and activity diagrams but also collaboration, communication and sequence diagrams to accentuate different aspects. A key to the UML diagrams employed in this thesis is presented in Appendix I. Models were managed using Visual Paradigm for UML 7.2.

#### 5.2.1.1 Use case models

A use case is a class of a partially ordered sequence of actions that provides value to one or more actors independently of other use cases. Therefore, it represents significant functionality but also how functionality is bundled together. A use case is a feature of a subject: actors who are external to the subject (or system) may use the subject as specified by the use case. A use case provides an external view of the functionality of a subject and its interaction with others and does not itself specify the internal details that enable the use case. Somewhat confusingly, the term actor is used here to mean role (Booch et al., 2005), i.e. an actor need not be a physical entity and may be played by multiple classes of entity or one

entity may play multiple actors. Common practice is to identify the triggering or primary actor (the actor who initiates the use case) by placing an arrowhead on the association that joins the actor to the use case and not for other (secondary) actors, who may interact with the system as part of the use case (see figure 5.2).



**Figure 5.2 Example of a UML use case diagram**

Use cases primarily operate at one level, rather than being routinely decomposed. This has been named sea-level (Cockburn, 2000) and equates to an elementary business process (Hammer & Champy, 1993): a task that typically takes minutes to hours and satisfies your boss or customer (Larman, 2005).

A number of use cases were triggered by time or a schedule, rather than an individual or organisation. However, the ability to use time as an actor can encourage decomposition of a use case where there are pauses or delays in the observed instances of that use case. For example, when a patient contacts the anaemia team to inform them a blood test has taken place and prompt a review, but instead of reviewing straight away the anaemia team delay the review, informing and reviewing could be represented as two use cases. However, use cases should be at a consistent level and a complete transaction and therefore such decomposition is inappropriate.

### 5.2.1.2 Internal process models

Internal details of processes were described using a number of diagram types that show different aspects of structure, action and interaction. Activity diagrams represent the flow between actions for a class of activity in a similar style to flow charts. Collaboration diagrams show the roles that participate in a collaboration. Communication and sequence diagrams show an instance of an activity, and the interaction between different roles involved. Although

they both include the same details, a communication diagram emphasises structural links while a sequence diagram emphasises timing.

The process models, which combine the processes of multiple renal centres, used the approach of the MIT process handbook (Malone et al., 2003) to abstraction of processes, namely maximal set semantics. That is, the abstract process model includes actions each of which may only occur in one or some centres, rather than all (minimal set semantics). The actions themselves are abstracted where possible to describe multiple cases and strictness of sequencing is reduced as necessary to enable differences in sequences between cases (e.g. introduction of parallelism or alternative transitions).

### 5.2.1.3 State models

UML state diagrams were used to illustrate the status of a patient with respect to the treatment they receive. State diagrams appear similar to activity diagrams but have different logic and show how the condition or situation of a class changes with the occurrence of different events. State diagrams were used for patient types because they enable a high level view of how the patient role can change over time. The LRA model of renal care chose to present a high level view for the patient as an activity diagram, but this resulted in an overwhelmingly complex diagram (reproduced in Appendix M) because of the chronic and therefore ongoing nature of renal care, the number of activities this involves and the many possible sequences in which they can occur. State diagrams allow an abstraction to a type of patient that can participate in many types of activity.

### 5.2.1.4 Boundaries

Multiple systems boundaries were explored and used: the renal centre, individual teams within and later a reification of the service as a whole were defined as subjects of use cases. From the observations, documents and interview data I had (focusing on the work of renal centre staff members rather than patients) it was often easiest to build up to renal centre use cases having examined the use cases of individual teams. I decided to include satellite units within the boundary of the renal centre to simplify the model; this is because the work of satellite units is for our purposes almost identical to onsite haemodialysis units, there is considerable integration between the two and each satellite unit only provides haemodialysis services on behalf of one centre. The criticism of this would be that satellite units can be a part of different legal entities, either other NHS trusts or private providers, and that by treating them as external to the renal centre one could better explore the effects of physical separation

on communication. The exploration of a boundary that was not representative of real entities (the reification of the service) was to provide a better overview of the functionality of an anaemia management service, given that multiple entities contribute to this and that the set of roles they take on differ from case to case. This is an approach similar to Soft Systems Methodology (Checkland, 1999; Checkland & Scholes, 1990) and has been recommended for business process modelling with use cases (Behrens, 2004). I decided to keep the patient outside of the system boundary (for example self-medication), and any use case that was not specifically about anaemia management (for example a haemodialysis session). Use cases that are not specific to anaemia management would occur regardless of the anaemia management service, which instead interacts with them and there would be a danger of trying to include everything within the system boundary.

### **5.2.2 Process categorisation**

The processes identified in the form of use cases were categorised according to the observing, planning, intervening model and a fourth category, supporting. This was partly as a means of organising the use cases because of the number of them. It was also partly to examine how the model compared with observed processes.

## 5.3 Results

### 5.3.1 The patient

Patients treated for renal anaemia are primarily treated with ESA and iron. Their status in relation to these two drugs affects the services they will access, and is summarised in figure 5.3 and in expanded detail for ESA and IV iron in the appendix (Figure J.1 and Figure K.1).

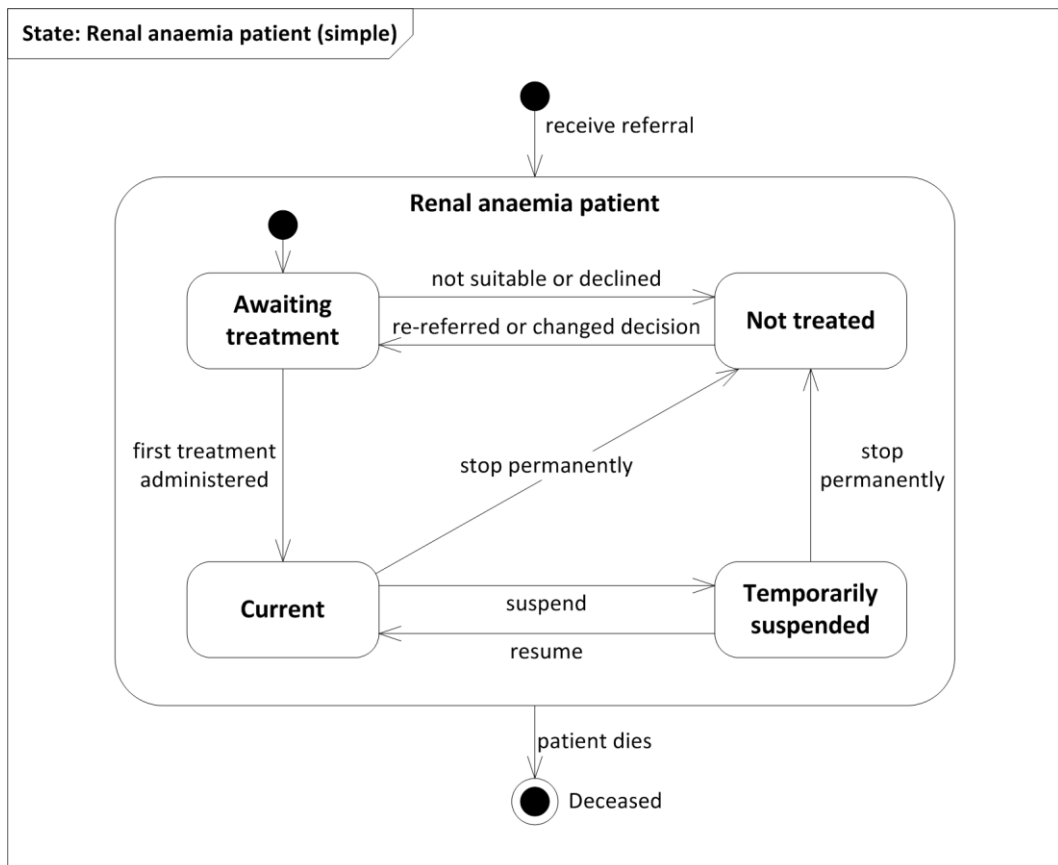


Figure 5.3 State diagram for renal anaemia patient

In addition, the patients are renal patients and their treatment for that disease affects their patterns of interaction with the health service and therefore the means of providing renal anaemia management. In the context chapter of this thesis, figure 3.2 and figure 3.3 (pp.23-24) summarised a patient's status with respect to renal care, also known as their treatment modality (see also section 3.2). Typically, a patient will remain in one of these modalities for months or years before transitioning to another.

### 5.3.2 The service

A group of organisations delivers the complete set of services for renal anaemia management and to get an overview, a use case model that treats the service as the subject was produced (see Figure 5.4 to figure 5.8). The subject boundary was defined as including all use cases whose primary purpose was renal anaemia management, therefore a use case that included anaemia management as a subsidiary part (for example a consultant clinic) is not a part of 'Renal anaemia management: the service'. For clarity, the use cases were organised into three groups according to their primary purpose: observing and planning; intervening; supporting (i.e. not primarily observing, planning or intervening but enabling).

Specialisations of the three basic healthcare activities (observing, planning and intervening) were defined as abstract use cases because they are representative of an abstract function rather than a real bundle of functionality. The use cases of the service were traced to the abstract use cases of the service in order to show what functionality is within each. Table 5.1 summarises these relationships.

As can be seen from table 5.1, four of the use cases include functionality from two of the basic abstract use cases. For *attend anaemia clinic for assessment* this is because both observing and planning may occur during this type of interaction. For *receive ESA therapy* and *receive IV iron therapy* this is because in addition to the therapy, the service may take samples for testing. I have categorised *receive education and training in administration of ESA* as a supporting use case and yet it can also include the taking of samples and the administration of ESA. In addition, five of the use cases do not trace to any of the three basic abstract use cases.

One of the actor types (figure 5.5) is *renal anaemia patient carer* who may participate in a number of use cases on behalf of, or in addition to, *renal anaemia patient*. Therefore, *renal anaemia patient* is illustrated as a type of *renal anaemia patient carer* because they can use the service in all of the ways a carer can. Intuitively, a renal anaemia patient will often provide care to himself or herself that in other circumstances another person would provide.

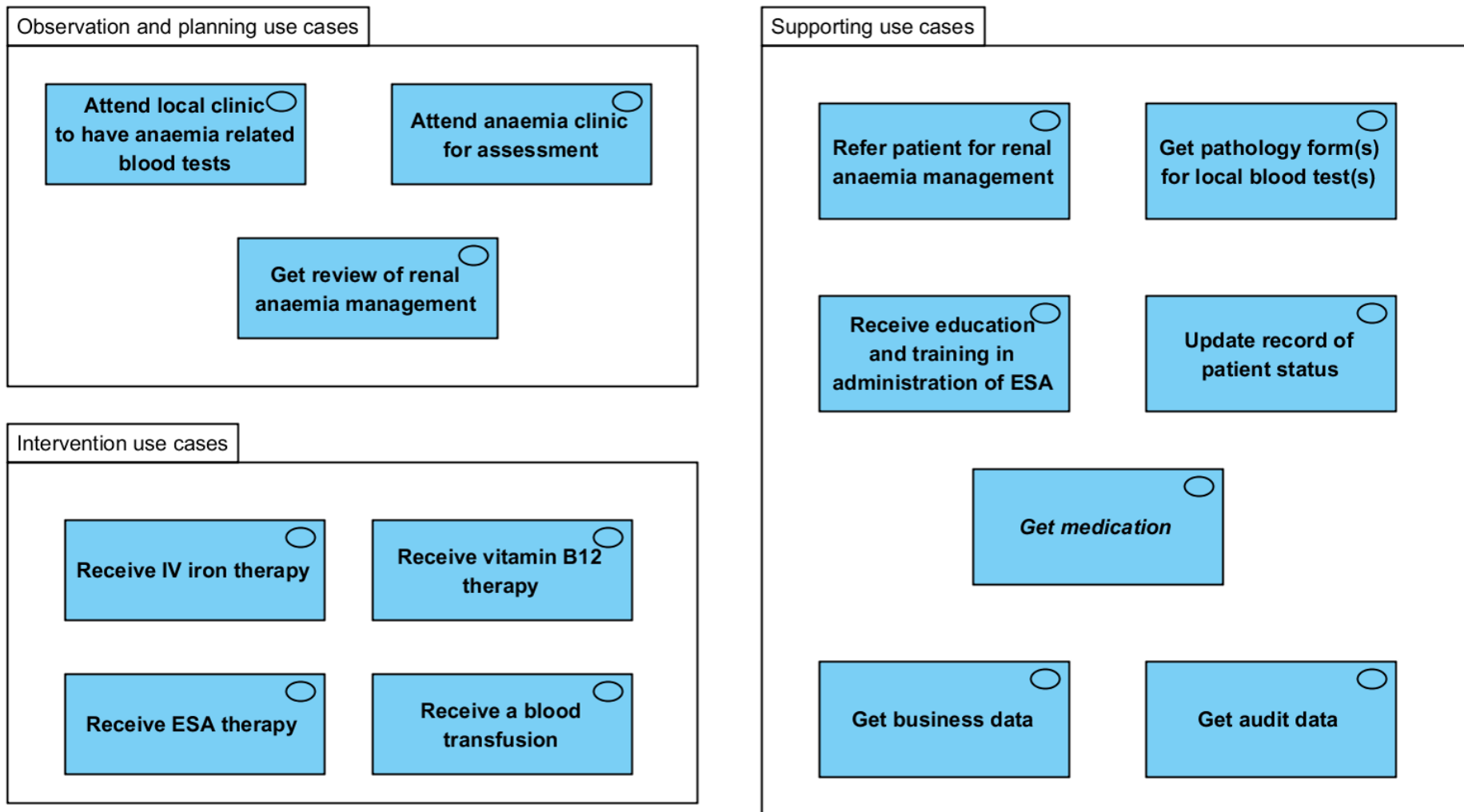


Figure 5.4 Use cases for renal anaemia management: the service organised into packages. This shows the bundles of functionality that may be delivered as part of a renal anaemia management service.

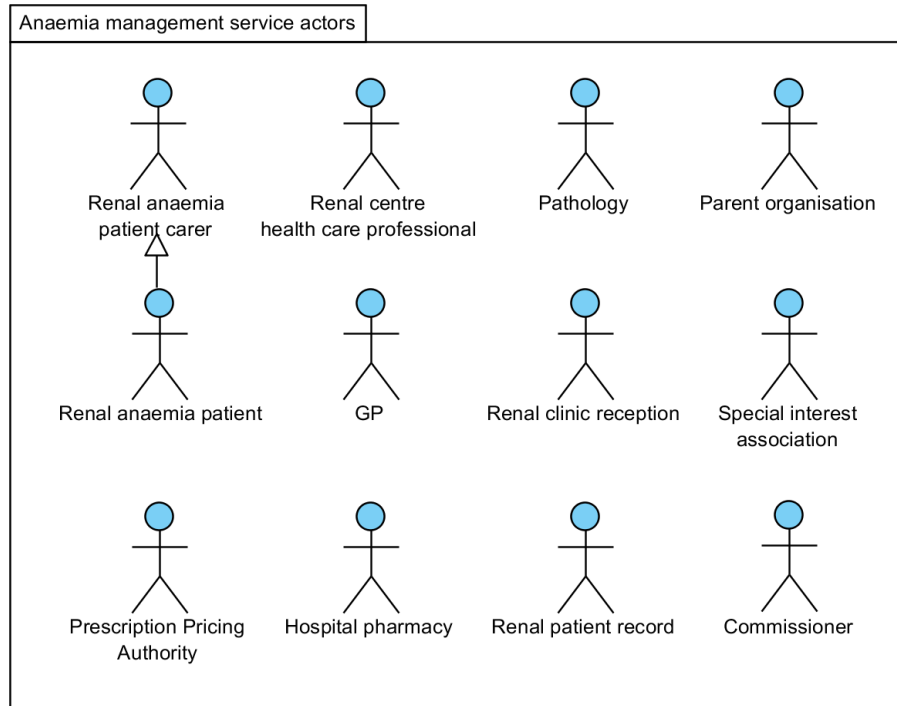


Figure 5.5 Actors to renal anaemia management: the service. These are the roles that interact with the renal anaemia management service.

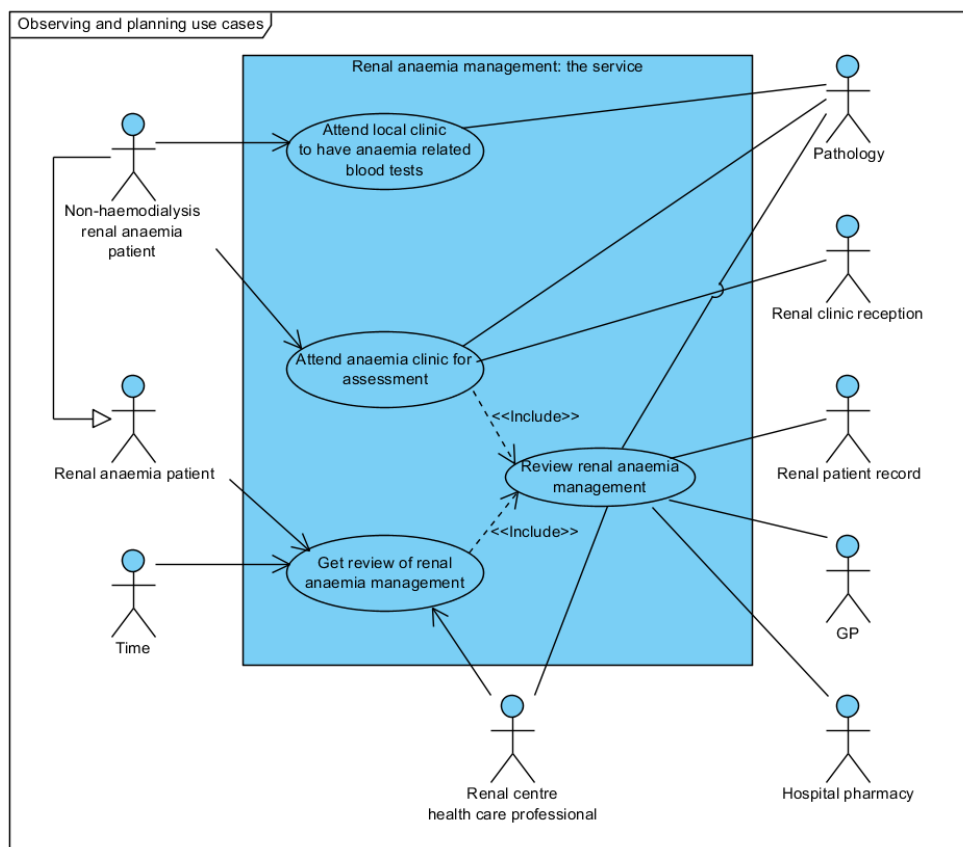
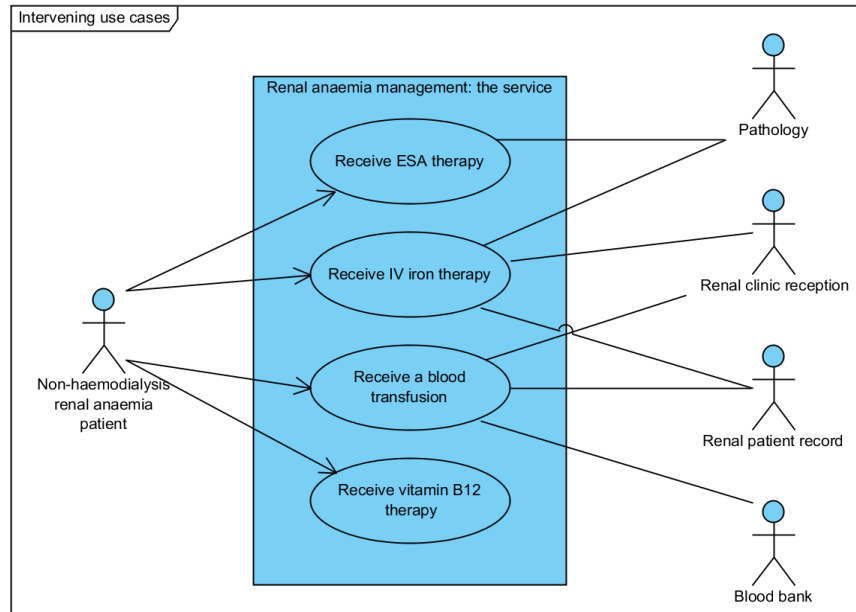


Figure 5.6 Observing and planning use cases of the renal anaemia management service associated with the actors that may interact with the service as part of each use case.



**Figure 5.7** Intervening use cases of the renal anaemia management service associated with the actors that may interact with the service as part of each use case.

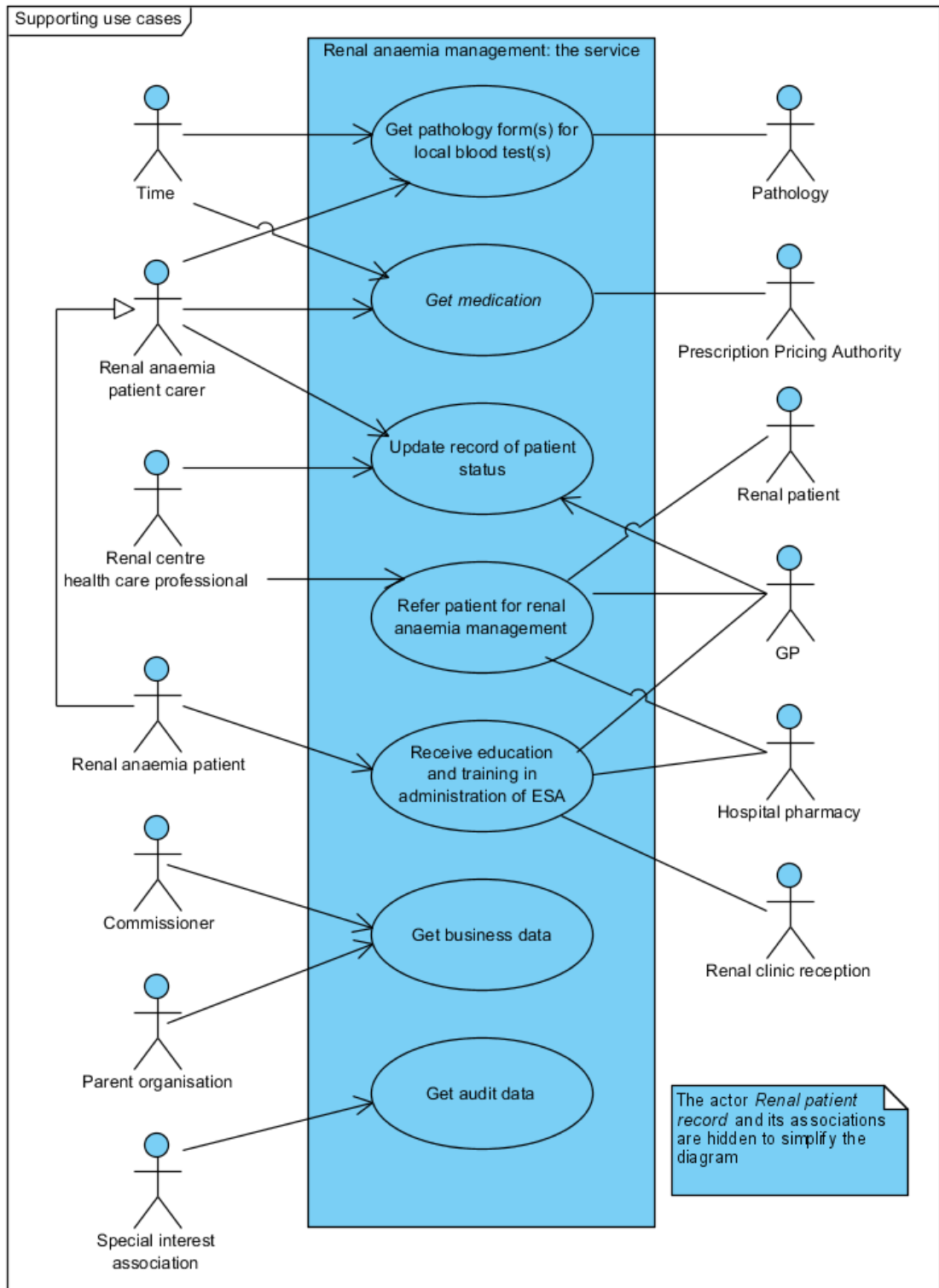


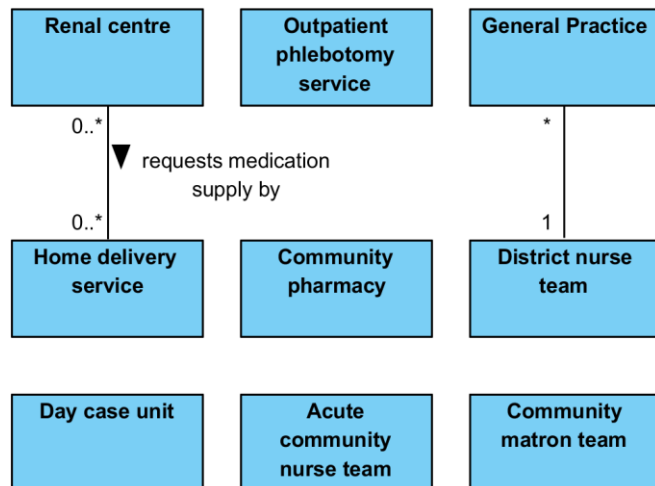
Figure 5.8 Supporting use cases of the renal anaemia management service associated with the actors that may interact with the service as part of each use case.

**Table 5.1** The relationship of renal anaemia management service use cases to the basic healthcare functions of observing, planning and intervening.

	<i>Observing</i>	<i>Planning</i>	<i>Intervening</i>
Attend local clinic to have anaemia related blood tests	✓		
Attend anaemia clinic for assessment	✓	✓	
Refer patient for renal anaemia management		✓	
Get review of anaemia management		✓	
Receive IV iron therapy	✓		✓
Receive ESA therapy	✓		✓
Receive education and training in administration of ESA	✓		✓
Receive vitamin B12 therapy			✓
Receive a blood transfusion			✓
Get medication			
Get pathology form(s) for local blood test(s)			
Update record of patient status			
Get audit data			
Get business data			

### 5.3.2.1 Service structure

A group of organisations, illustrated in figure 5.9, collaborate to deliver the complete set of services for renal anaemia management, although this is led by the renal centre. For any one set of observe, plan and intervene functions there may be multiple legal entities working together to provide the service. In addition to the healthcare service functions of the type observe, plan and intervene there are supporting functions such as dispensing medication. The use cases (as defined in terms of the service) that they participate in providing are summarised in table 5.2.



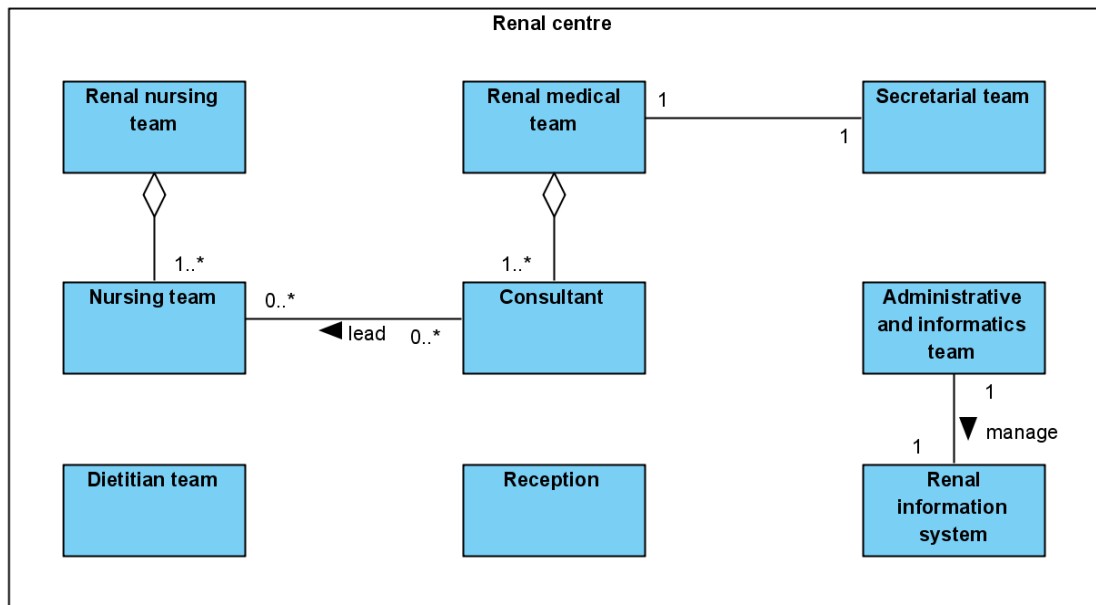
**Figure 5.9** Types of organisation that directly deliver renal anaemia management services.

**Table 5.2 Renal anaemia management service use cases and the organisations that may participate in their provision.**

	Renal centre	Home delivery service	Community pharmacy	General practice	District nurse team	Community matron team	Acute community nurse team	Day case unit	Outpatient phlebotomy service
Attend local clinic to have anaemia related blood tests				✓				✓	✓
Attend anaemia clinic for assessment	✓								
Refer patient for renal anaemia management	✓								
Get review of anaemia management	✓								
Receive IV iron therapy	✓						✓	✓	
Receive ESA therapy	✓			✓	✓	✓			
Receive education and training in administration of ESA	✓	✓		✓					
Receive vitamin B12 therapy	✓			✓	✓	✓			
Receive a blood transfusion	✓								
Get medication	✓	✓	✓	✓					
Get pathology form(s) for local blood test(s)	✓								
Update record of patient status	✓								
Get audit data	✓								
Get business data	✓								

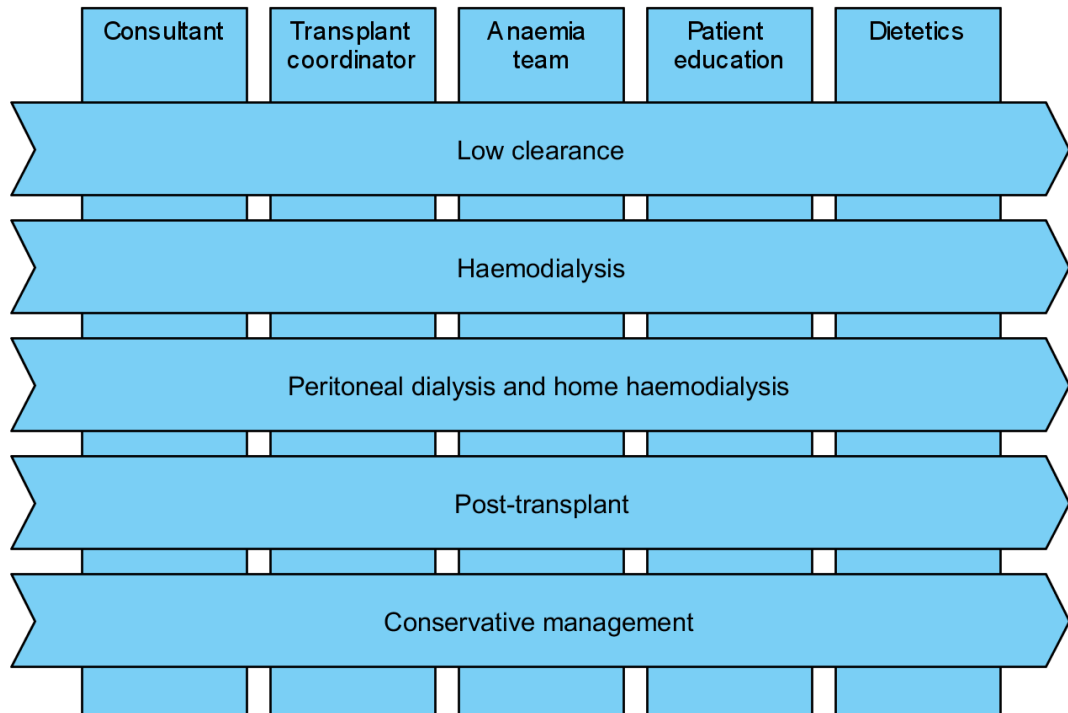
### 5.3.2.2 Renal centre

The renal anaemia management service is primarily coordinated from within the renal centre and, as was illustrated in table 5.2, it delivers much of the functionality of a renal anaemia management service. The renal centre cares for renal patients, who are organised into patient modalities according to the typical services they require and have agreed to, as described in section 5.3.1 above. Figure 5.10 describes the entities and roles contained within a renal centre as a UML class diagram.



**Figure 5.10 A view of entity and role classes within a renal centre**

Figure 5.11 illustrates some of the common functional units within a renal centre to highlight how some are aligned with patient modality (e.g. haemodialysis) while others cut across these modalities (e.g. the anaemia team). Typically the patient modalities illustrated in figure 5.11 have a nursing team dedicated to them and, with respect to renal anaemia management, these modality teams may have responsibility for taking blood samples, reviewing a patient's signs, symptoms and test results and administering treatment. At some renal centres the consultants are also organised by modality, at some they remain attached to the patient as they move between modalities (as in figure 5.11) and at others there is a mix, with some patients moving to a consultant with a special interest as appropriate. The order of different functions illustrated here is not intended to suggest some order in which a process occurs, indeed a renal patient will typically interact with many of these units regularly and in no one sequence.



**Figure 5.11** The alignment of different functional units within a renal centre

Use cases for the renal centre that are involved in renal anaemia management are illustrated in figure 5.12 to figure 5.15. These broadly resemble the use cases of the renal anaemia management service, but also include use cases whose primary purpose is not renal anaemia management (e.g. *Attend HD session* in figure 5.13). However there are a wide range of renal centre use cases not shown here because they are not directly involved in renal anaemia management (for example, get vascular access). For clarity, as for *renal anaemia management the service* the use cases have been organised into groupings; in this case the supporting use cases have been further partitioned according to whether they are associated with a patient or not.

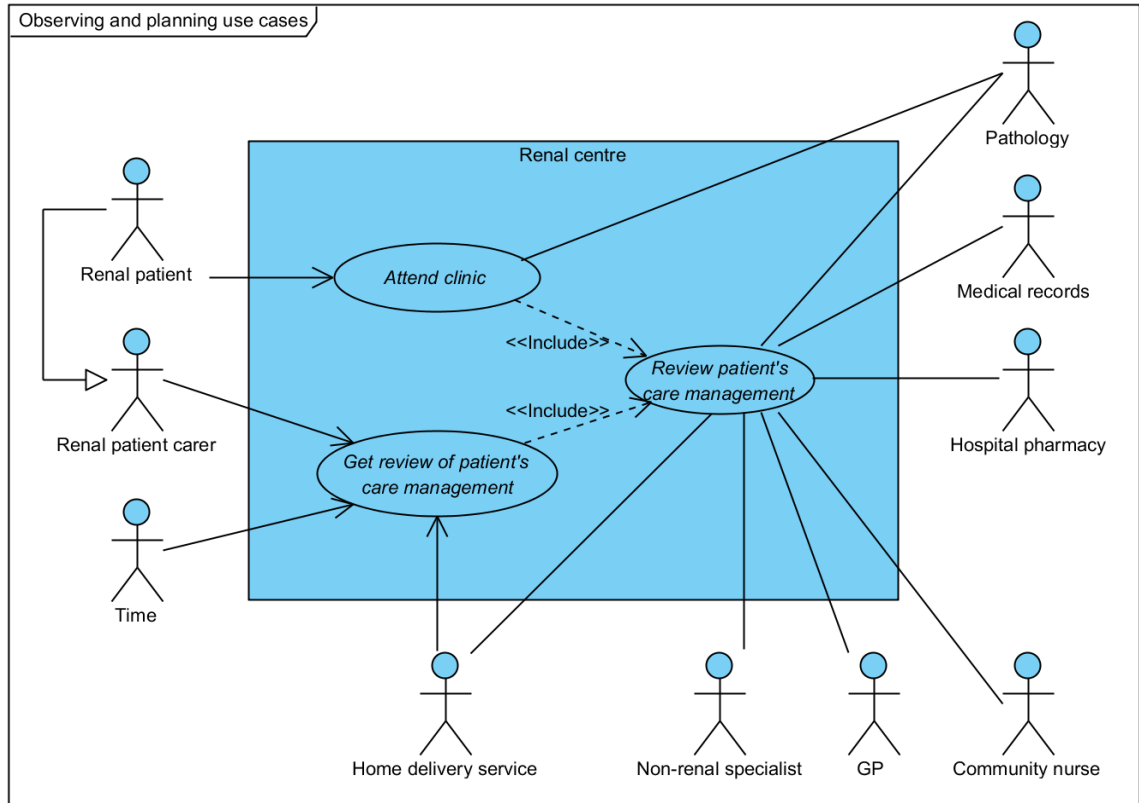


Figure 5.12 Observing and planning use cases of the renal centre related to renal anaemia management.

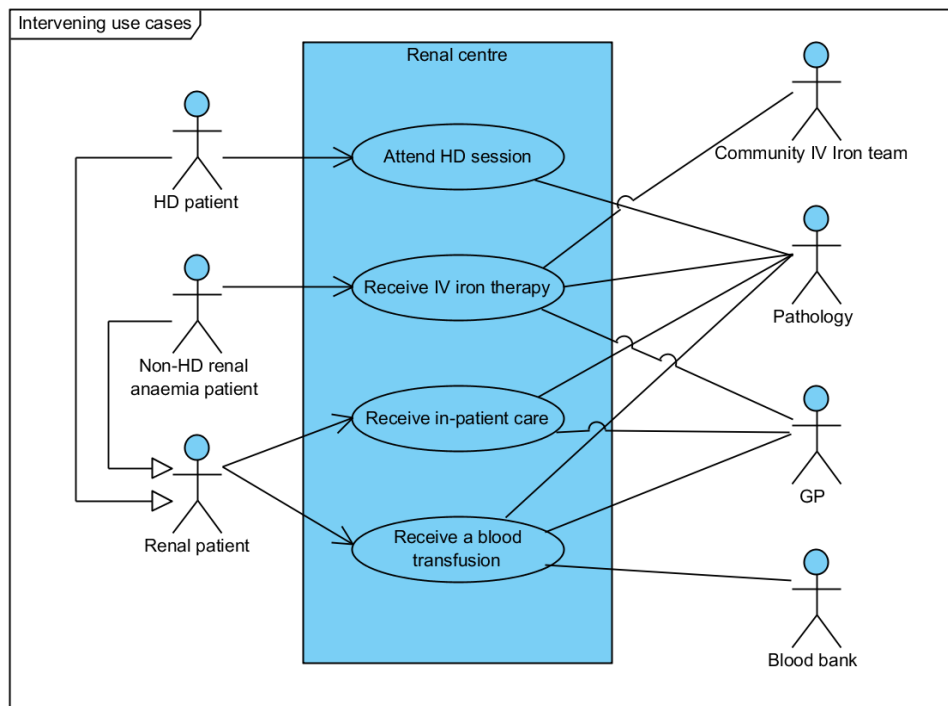
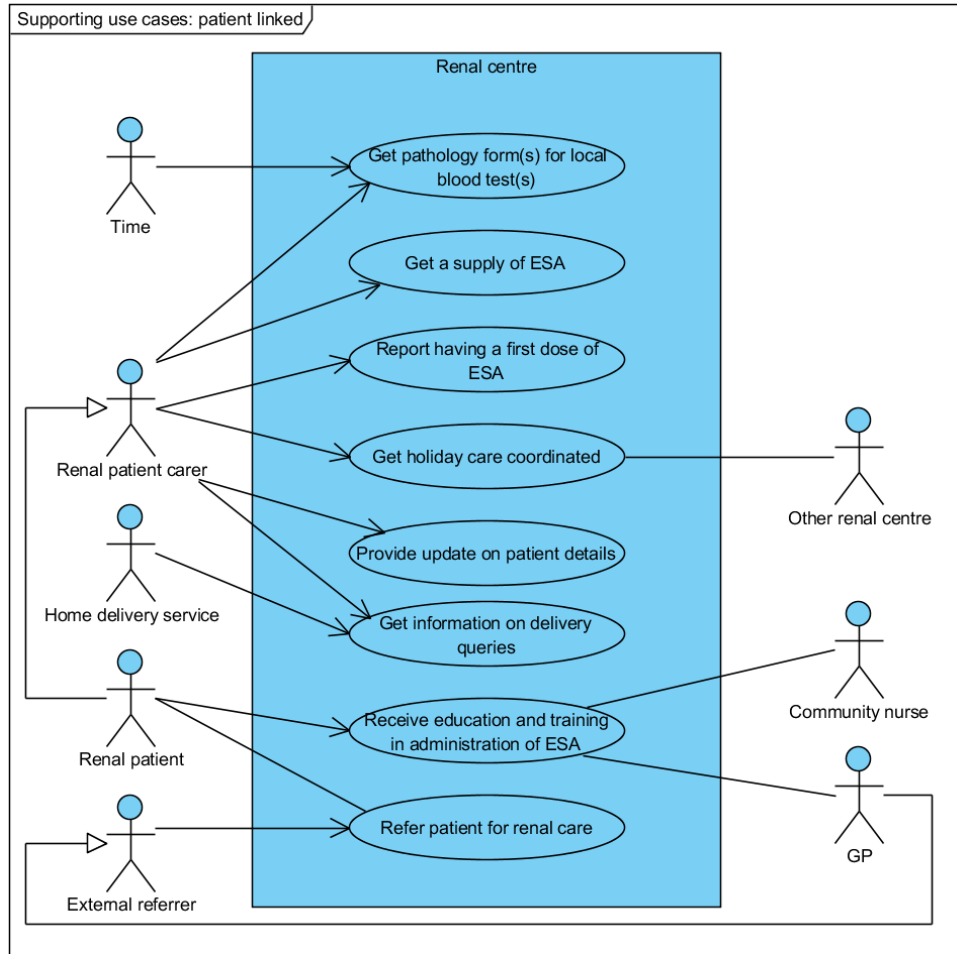
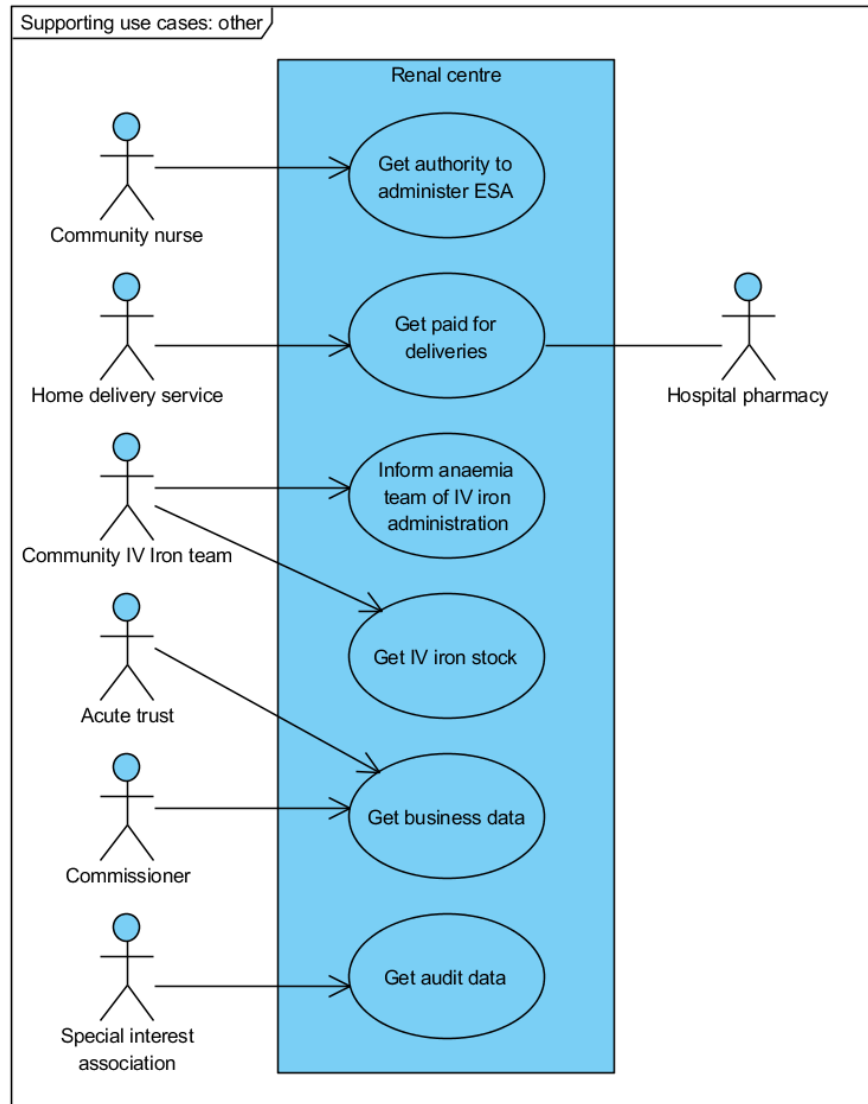


Figure 5.13 Intervening use cases of the renal centre related to renal anaemia management.



**Figure 5.14 Supporting use cases of the renal centre related to renal anaemia management that are associated with a patient.**



**Figure 5.15 Supporting use cases of the renal centre related to renal anaemia management that are not associated with a patient.**

### 5.3.2.3 Anaemia team

An anaemia team was responsible for the coordination of renal anaemia management at all renal centres in the study, although this is not the case at all English renal centres. Figure 5.16 illustrates the functions of an anaemia team with respect to a renal centre and the renal anaemia management service: the renal centre provides more of the renal anaemia management service than that provided by the anaemia team alone. Figure 5.17 shows an anaemia team has one or more anaemia nurses and may have administrators. In addition, it may be led by a consultant.

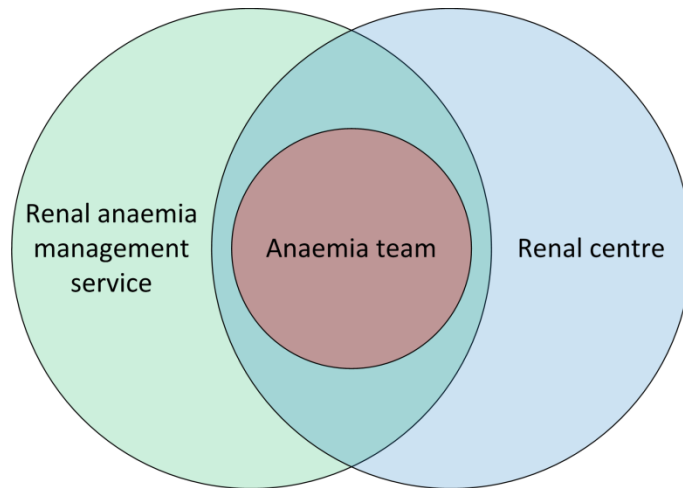


Figure 5.16 Venn diagram of the overlapping functions of the renal anaemia management service, renal centre and anaemia team

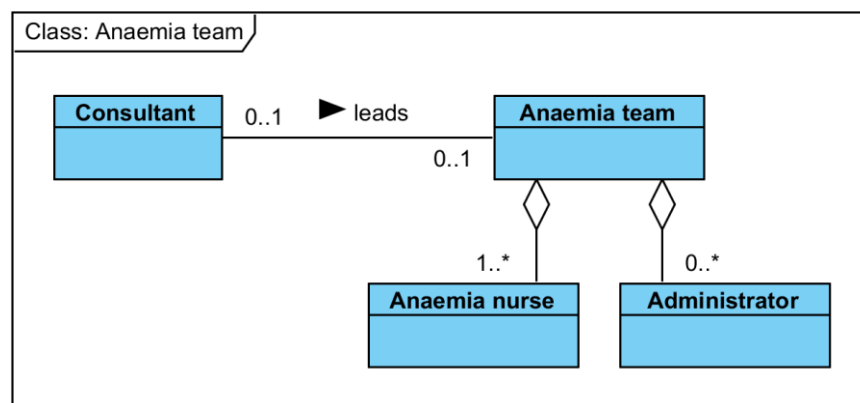


Figure 5.17 Class diagram of the anaemia team, its parts and relationship with a lead consultant

Use cases for the anaemia team are presented in figure 5.18 to figure 5.21. As for the renal centre, these are split into four diagrams to aid clarity.

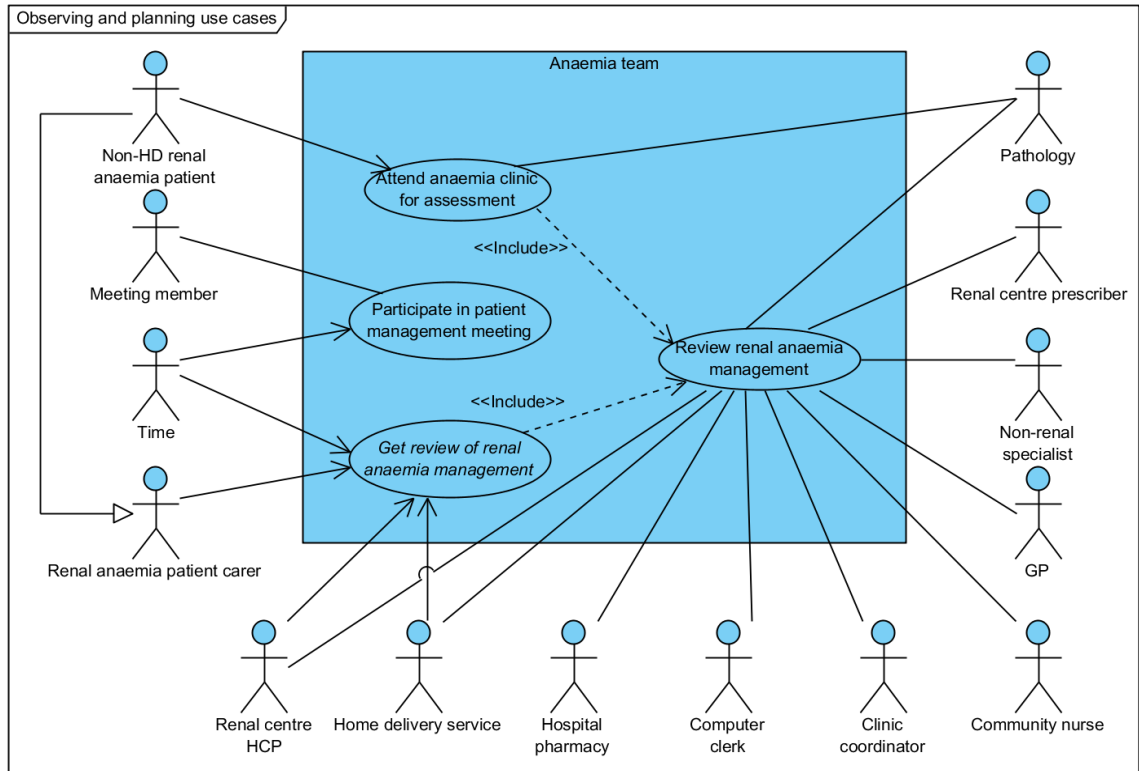


Figure 5.18 Observing and planning use cases of the anaemia team associated with the actors that may interact with the team as part of each use case.

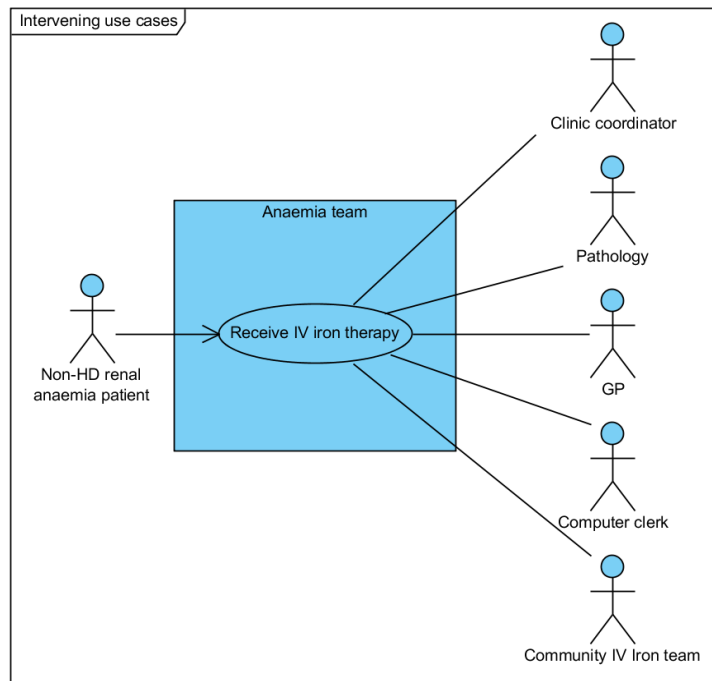


Figure 5.19 Intervening use cases of the anaemia team associated with the actors that may interact with the team as part of each use case.

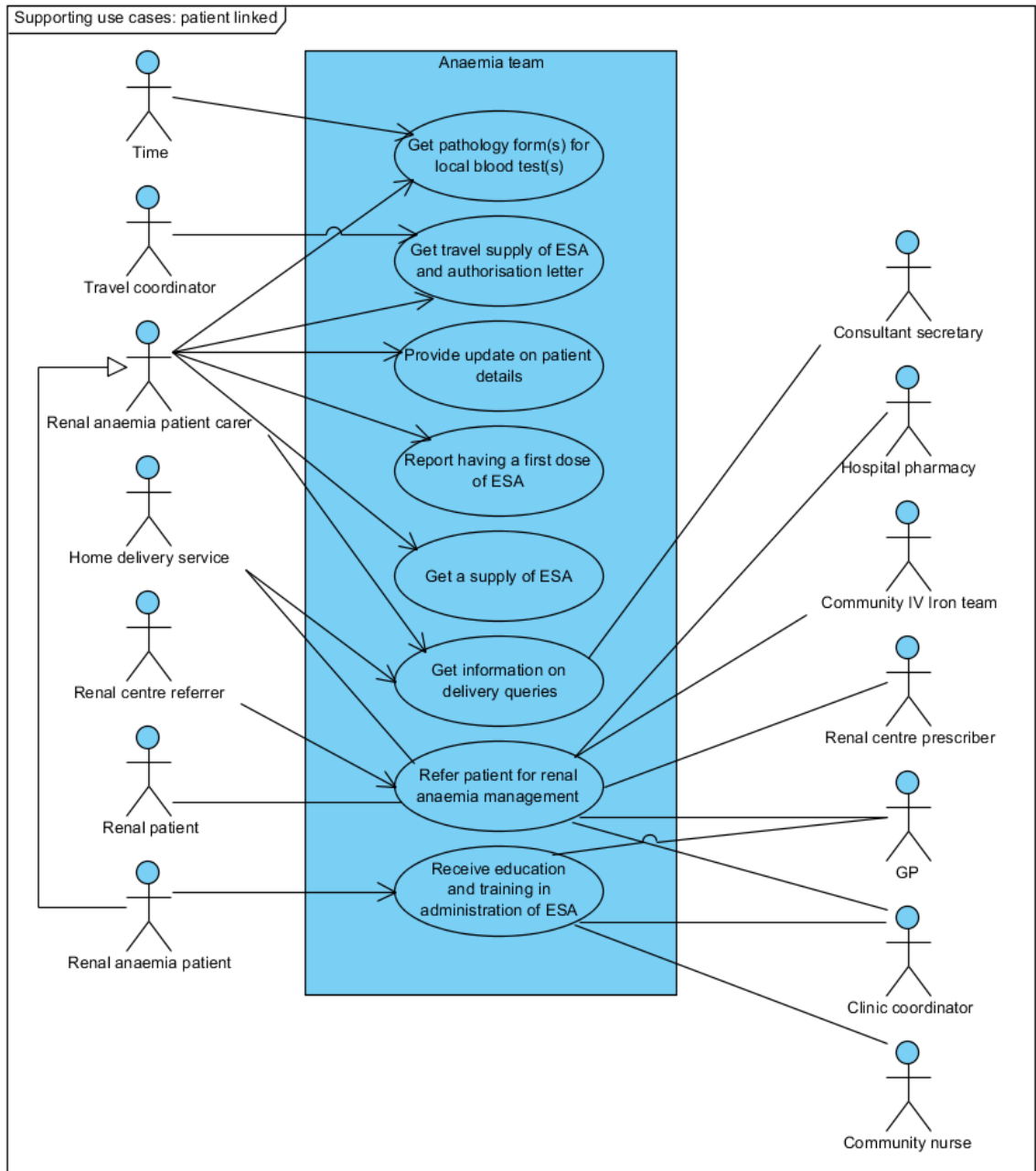
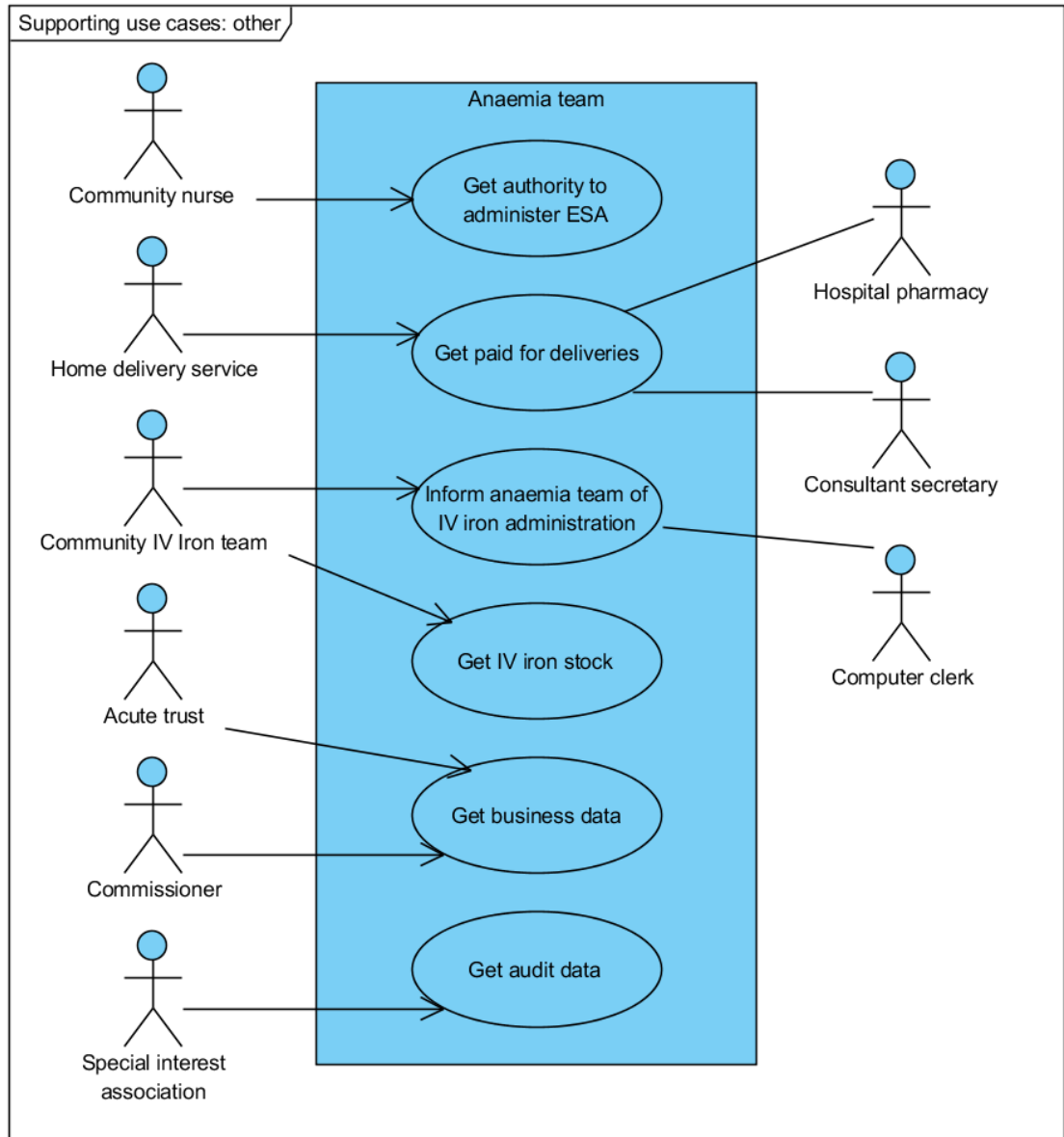


Figure 5.20 Supporting use cases of the anaemia team that are associated with a patient.



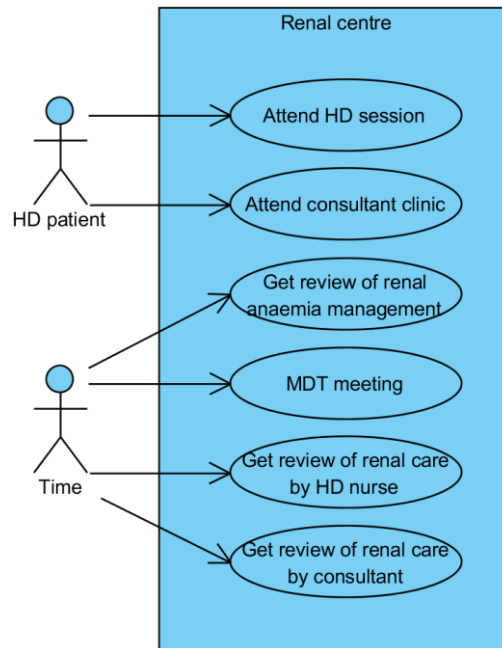
**Figure 5.21 Supporting use cases of the anaemia team that are not associated with a patient.**

The monitoring and treatment of patients with renal anaemia is significantly different depending upon whether they are treated with haemodialysis in a clinical setting or not because of the opportunities for regular contact that this affords and the activities conducted as part of this regardless of the patient's anaemia management. Therefore, the analysis will focus on these two groups separately, beginning with haemodialysis patients.

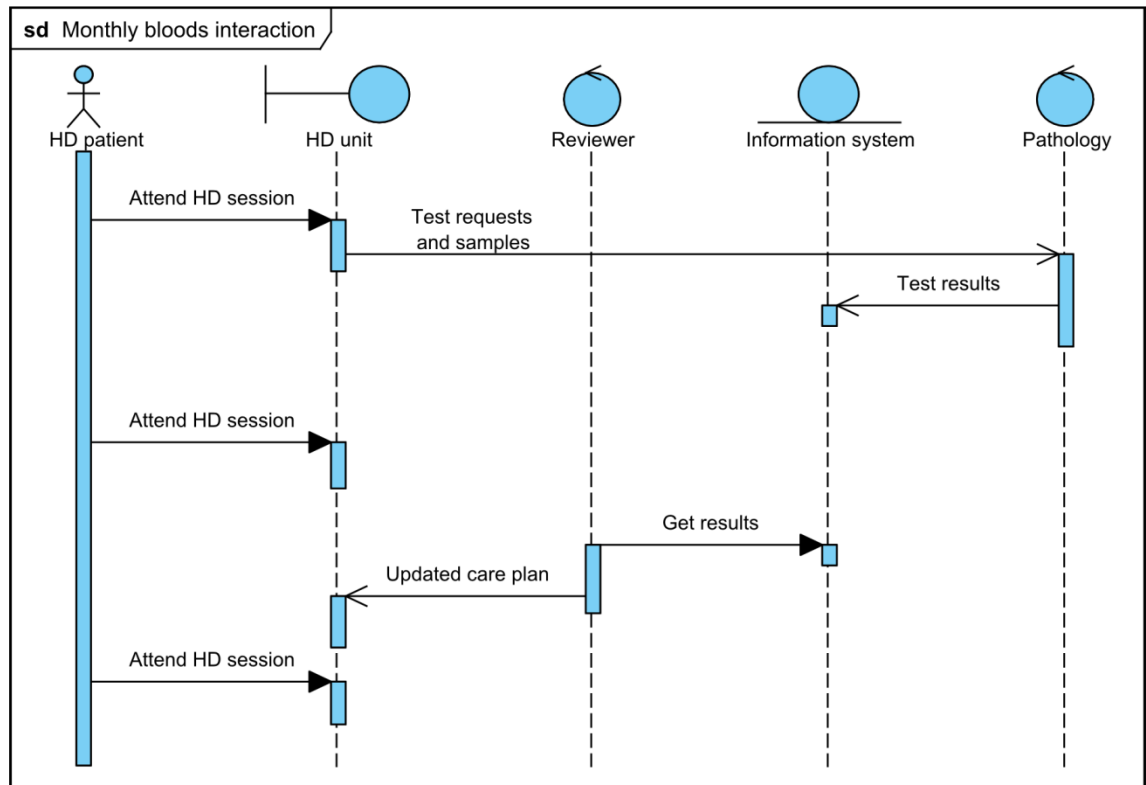
### 5.3.3 Haemodialysis patients

Haemodialysis patients, not to be confused with home haemodialysis patients, require regular haemodialysis in a clinical setting provided by the use case *attend HD session*. This is a use case of a renal centre and its satellite units and is not specific to anaemia management,

although it is vital to anaemia management. Instead of attending a healthcare setting or receiving a visit for a blood test or specific therapy, this use case provides the opportunity to combine these functions together. This is one of two typical points of contact with the renal centre for an HD patient, the other being a consultant clinic, as demonstrated by figure 5.22. In addition, a variety of planning functions occur on their behalf. Figure 5.23 illustrates a possible sequence of interactions for an HD patient, highlighting the role of the HD unit and HD session in direct patient contact.



**Figure 5.22 Primary use cases of a renal centre of relevance to an HD patient and renal anaemia management, not showing secondary actors.**



**Figure 5.23** Sequence diagram showing the interaction involved in an example 'monthly bloods' routine between abstract entities over time.

### 5.3.3.1 Haemodialysis session

The haemodialysis session (activity illustrated in figure 5.24 and in detail in Appendix L) is the main point of contact for haemodialysis patients with a renal centre. Patients typically attend three times a week as suggested by Renal Association guidelines (although sometimes two) and receive dialysis as part of a package of care. The haemodialysis session is the typical location for receiving drug therapy and for having blood samples taken for testing. These are organised in shifts, with a set of patients arriving at a similar time in the morning, afternoon and often evening (known as twilight). The sessions last several hours and involve being connected to a dialysis machine, a large and immobile object. In each session a range of basic measurements are taken including weight, pulse and blood pressure both before and after treatment (and often during). In addition, the nursing team assess patients and may discuss symptoms with them. Low-dependency haemodialysis was also available at some centres, where patients are trained to manage most of their care during a session including setting up a machine and administering treatment.

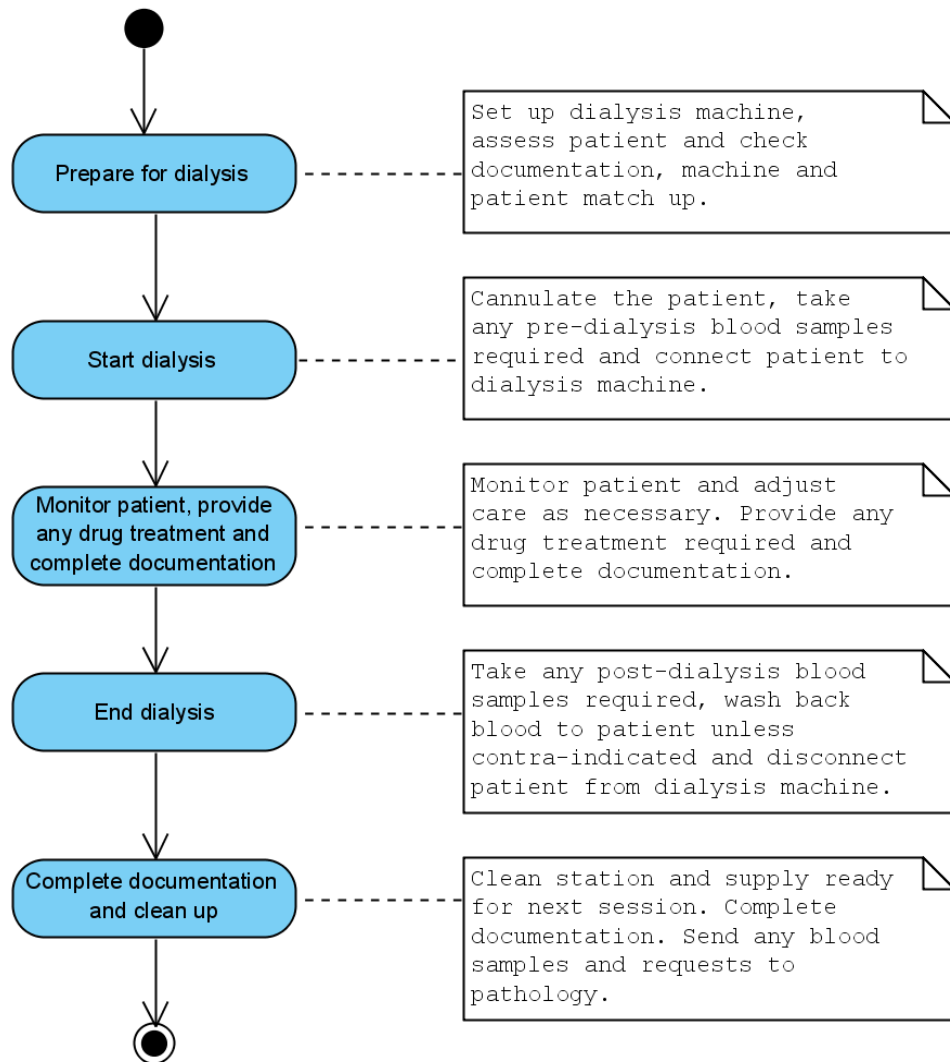


Figure 5.24 Activity diagram for the use case attend haemodialysis session (simple version).

### 5.3.3.2 Therapy

When an HD patient has been prescribed IV iron, it is always administered as part of an HD session via the dialysis machine. For patients who have been prescribed ESA it may also be administered as part of an HD session or alternatively in the community: self administered, administered by a carer or a community nurse. The frequency of administration for both iron and ESA depends upon both the specific agent used and the choice of the combination of dose and frequency made by the prescriber. For ESA this varies between three times weekly (the typical frequency of HD session) to once monthly and this variance means patients in the same HD session who are both prescribed ESA may or may not be due a dose.

The place of administration for ESA is loosely related to how the drug is supplied to the patient: from the renal unit, via a home delivery service or from a community pharmacy, the latter two suggesting ESA would be administered in the community. However this was not

always the case as past and current practices included providing ESA from the unit for the patient to take home and self-medicate or patients being supplied ESA in the community and bringing it with them for administration by staff (see also figure 5.25).

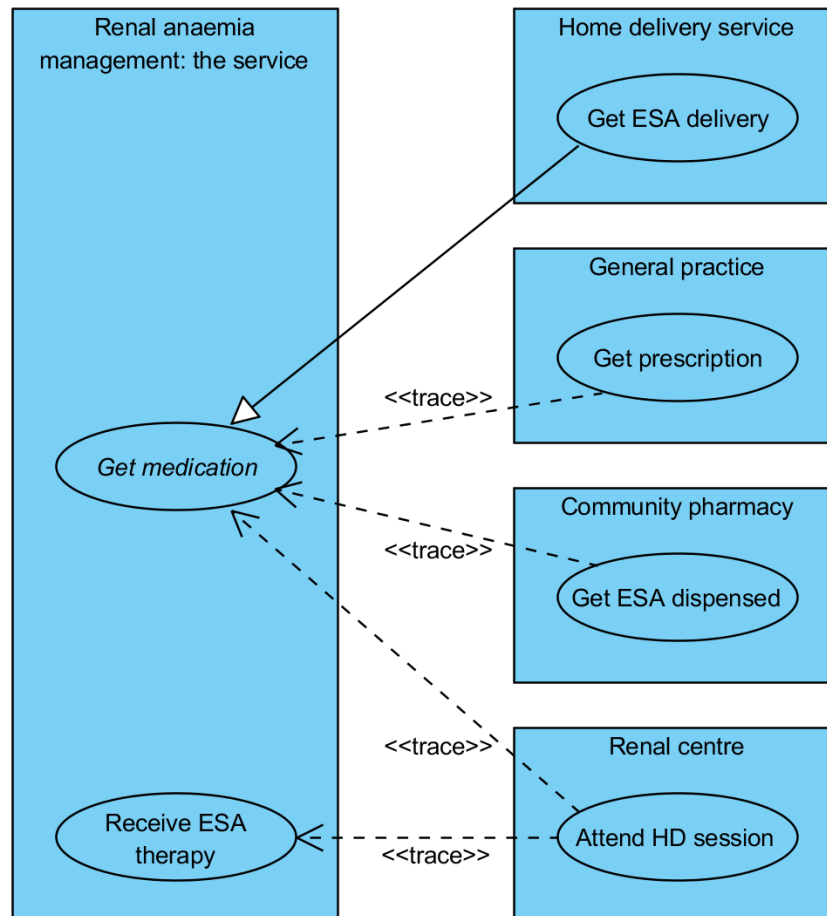


Figure 5.25 Different use cases for supplying and administering ESA for HD patients.

### 5.3.3.3 Blood tests

Regardless of anaemia status, all HD patients are routinely tested in HD sessions with ‘monthly bloods’, although these are not always calendar monthly: other strategies include four weekly, six weekly or partially randomised to reduce patient gaming (personal behaviour such as diet better aligned with clinical advice only prior to testing). Additional tests can be performed for a number of reasons including checking unexpected results, monitoring a change in treatment or because the patient does not appear ‘fit and well’, a phrase used by dialysis nurses at two centres.

The exact set of tests performed varies from centre to centre as well as period to period and sometimes patient to patient. Some tests are performed each period while others are performed less frequently or are dependent on attributes related to the patient. With relation

to anaemia management, FBC and CRP are always performed monthly, while centres use different iron tests at varying frequencies or under different circumstances.

### 5.3.3.4 Reviews

Haemodialysis patients are usually reviewed via multiple mechanisms, few of which involve face-to-face contact, as seen in figure 5.22. The main review of care is typically at a multidisciplinary team meeting, herein MDT, but also known as a quality assurance (QA) meeting, sit-down round and additional local names. In addition to or instead of the MDT, multiple health care professionals may individually review the results of tests, including (of relevance to anaemia management) a haemodialysis nurse, anaemia nurse and consultant. Patients may be seen for a face-to-face review at a consultant clinic, typically 3-6 monthly, as part of a consultant ‘walk round’ during their haemodialysis session or both.

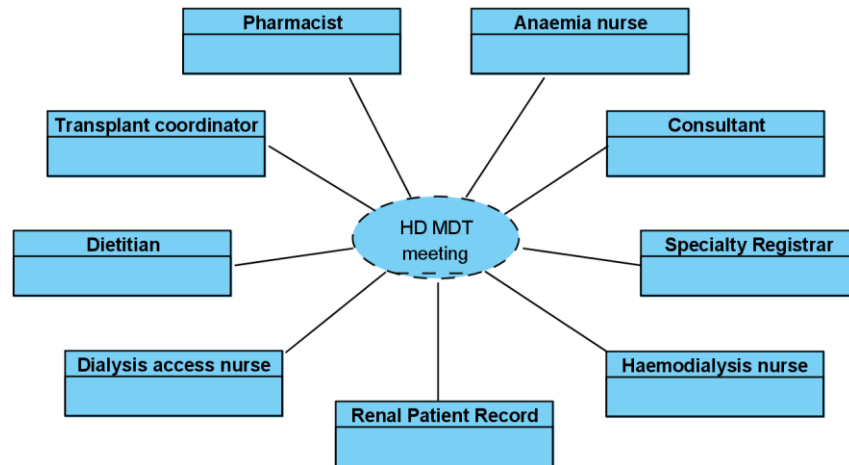


Figure 5.26 Collaboration diagram showing the possible participants in a HD MDT meeting.

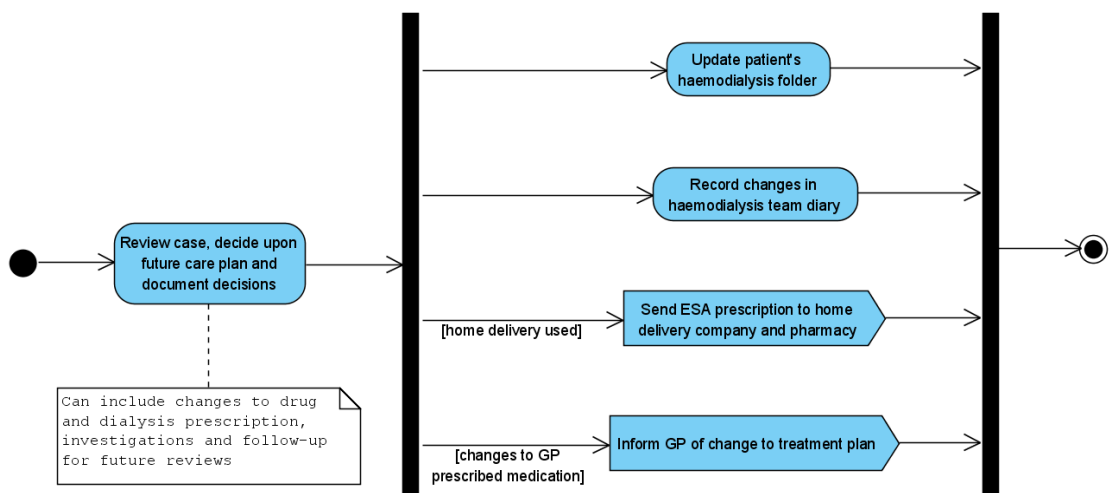


Figure 5.27 Activity diagram for a patient case within an HD MDT meeting.

#### 5.3.3.4.1 MDT

The haemodialysis MDT (see figure 5.26 and figure 5.27) is a regular meeting involving members of staff in a renal centre who are involved in the care of a group of haemodialysis patients. This patient grouping is usually at unit or ward/room level (patients who routinely dialysed in that location) but in the case of one large dialysis unit the meetings were further decomposed by a range of factors including the shift attended and the use of certain drugs. In each case, the gathered team review each patient in turn, considering new blood results and information from an HD nurse, who has regular contact with the patient and awareness of operational problems arising in the dialysis session. At one satellite unit of one centre, the MDT cycles through the patients several times, each time concentrating on a different facet of their care (transplant, anaemia, etc.). In addition to one or more HD nurses, an MDT may be composed of: medical staff, typically one consultant but often accompanied by one or more specialty registrars; specialist nurses; a dietician and a pharmacist. The other significant class involved in the meeting is the renal information system, which is used for viewing test results and in some instances to view details of dialysis sessions and further notes, alter prescriptions and summarise the outcome of the review. In addition, the renal information system may be used to cycle through each patient where the grouping of patients is recorded in the system.

The MDT usually occurs at the same time interval as routine bloods, although in some cases the period is different and up to eleven weeks. Where its periodicity was the same as routine bloods it was always a minimum of one week following them, but at some sites much longer and in some cases was not consistently scheduled.

The meeting is usually led by a consultant who tended to control the main display of the renal information system. In all but one case, a large display (e.g. projector) was used, although in one meeting this was not visible to all team members. In one centre, multiple instances of the renal information system were accessed by members of the team, allowing them to look at different aspects, change prescriptions or make notes concurrently.

Team members are asked for, or volunteer, information. They often had their own notes on paper that they had brought to the meeting and would then add to these as the meeting continued. Decision making may be by consensus or an individual.

In addition to the main purpose of the meeting, discussions between members of the group about other topics, typically work related, often occurred at some point. It is unusual for this group of people to get together as their workspaces and routines are largely separate and

it therefore appeared to provide an opportunity for coordination, team-building and discussions of notable events with other patients or colleagues.

The outputs of the meeting itself (changes to the care plans of patients) were often documented in multiple places: on the renal information system and in team members' individual notes. There were multiple instances where there was uncertainty within the team as to why a particular strategy was in place for a patient, or sometimes who had put it in place. In some circumstances this led to anxiety about changing the strategy. I did not observe reasoning being recorded in any MDT, just the decision (or resulting actions) and in some centres the identity of the decision maker.

Following the meeting, it was usual for the HD nurse to update the patients' haemodialysis folders (paper) with new prescriptions and notes of additional tests or observations. Additionally, they would often place summaries of changes in a haemodialysis team diary that is used to communicate between shifts. Specialist nurses may have further administrative tasks, for example an anaemia nurse may change a patient's home delivery prescription. A consultant's secretary may write to the patient's GP to inform them of changes. At some centres the patient is also provided with a written copy of changes or their current drug list and at all they claimed to discuss the outcomes with their patient during a haemodialysis session.

#### **5.3.3.4.2 Anaemia nurse review**

A routine bloods review by an anaemia nurse is variable between centres in process, output and speed. It is a review that occurs at four centres for a group of patients after they have had routine blood tests performed and prior to an MDT (whether or not the anaemia nurse will be attending). In general, all patients in the group are reviewed with some consideration given to their future anaemia management. Some anaemia nurses produce the list of patients to review, sometimes including a number of manual information retrieval, copying and display operations. In some cases the patients are triaged according to their results. Changes to treatment may be instigated at this point or, if the anaemia nurse will be attending an MDT, may be held for discussion there. At two centres (D and H), the review is supported by a computerised decision support system.

A routine bloods review focused on anaemia management and involving an anaemia nurse and consultant occurs in two centres, F and H. In F it is the only anaemia-related review of routine bloods and at H it follows an anaemia nurse review. At F it therefore proceeds as a routine bloods review by an anaemia nurse with no MDT (i.e. all changes identified in the

review are instigated straight away). At H it is a selective review of those patients who fall outside of NICE/RA guidelines (Hb 10.5-12.5 g/dl) to ensure that there is a suitable plan in place for their management, the list for which is extracted via an automated query of the renal information system.

### 5.3.4 Community-based patients

Renal patients who are non-HD patients or community-based patients are cared for by a consultant or team of consultants and often by one or more nursing teams (see section 5.3.2.2 above). Patients who are identified as anaemic may be investigated to rule out alternative causes of anaemia (e.g. gastrointestinal bleeding) and may be treated with oral iron or vitamin B12 without or before being referred to the renal centre’s anaemia team. At two centres, the anaemia team review all nephrology and low clearance patients prior to a clinic attendance, based on which they may recommend that a consultant refers the patient for renal anaemia management.

#### 5.3.4.1 Referral

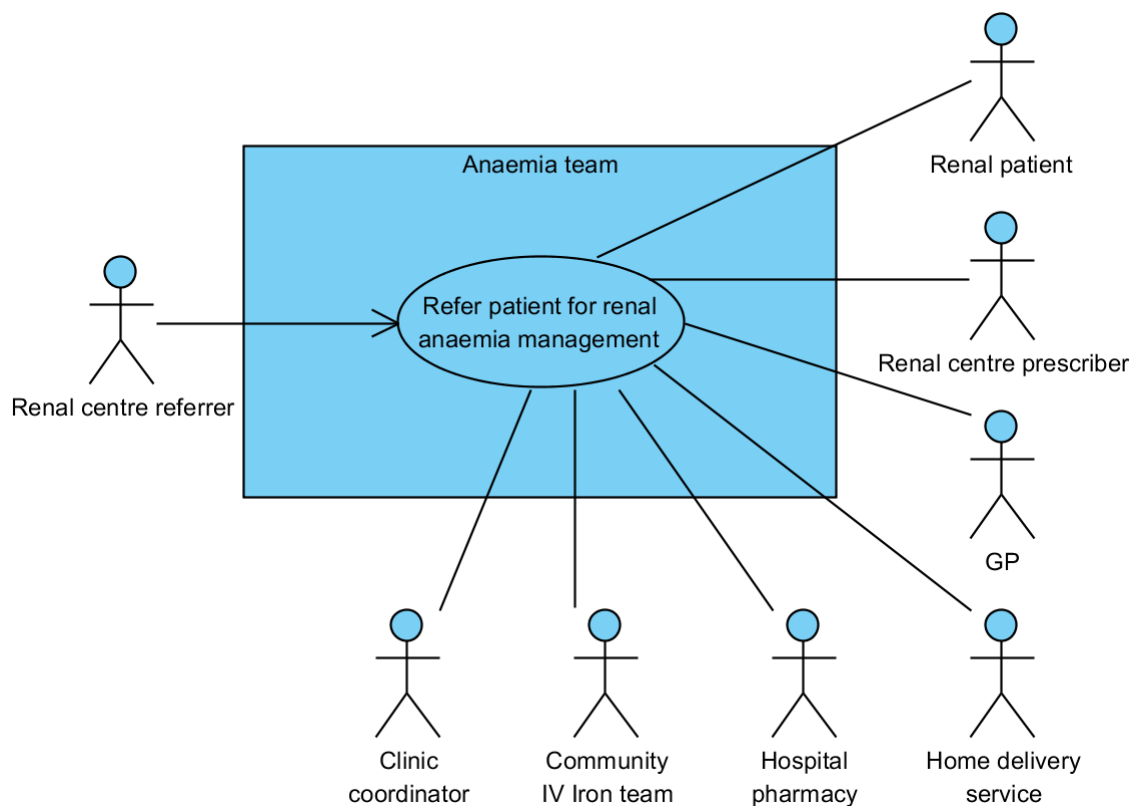


Figure 5.28 Refer patient for renal anaemia management use case.

A patient gains access to renal anaemia management from a renal health care professional who refers them to the anaemia team either for anaemia management in general or specifically ESA and / or IV iron (see figure 5.28 to figure 5.30). The anaemia team review the referral to ensure that such treatment is appropriate for the patient and then offer that to them. Patients are often iron deficient when they are first referred for anaemia management and therefore given iron (oral or IV) prior to commencing ESA to help establish whether they have iron deficiency anaemia or renal anaemia.

If a patient accepts the offer of therapy the anaemia team organise this, which typically involves arranging an appointment for iron therapy and / or training in self-medication with ESA. Where the patient is to be treated with ESA, additional arrangements are usually made for its supply, either by request to the patient's GP or with a home delivery company. The exception to this is when the centre will directly supply ESA or prescriptions for ESA.

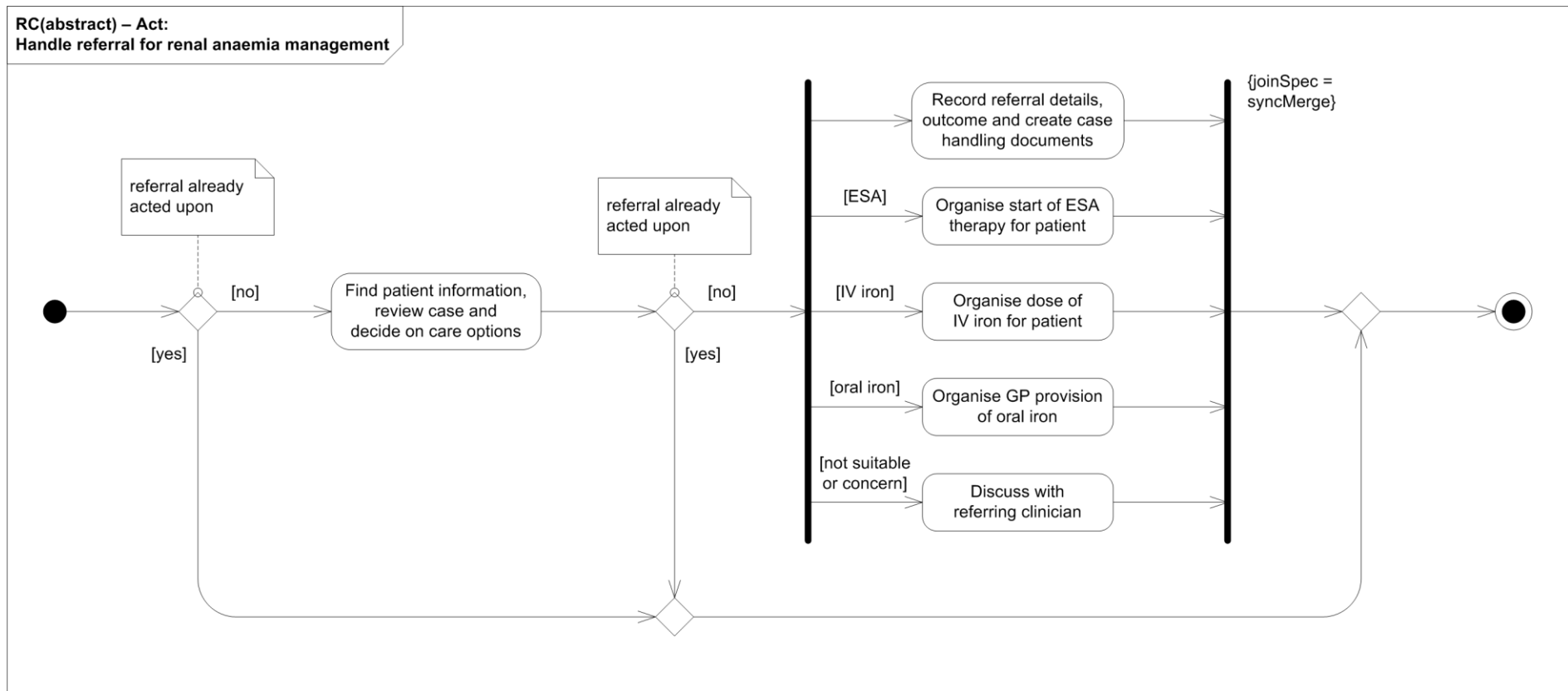


Figure 5.29 Activity diagram for the use case refer patient for renal anaemia management

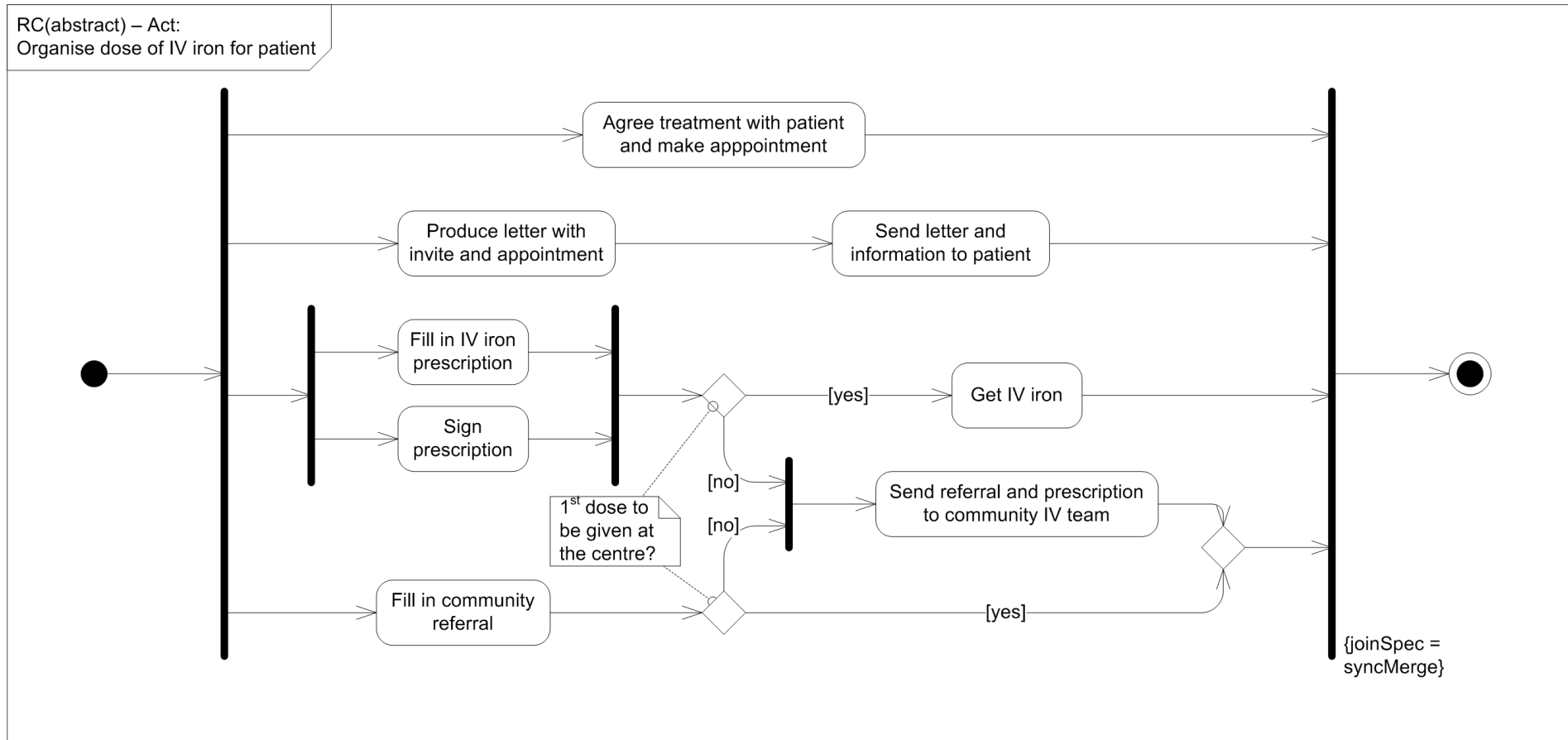


Figure 5.30 Activity diagram for organising a dose of IV iron for a patient

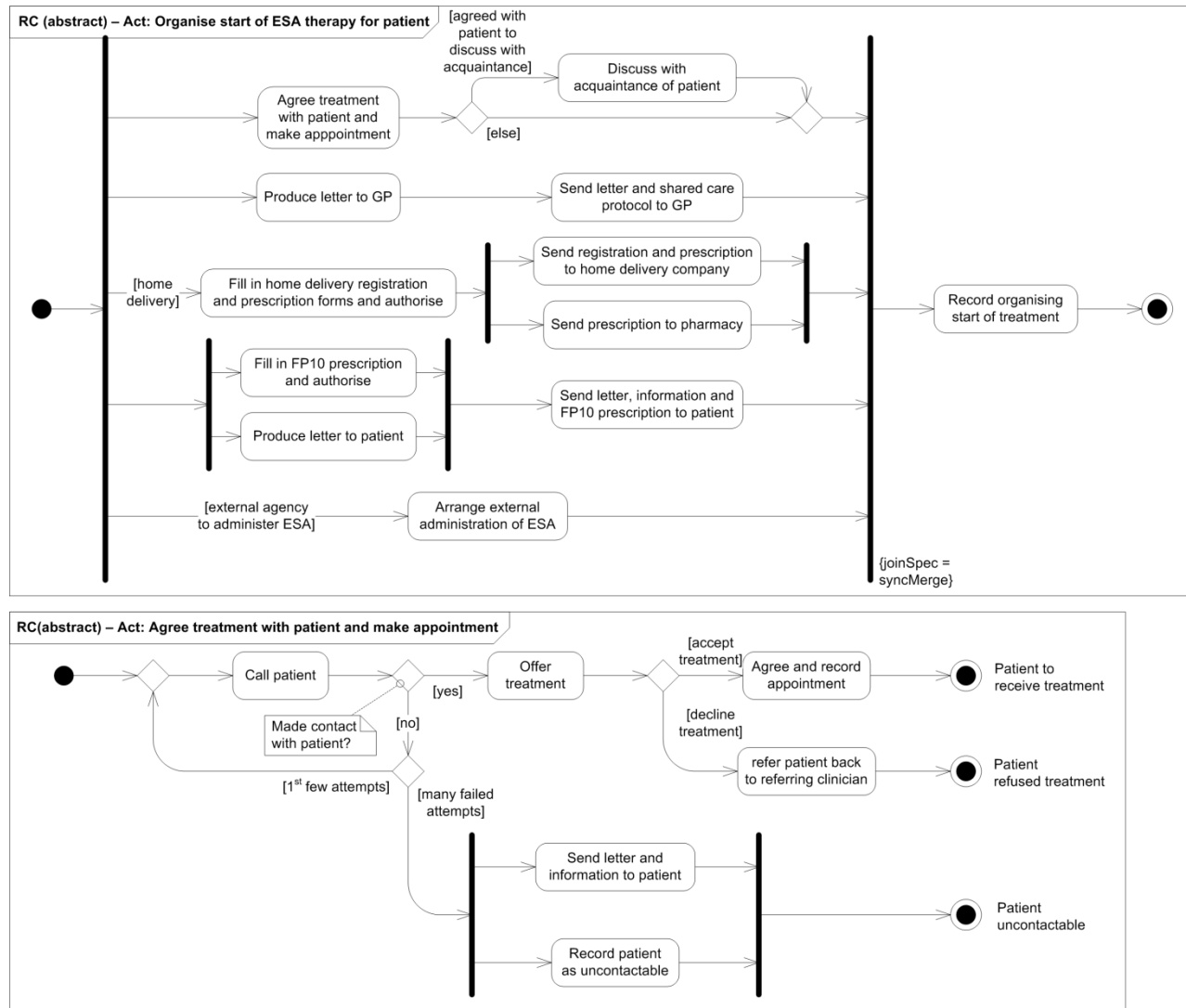
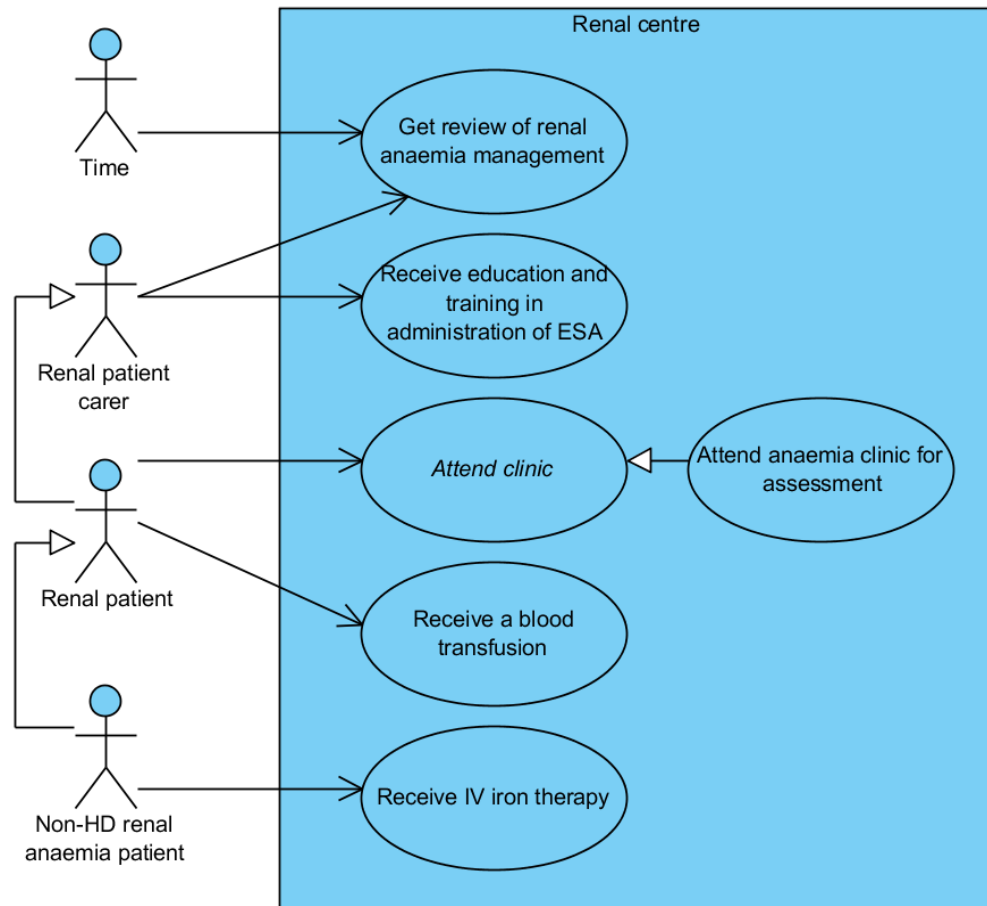


Figure 5.31 Activity diagrams for organising the start of ESA therapy for a patient (decomposes activity in figure 5.29)



**Figure 5.32** Use cases of the renal centre for non-HD patients of relevance to renal anaemia management and the basic healthcare activities. Secondary actors not shown.

#### 5.3.4.2 IV iron therapy

IV iron is given as an occasional rather than routine drug for patients not on haemodialysis, sometimes as single doses and sometimes short courses depending on need and drug preparation. Where a short course is provided these are typically weekly to monthly and between three and seven doses. It is, with the exception of home haemodialysis patients, always administered by a health care professional.

In some cases, IV iron can be provided in a community setting rather than a renal centre. This involves a local agreement with community hospitals or acute community (intravenous) nursing teams as district and practice nurses are not able to provide such treatment.

#### 5.3.4.3 Education and training in administration of ESA

Unlike IV iron, community patients rarely receive ESA in a clinical setting and therefore most patients starting ESA will be trained to give the drug subcutaneously themselves (see figure 5.33). Alternatively, an acquaintance of theirs may be trained or the anaemia team may

arrange for a district or practice nurse to give the drug. The anaemia team usually provides this training, although at one centre the home delivery company provided nurses who would go out to train the patient.

Education and training in administration of ESA is usually a one-off event for a patient, although where they or the trainer is unsure of their competency they may come back on several occasions. If a patient has a long time where ESA treatment is suspended they may also be invited to retrain. In some cases the centre supply a small stock of ESA at the training session while in others they wait until the delivery service has started before bringing the patient in unless the start of treatment is considered urgent.

The patient is educated in the need for the treatment and its mechanism of action as well as the need for regular tests and safe storage. The person who will give the medication is trained to ensure they can do so safely and effectively and is assessed, usually with the assistance of a checklist. At one centre, a contract is signed by the patient acknowledging that they have understood the training, safe storage and the need for regular tests.

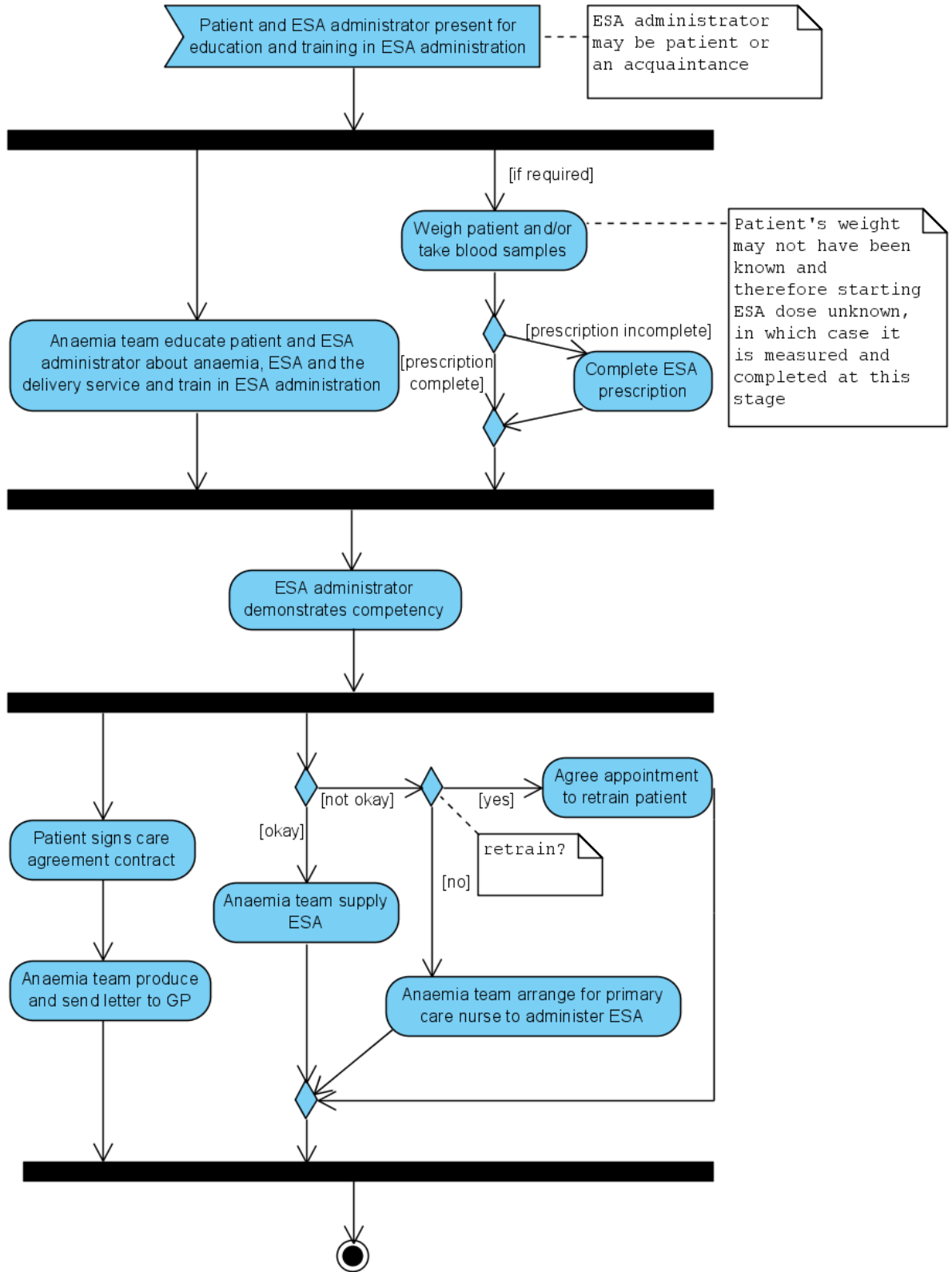


Figure 5.33 Activity diagram for the use case receive education and training in the administration of ESA.

### 5.3.4.4 ESA provision

Because ESA is typically administered in the community, stocks need to be supplied to the patient (see figure 5.34). The majority of centres used a home delivery service to do this, although one supplies ESA directly from the centre and for some patients at two others the GP prescribes ESA and it is therefore dispensed from a community pharmacy. Historically some of the centres issued prescriptions to their patients and in those cases it was also dispensed from a community pharmacy. The supply of ESA directly from the centre at F often involves the patient attending a clinic at either the main centre or a satellite and this is used as an opportunity to review the patient and take blood samples for testing, alternatively it may be collected by a carer.

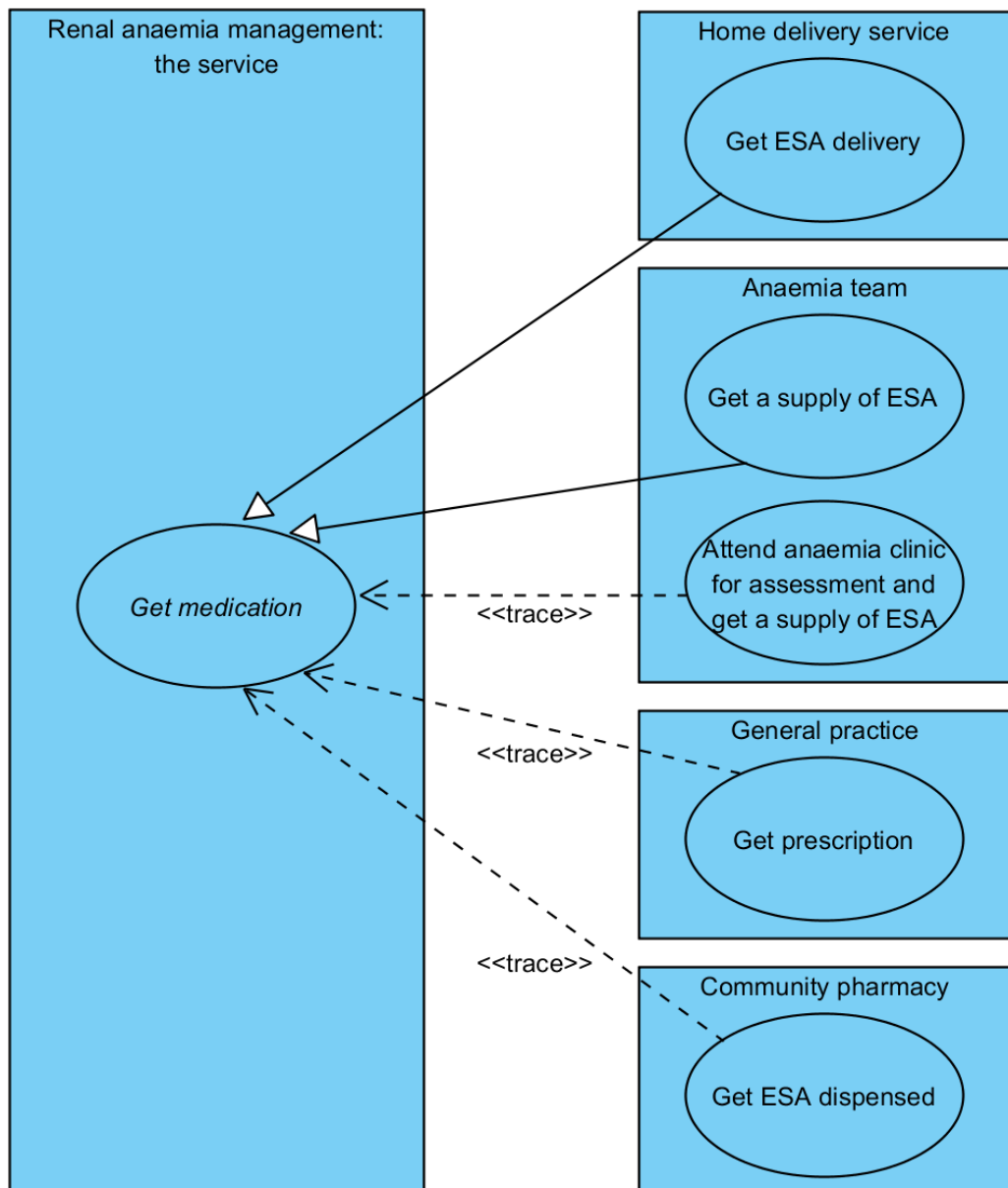


Figure 5.34 Use case model of different means by which ESA is provided to non-HD patients.

#### 5.3.4.5 ESA administration

As was discussed earlier, ESA is usually administered by the patient or an acquaintance. Alternatively, the anaemia team may refer the patient to a practice nurse (located in a general practice) where the patient is mobile or a district nurse or community matron who will visit their home. At different centres there is varying willingness to make such a referral, some considering it safer that the patient is regularly seeing a health care professional and others considering it an unfair burden unless the patient is physically incapable.

Treatment frequency is largely determined by the type of ESA used, although there is some flexibility for different dosing schedules with each, and these range from three times weekly to monthly.

#### 5.3.4.6 Monitoring and review

All renal patients have reviews of their general care, primarily associated with a clinic visit but additionally in some centres select groups of patients (including PD, Home HD, conservative care and low clearance) will receive home visits. These reviews will normally consider anaemia as part of the general care and may result in changes to treatment directly or via the anaemia team. This monitoring varies in frequency from centre to centre, patient group to patient group and between individual patients. However, typically community dialysis (PD or home HD) patients are seen monthly while others are seen 3-12 monthly, although patients due to start dialysis or who have just received a transplant will be seen as often as weekly. Such reviews will normally occur in conjunction with a new set of blood test results being produced, with tests occurring just prior to or during the visit.

Once a patient is having regular doses of ESA they will usually be monitored on a routine basis by the anaemia team (see figure 5.37 and figure 5.38). This monitoring is usually more frequent than for other areas of renal care (usually monthly or 2-monthly although NICE (2006a) guidance recommends every 1-3 months) and therefore different strategies for blood testing and patient review have evolved. At some centres, the anaemia team will bring in a patient for blood tests and potentially a review; at centre F, ESA is also dispensed at this meeting. At others, patients will attend their GP practice or an outpatient department of a local hospital to have test samples taken. Where the patient is visited in their home by renal centre or community nurses blood samples will be taken there. The choice of approach is influenced by ability to access external blood test results, desire for direct contact by the anaemia team as part of the observation process, arrangements for ESA supply and administration and local relations with primary care.

Where the anaemia team did not take a patient's blood samples, they needed a mechanism for identifying and reviewing the result and these varied significantly. In any one centre there were usually multiple mechanisms in place and these can be categorised broadly as scheduled (time-triggered) and requested (role-triggered); see figure 5.35 and figure 5.36.

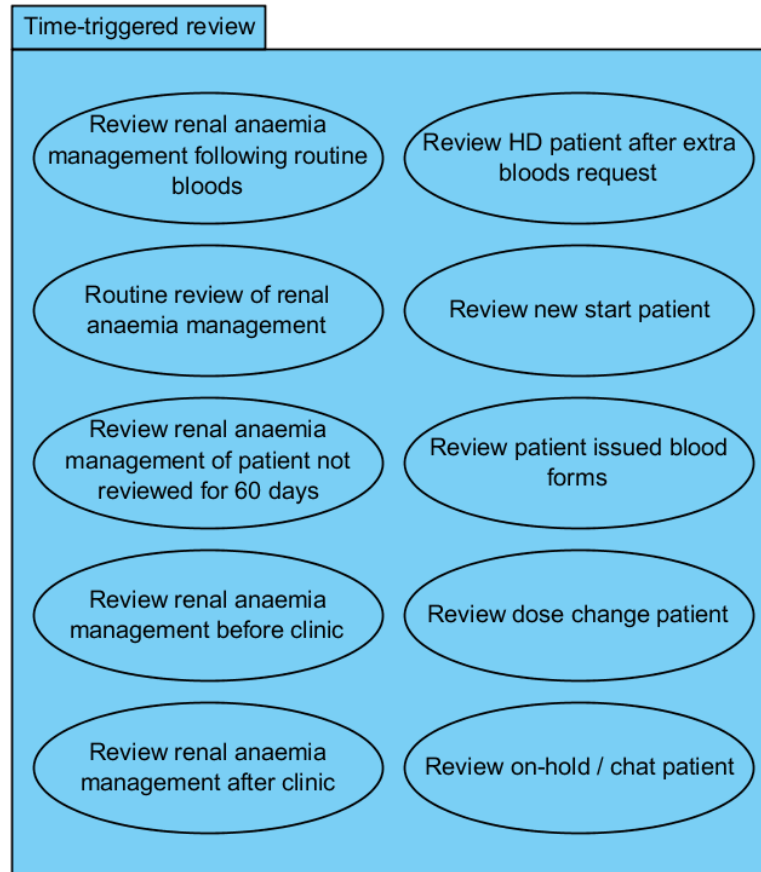


Figure 5.35 Types of the *get review of renal anaemia management* use case triggered by time.

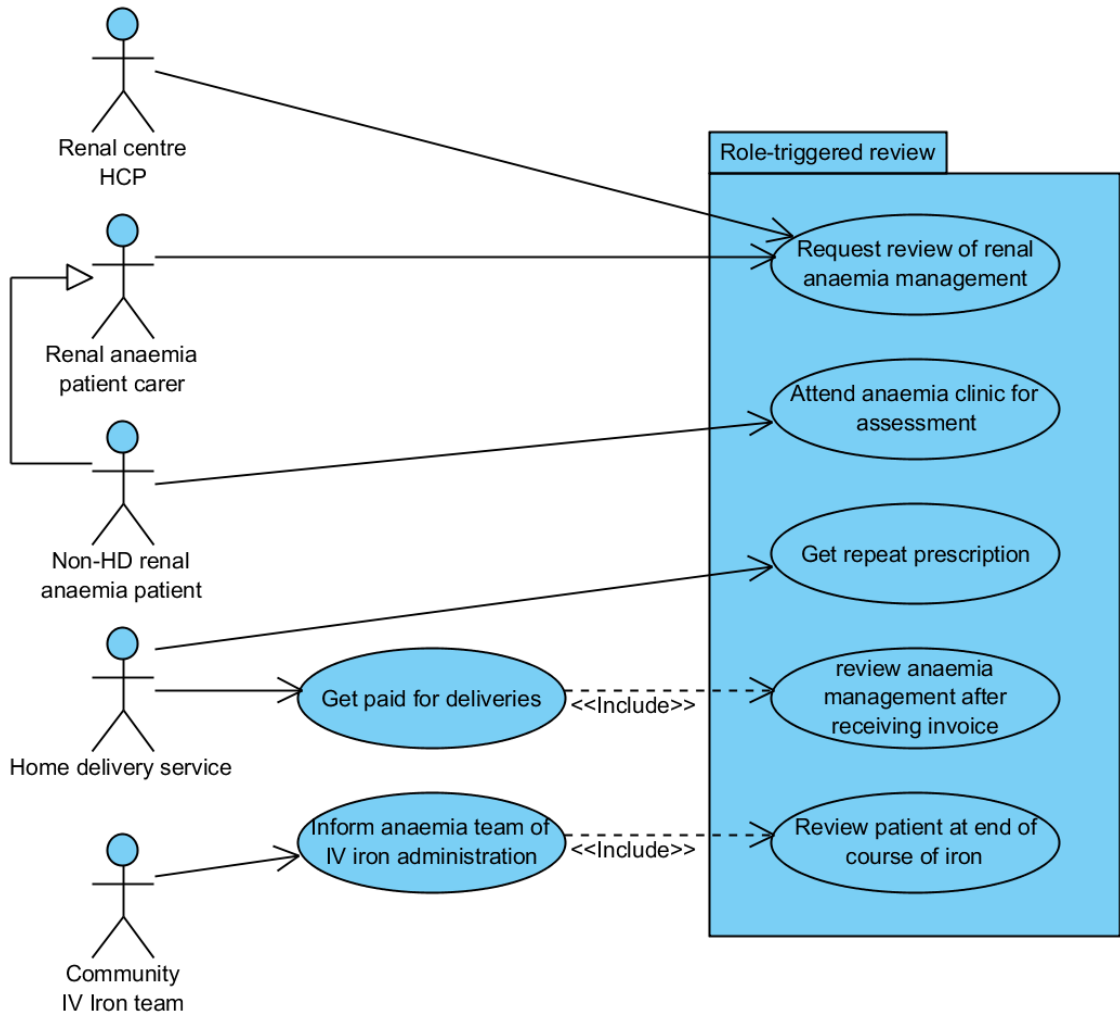


Figure 5.36 Types of the *Get review of renal anaemia management* use case triggered by others.

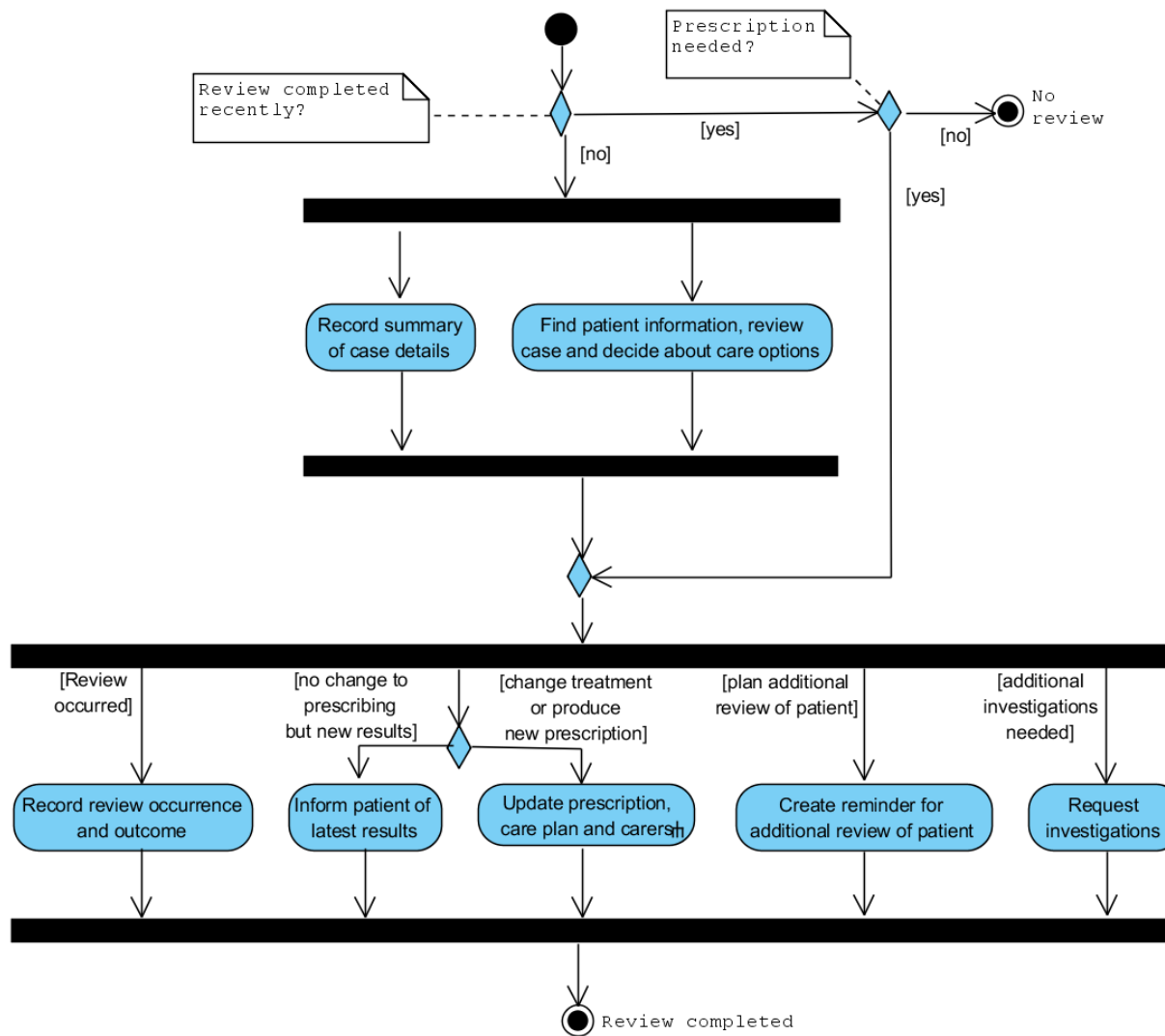


Figure 5.37 Activity diagram for review renal anaemia management

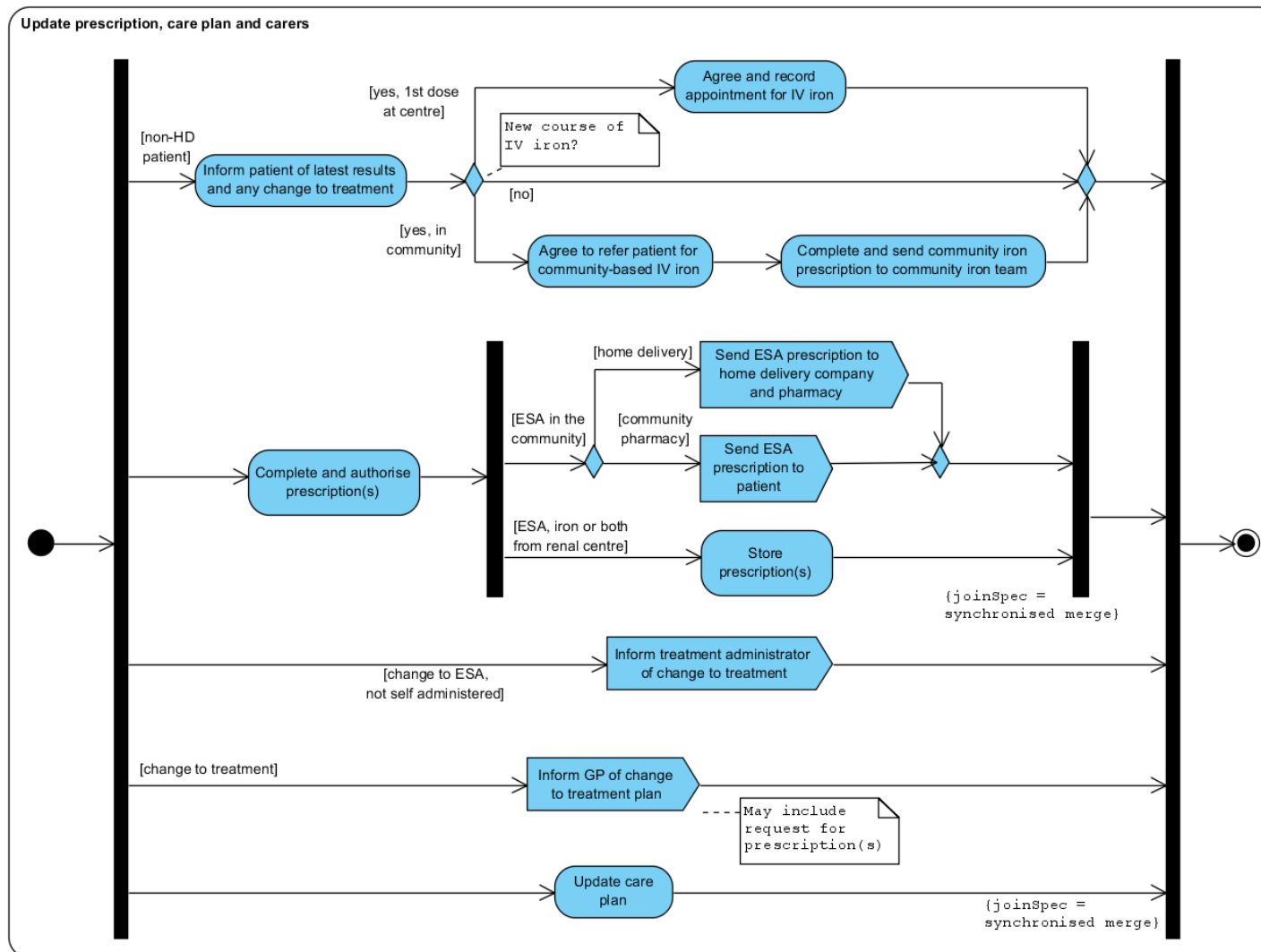


Figure 5.38 Activity diagram that decomposes the activity *update prescription, care plan and carers* from *review renal anaemia management*.

## 5.4 Discussion

This analysis has produced a framework describing the structure and processes of renal anaemia management. The service is described in terms of patient states, the use cases that make up the service categorised as observing, planning, intervening or supporting and the entities that collaborate to provide the service. Such a model provides a basis for drawing comparisons between differing approaches to renal anaemia management and may provide ideas where service delivery planning is occurring, either de novo or to reshape existing services.

The results described variety in process and structure, both between centres but also patient types and individuals. Much of this variety is so that the processes and provision of services fit with context. The care provided to a patient that is not renal anaemia management shapes the provision of renal anaemia management through opportunities for patient contact and the pre-existing conduct of tasks that would be required to manage renal anaemia successfully. Primarily this is renal care, in particular the HD session and also other opportunities for observation and planning. However, it is also the care that is provided for patients with chronic diseases by community services such as general practice and community matrons. It is also dependent on the configuration of care services in England and the ability to forge local arrangements, for example to provide IV iron in the community.

The extensive use of community services for non-HD patients means that a significant feature of the anaemia team role is of coordination. This is demonstrated in figure 5.18 for example, with potentially 12 different roles being requested to act or informed of the outcome of a single review, although usually it would be fewer. It is also highlighted by the few use cases of the anaemia team that involve face-to-face contact with the patient; after training the patient there may be occasional treatment with IV iron and at some centres anaemia clinics.

There is a structural network of carers, although it appears to be largely a hub and spoke type of network with relation to anaemia management (although with two hubs, patient and anaemia team). However, it may be that with a broader view of the network (i.e. not restricted to anaemia management) the pattern would look quite different. The high-level sequencing of activity is also network like and hence the number of use cases presented which are not represented with a high level activity diagram. Such a diagram is used to describe renal care in the Logical Record Architecture example (NHS Connecting for Health, 2010b) but is problematic because of the way it restricts sequencing and the ways it attempts to combat this (the diagram is reproduced in Appendix M). However, the activity diagrams presented here at an

elementary business process level are much more linear in their structure, with defined start and end points and a sequence between, although often one that allows for significant variety in the selection and ordering of actions within. This is a product of the identification of use cases that are required to have an identified start and end point, which in turn assists with comprehension.

#### **5.4.1 Strengths and limitations of the study**

This study used extensive observation, interviews and document sampling to ground the theoretical model in a rich dataset containing the conveyed knowledge and views of multiple stakeholder types. The use of eight sites provides increased abstraction from a single site and the likelihood of greater transferability of the framework. Although multiple centres were used, their selection was guided by the purpose of identifying causal factors in high and low performance in renal anaemia management, not of being representative of the population. However, as discussed in section 4.3.2 above, the centres that were selected represent a varied spread across many of the features that may have been used with that type of purposive selection.

The data collection was based in renal centres and the scope of the ethical clearance was limited to staff attached to the renal centre. For this reason the study did not involve patients, their carers and workers involved in renal anaemia management including GPs, members of the home delivery teams, practice and district nurses. This limits the degree of cross-checking possible between sources and the extent of detailed information about the practice of these workers. However, the lead role is taken by the renal centre and it is here that most care is provided.

Using the UML to provide semantics and syntax for the modelling approach, while challenging, resulted in models that should be less ambiguous than if it had not been used. However, breaking free from the limitations of an information systems textbook approach to the modelling and creating different views, in particular remodelling the boundary as the service, was beneficial in the analysis and synthesis.

#### **5.4.2 Observing, planning, intervening and supporting**

Comparing these models with the observe, plan, intervene type models two features are apparent: the multiple functions that may be served by these groups of activities and the presence of a large proportion of supporting or enabling activities. In table 5.1, four of the fourteen use cases serve more than one of the basic healthcare functions. For example, the

supporting use cases for the renal anaemia management service as defined here equal the observing, planning and intervening use cases in number (see figure 5.4). Interestingly, this echoes the role described by Sanders et al. (1999) of administration rather than patient care in section 3.3.4.

### **5.4.3 Unanswered questions and future research**

This research has not addressed the configuration of services where an anaemia team is not present. While it may be that service provision is similar in the absence of an anaemia team, it is possible that functionality is more integrated into other functions and without further research this cannot be known.

While this research has described some of the variety between services, it has not attempted to examine the appropriateness of different strategies or their impact on performance. In chapter 7, the research will go on to attempt to answer these questions.

This research has described the organisation of the management of renal anaemia using the Unified Modelling Language. This will enable the future description of individual approaches to renal anaemia management in a systematic manner, planning and sharing of service designs.

## Chapter 6

### **Relationship between performance and basic contextual features**

The aim of this research is to understand how the organisation of renal anaemia management influences its performance, with the purpose of enabling improvements to be made. As was described in chapter 3, several studies have suggested that organisational processes explain much of the variability in clinical performance measures for renal anaemia management between renal centres. Therefore, in chapter 7, organisational factors that may affect anaemia management will be examined. However, this chapter will consider whether and how more basic and contextual features affect performance within the renal centres in this research.

Several statistical analyses of large clinical databases have examined which variables are associated with achievement of clinical performance measures (Burton et al., 2000; Chan et al., 2008; Fink et al., 2007; Madore et al., 1997; Reddan et al., 2003). While these studies have used different measures of clinical performance, it is useful to compare and contrast their findings for variables, in particular because they have often used different variables and have not been brought together before. In table 6.1, the variables reported in each of these studies are listed along with details of which were statistically significant or not.

**Table 6.1 Comparison of factors associated with haemoglobin or haematocrit in five large statistical analyses (Burton et al., 2000; Chan et al., 2008; Fink et al., 2007; Madore et al., 1997; Reddan et al., 2003). \* = statistically significant (P < 0.05), NS = not significant, blank = not used.**

Group	Variable	Madore	Burton	Reddan	Fink	Chan	
Demo-graphics	Gender	*	*	*	*	*	
	Age	*	NS	*	*	NS	
	Race	*		NS	*		
Treatment	ESA dose	*		*	*	*	
	Dialysis dose (URR or Kt/V)	*		*	*		
	Prescription of IV iron			NS	*	*	
	Prescription of IV Epo			NS			
	Assignment to EPO protocol					*	
	Assignment to iron protocol					*	
	Length of time on RRT		*	NS	*	NS	
	Change of dialysis modality		*				
	Hct records per patient				*		
	Type of vascular access			NS			
	Dialyser KUF category			NS			
	Diagnosis and comorbidity	Cause of ESRD	NS	*	NS	*	
		Charlson comorbidity index				*	
Hospital days during year					*		
Diabetic status		NS					
Laboratory values	Ferritin	*		*		*	
	Transferrin saturation	*		*		*	
	Serum iron	*					
	Total iron-binding capacity	*					
	Serum albumin	*		*		*	
	Creatinine concentration	*					
	C-reactive protein					*	
	Total cholesterol					*	
	Parathyroid hormone					*	
	Anion gap	*					
	Calcium	*				NS	
	Lactate dehydrogenase	*					
	Bilirubin	*					
	Glucose	*					
	Cholesterol	*					
	Uric acid	*					
	White blood cell count	NS					
	Phosphorus	NS				NS	
	Sodium	NS					
	Potassium	NS					
Sociological factors	Employment				*		
	Health access				*		
	Socioeconomic status				*		
	Poverty factor				*		
	Urban factor				*		
Facility factors	No. of patients				*		
	Patients per station				*		
	profit status				*		

The results of these studies, although largely based on data from the US, suggest that centres with a higher proportion of older, female, non-white patients in urban areas with high poverty and low socio-economic status are likely to have a lower percentage of patients achieving their clinical performance measure for haemoglobin. In addition, a large number of laboratory and treatment related variables that are significantly associated with haemoglobin are identified. Associations with comorbidity are confirmed, while two studies identify diagnosis as significantly associated while two find it not significantly associated with haemoglobin. However, for many of these associations, the direction and mechanism of causality are unknown.

Two of the three studies to include race in their analysis found it to be a significant factor. In a recent study, the impact of ethnicity and socio-economic status on attainment of  $Hb \geq 10$  g/dl in the UK was examined using Renal Registry data (Udayaraj et al., 2009). Because ethnicity and socio-economic status are correlated, the analysis examined each separately and examined socio-economic status among white patients only. Socio-economic status was significant after adjustment for patient factors, but following adjustment for a centre effect the difference became insignificant. Ethnicity remained significant after adjustment for patient factors, area-level social deprivation and a centre effect; specifically, Black patients were statistically less likely to have  $Hb \geq 10$  g/dl than White or south Asian patients were. Therefore, it appears that in the UK, socio-economic status is simply correlated with low haemoglobin whereas Black patients may be more likely to have a low haemoglobin level because of underlying genetic differences, although the reasons are not known. This concurs with a finding of reduced erythropoietic response to epoetin alfa among Black US patients (Jones-Burton et al., 2005).

Of the five studies presented in table 6.1, only one analysed centre-specific features and this was in a US context (Fink et al., 2007). The authors found that the number of patients (+ve), patients per dialysis station (+ve) and profit status (for-profit) were associated with higher haematocrit values. Profit status is of little relevance in England with the NHS providing care free at the point of use, because although some satellite dialysis units are privately owned, the care offered is directed from within the NHS. The finding that more patients per dialysis station is associated with improved performance for anaemia management is interesting and goes unexplained in the study, although one could imagine this was not an association with over-population but with a popular facility. A finding of greater patient numbers being associated with improved performance for anaemia management is also interesting. However, the analysis was of US data and the dialysis facilities associated with the

middle quintile of haematocrit had  $66.9 \pm 43.4$  patients, which is similar to a large satellite unit in England; whereas, renal centres in England are typically much larger, with an average population of 312 HD patients (calculated from data in Farrington et al., 2009).

None of these studies examined the impact of resource on anaemia management, although the finding of non-profit and government facilities being associated with low haematocrit in the US may be a surrogate for resource. However, intriguingly at an individual level, four of these studies examined ESA dose and found it negatively associated with haemoglobin, suggesting resistance to ESA outweighs any potential rationing effect. Yet none have studied whether the number of clinicians is associated with achievement of clinical performance measures for anaemia. A recent survey of UK renal centres has found increasing relative numbers of nephrologists are significantly associated with better phosphate control and increasing relative numbers of dieticians significantly associated with better parathyroid hormone levels (Casula et al., 2009; Hodsman et al., 2009). Typically, an increase in labour input would result in some increase in output.

While the studies by Chan et al. (2008), Fink et al. (2007) and Burton et al. (2000) have shown that after the parameters they included are taken into account the organisation itself is still strongly associated with performance, it is still useful to understand how such parameters may affect the performance of the centres in this study. Furthermore, clinical resource has not been analysed with haemoglobin in renal anaemia management.

## 6.1 Methods

During the course of this research, a large number of basic details about each centre were recorded including data on staff numbers, number of patients per group, type of ESAs and IV iron treatments used, and regularity of testing per patient group. Data available from the Renal Registry report includes number of patients and ethnicity of HD patients. Using a combination of this data, a wide range of comparisons were performed at a centre level including comparisons of resource, ethnicity and size with performance, which are presented in this chapter.

### 6.1.1 Resource

To examine how performance was affected by resource, a relative resource of full time equivalent (FTE) clinicians per thousand population (HD patients) was calculated and compared with performance. Separate comparisons were made for consultants and anaemia nurses. Because some centres have a specific iron nurse role, while for others this is included in the anaemia nurse role, two alternative analyses of nurse resource were performed, one using just anaemia nurses and one using the sum of anaemia nurses and iron nurses. Regressions of the performance according to the NICE indicator on the log of relative resource were also performed for the calculations of resource. A log transformation of relative resource was appropriate because one would expect that as resource increases, increases in achievement of percentage performance would decline. The regression analyses were performed in Microsoft Excel (2007).

### 6.1.2 Ethnicity

To protect the anonymity of participating centres, a scatter plot comparison of ethnicity and performance cannot be presented because the data are publicly available and easily comparable. Percentage of Black prevalent dialysis patients on 31/12/07 in English centres was calculated for each centre, which were then split into quintiles where 1 is the quintile of centres with the smallest percentage population of Black patients and 5 relates to the largest (calculated from data in Farrington et al., 2009). Where ethnicity data was missing, an assumption was made that relative proportions in each category were not affected.

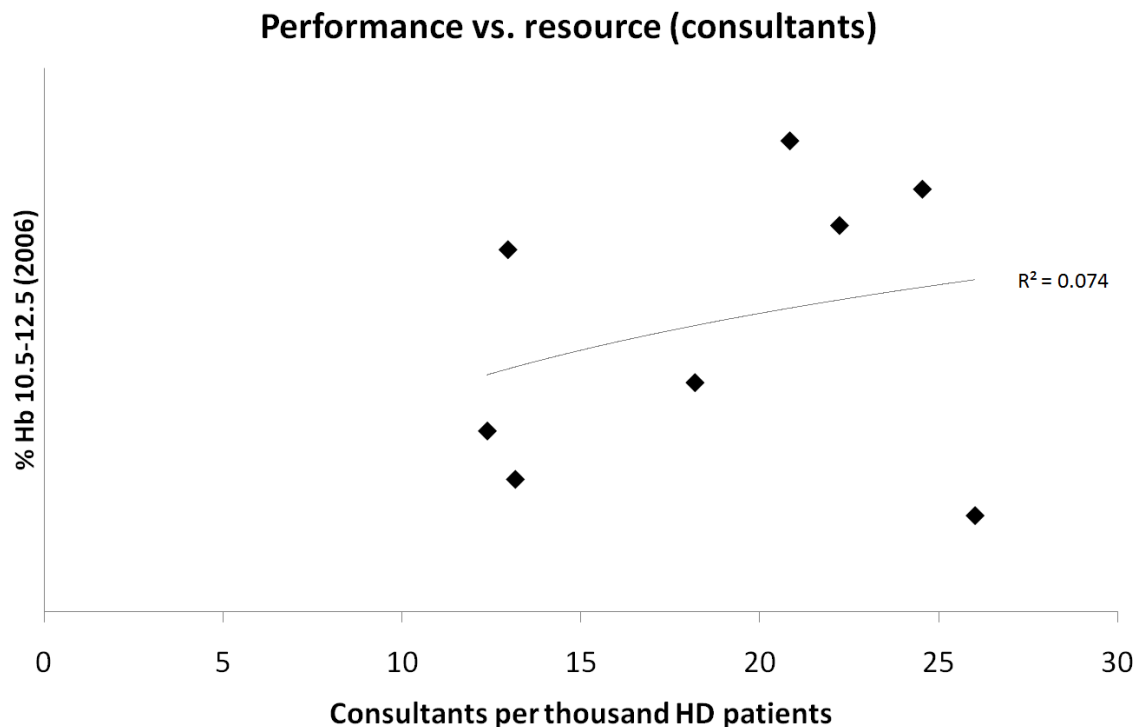
### **6.1.3 Centre size**

Data on centre size (number of patients) is available from the Renal Registry. A scatter plot comparison of size and performance cannot be performed here because the data are publicly available and easily comparable. The centres were categorised by number of prevalent dialysis patients on 31/12/2007 in English centres into quintiles where 1 is the quintile of smallest centres and 5 relates to the largest (calculated from data in Farrington et al., 2009).

## 6.2 Results

### 6.2.1 Resource

The results of the comparison of performance on resource are presented in figure 6.1 to figure 6.3, including lines of regression. For consultants, the regression model shows no relationship with  $R^2 = .074$ ,  $F(1,6) = .48$ ,  $p = .51$ . For anaemia teams the regression models are statistically insignificant but close to  $p = .05$  and would explain a large proportion of variance in performance,  $R^2 = .429$ ,  $F(1,6) = 4.50$ ,  $p = .078$  and  $R^2 = .466$ ,  $F(1,6) = 5.23$ ,  $p = .062$  for anaemia nurses only and anaemia and iron nurses respectively. For anaemia and iron nurses, the means were 3.75 and 6.12 FTE per thousand patients for low and high performing groups respectively. If the relationship for anaemia and iron nurses held, a centre with three of these nurses per thousand patients would achieve 39% of patients with Hb 10.5-12.5 g/dl, while with six nurses per thousand patients they would achieve 54%. Despite the log transformation, it appears from figure 6.2 and figure 6.3 that the regression equation for nurses does not achieve linearity, with most points below the lines of fit for low resource levels and most points above the lines of fit for high resource levels.



**Figure 6.1 Anaemia management performance vs. relative resource (FTE consultants per thousand HD patients)**

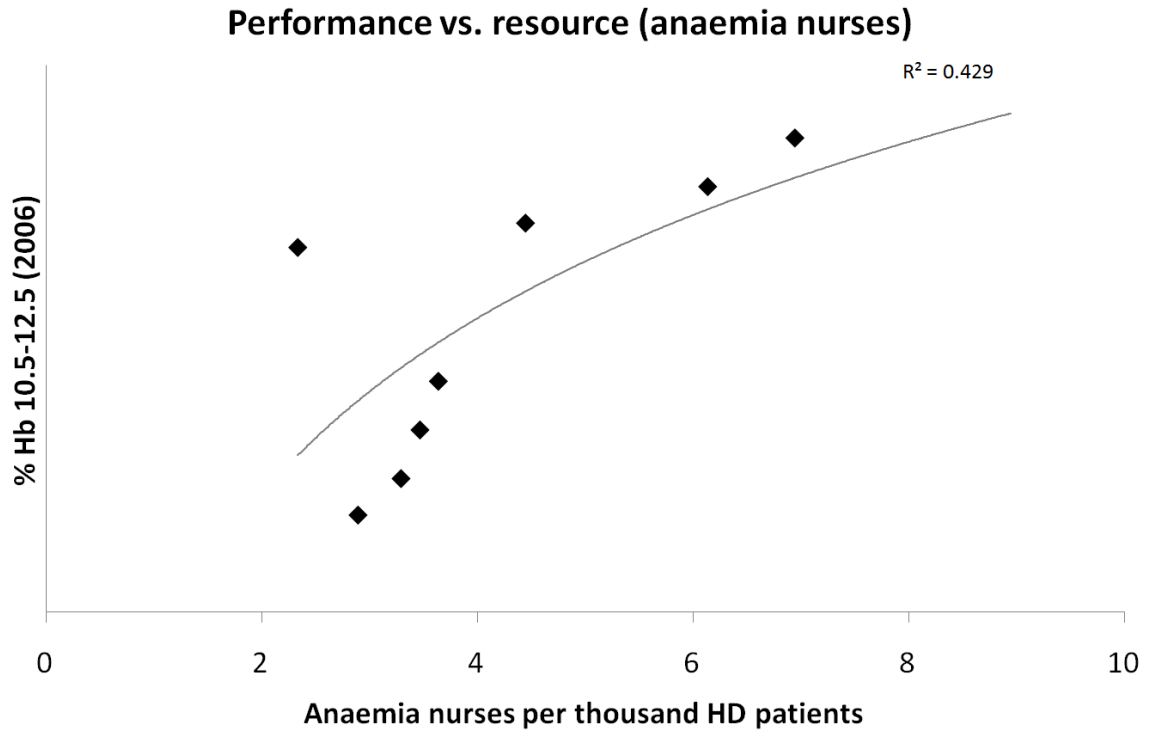


Figure 6.2 Anaemia management performance vs. relative resource (FTE anaemia nurses per thousand HD patients)

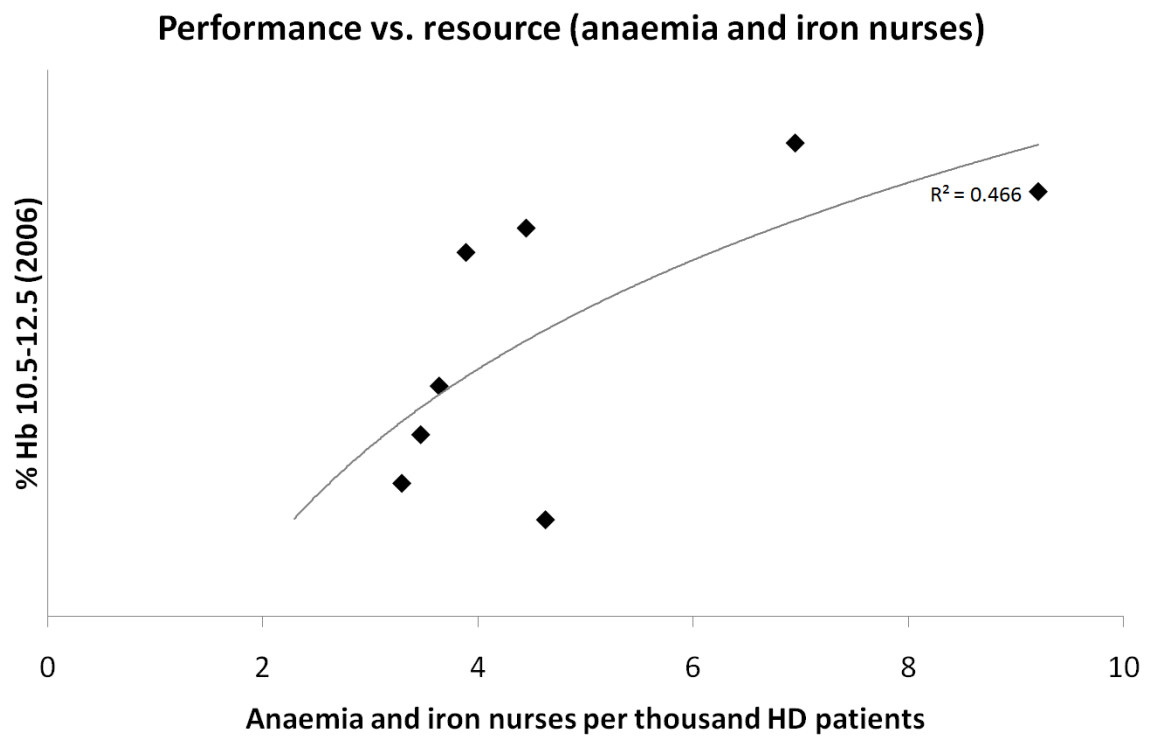


Figure 6.3 Anaemia management performance vs. relative resource (FTE anaemia nurses and iron nurses per thousand HD patients)

### 6.2.2 Ethnicity

At some participating centres, there were relatively few records of ethnicity (up to 40% missing data). However, a comparison of the adjusted percentages with the raw percentages found only one of the high performing centres would have changed quintile (up one, not identified here for the purposes of anonymity).

Table 6.2, reproduced from chapter 4, method, identifies some of the basic features of the participating renal centres including ethnicity and centre size. It can be seen that the high performing centres are in the central three quintiles of centres, while the two centres that are low performing against both the NICE clinical performance indicator and for Hb  $\geq$  10 g/dl are in the quintile of centres with the largest percentage of Black patients. The two centres that are high performing for Hb  $\geq$  10 g/dl but low performing against the NICE standard are in the 2<sup>nd</sup> and 5<sup>th</sup> quintiles of size.

**Table 6.2 Basic features of participating renal centres (reproduced from chapter 4, method and sorted by performance groups).**

Centre	Performance group Hb 10.5-12.5 <sup>a</sup>	Performance group Hb $\geq$ 10 <sup>b</sup>	Number of consultant nephrologists	Number of satellite units	Size (scale 1-5) <sup>c</sup>	Ethnicity (scale 1-5) <sup>d</sup>
<b>B</b>	High	High	5	2	3	2
<b>D</b>	High	High	4	2	2	3
<b>F</b>	High	High	4	2	2	2
<b>H</b>	High	High	7	2	4	4
<b>C</b>	Low	High	5	2	3	5
<b>G</b>	Low	High	9	3	4	2
<b>A</b>	Low	Low	11	6	5	5
<b>E</b>	Low	Low	13	5	5	5

<sup>a</sup> Group based upon percentage of HD patients with haemoglobin between 10.5 and 12.5 g/dl, 2006. (calculated from data in Richardson et al., 2008)

<sup>b</sup> Group based upon percentage of HD patients with haemoglobin greater than or equal to 10 g/dl, 2006. (calculated from data in Richardson et al., 2008)

<sup>c</sup> Size measured by number of prevalent dialysis patients on 31/12/07 in English centres split into quintiles where 1 is the quintile of smallest centres and 5 relates to the largest. (calculated from data in Farrington et al., 2009)

<sup>d</sup> Percentage of Black prevalent dialysis patients on 31/12/07 in English centres split into quintiles where 1 is the quintile of centres with the smallest percentage population of Black patients and 5 relates to the largest. (calculated from data in Farrington et al., 2009)

### **6.2.3 Centre size**

It can be seen from table 4.2 that in this study, the high performing centres are in the 2<sup>nd</sup> to 4<sup>th</sup> quintile of size while both of the low performing centres are in the quintile of largest renal centres. The two centres that are high performing on the UK minimum standard but low performing against the NICE standard are in the 3<sup>rd</sup> and 4<sup>th</sup> quintiles of size.

## 6.3 Discussion

This research has found an apparently strong, but statistically insignificant association between nursing resource and achievement the NICE performance indicator. In addition, there is some evidence of association with increasing numbers of patients and minority ethnic patients with decreased achievement of the NICE performance indicator.

### 6.3.1 Resource

The apparent relationship between resource (in terms of anaemia and iron nurses) and achievement of the NICE performance indicator, with a reported goodness of fit ( $R^2$ ) of 46.6% is statistically insignificant (taking  $p = .05$  as the threshold), although this is not surprising given the small sample size. These preliminary findings justify wider study of the association between nursing resource and clinical performance measures.

There seems to be little relationship for consultants, although it is possible one centre is acting as an outlier. However, a lack of relationship would not be surprising as a consultant has a much wider role and among these centres, the anaemia team performs the majority of work for anaemia management.

This apparent relationship with level of resource is a rather different finding to that from a very recent U.S. study that found no relationship between the presence of an anaemia manager and haemoglobin performance (Spiegel, Bolus, Desai, Zager, Parker, Moran, Bolus et al., 2010). The lack of such a basic relationship is something that this study concurs with, having centres from both extremes of performance, all of which have an anaemia nurse role.

The calculation of relative resource is limited in this analysis because the extent of the role of the anaemia nurse is not captured. For example, as described in sections 3.3.4 and 5.3.4.2, there are centres where some of the IV iron for non-HD patients is administered in a community setting, thus reducing the overall workload on an anaemia nurse. Similarly, there are differing degrees of information system support that automate certain tasks or may reduce the effort to perform them. A related problem is that there are renal centres outside of the present study that do not have an anaemia nurse (i.e. the role is performed by others), for which a comparison of performance with anaemia nurse resource would be a meaningless calculation.

### 6.3.2 Ethnicity

Performance appears to be correlated with ethnicity among this group of renal centres, which is in line with the expectations based on the analyses presented in the introduction. However, interestingly none of the high performing centres are in the 1<sup>st</sup> quintile, although three of the four centres that are low performing against the NICE guideline are in the fifth quintile. Therefore, while it would seem that the low performing centres have a particularly high proportion of Black patients, which is likely to affect their performance, the high performing centres do not have a particularly 'easy' population and one is in the fourth quintile.

### 6.3.3 Centre size

Performance appears to be correlated with centre size in a similar way as for ethnicity. This is apparently in disagreement with the finding of Fink et al. (2007) who found a larger centre was associated with better performance, although as was noted earlier, that was among a sample of much smaller centres in the US.

### 6.3.4 Study limitations

The study only examines the characteristics of eight centres so statistical comparisons are weak. Moreover, the comparisons are against a raw performance measure, rather than one weighted for other factors. Although, the small number of centres mean the introduction of additional variables into a regression would increase the likelihood of spurious correlation. Statistical comparisons were only reported for the comparisons of resource, although the purpose of the comparisons was not to establish generic trends, for which a larger dataset would be necessary but to examine how these factors appear to affect these centres.

### 6.3.5 Conclusion

The performance of the centres in this study may be associated with resource, ethnicity and centre size, although these were not statistically significant, perhaps due to the small sample size. However, previous studies that have adjusted for similar factors have still found significant differences that are associated with the centre and believed to be related to organisational processes.

## **Chapter 7**

### **Factors affecting the performance and organisation of renal anaemia management**

Differences between renal centres' performance in the management of renal anaemia are believed to be partly related to the processes by which patients are managed, and partly to differences in factors such as resources, case mix and socio-economics (Burton et al., 2000; Fink et al., 2007). While the latter have been examined quantitatively using large datasets, the former have largely been the subject of speculation. It is important that the relationships between these processes and performance are examined in detail so that there is greater evidence behind recommendations for organisational change. It is also important to examine the contexts that shape existing services to consider whether features of one service may be transferrable to another, or whether changes in regional or national policies, contracts, laws, etc. could enable improvements.

#### **7.1.1 Chapter context**

This research aims to identify and explore the features that explain differences in performance between renal centres, to provide an evidence base for service improvement. As described in chapter 4, observations, interviews and document sampling were used to gather data that would elucidate the organisational factors that may be significant in the performance of renal anaemia management. Chapter 5 developed a framework of the services provided and approaches to the delivery of renal anaemia management, which provides a context for examining differences in process. Chapter 6 compared three key features between the centres and found limited evidence that they may contribute to performance differences. This chapter reports on other organisational differences between the renal centres studied and the way they can influence performance.

#### **7.1.2 Outline of chapter**

This chapter presents the results of exploratory fieldwork and analysis, much of which was not anticipated to be of relevance from the outset. An overview of the analysis specific to this chapter is presented in section 7.2, with reference to the methods chapter for the fieldwork and much of the analytical process. In section 7.3, the findings of the analysis are

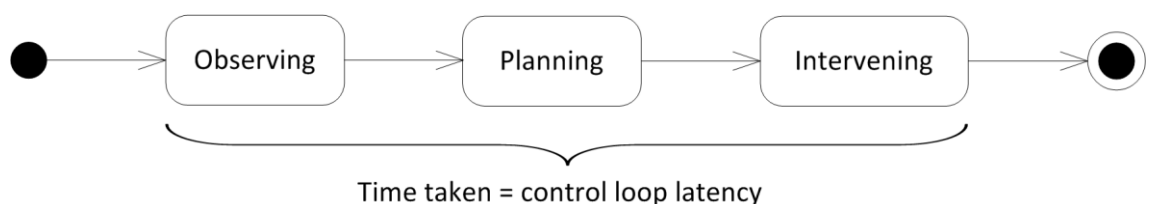
presented, including details of specific methods and summary discussions for each theme in order to contain them. The main findings are that latency in the control loop (delays), reliable administration of ESA, coordination of ESA administration, interaction, roles and relationships may all affect the quality of renal anaemia management. In addition, decision support systems and interventionism (likelihood of making a change to treatment) are weakly associated with performance indicators. These findings are synthesised into a network in section 7.4 and the implications of the findings are discussed in section 7.5. Background information and literature of relevance to the findings is presented below.

### 7.1.3 Background

#### 7.1.3.1 Control loop latency

Delays are a recognised problem in many areas of the health service and have been the subject of government targets such as a maximum four hour waiting time for emergency departments (Department of Health, 2007b) or eighteen weeks between identification and treatment for all hospital patients (Department of Health, 2006b). However, there is little evidence in the literature of examination of the impact of delays in the response of clinicians in the ongoing processes of chronic care. Nevertheless, latency in the control loop for diabetes has been examined in reference to the development of an artificial pancreas and a closed loop (automated) control system, as delays in measurement of glucose and circulation of subcutaneously injected insulin to its sites of action are currently too great to prevent damage to patients (Aström & Murray, 2008; Hovorka et al., 2010; Renard, 2010).

With respect to the models of clinical process examined in the introduction to chapter 5, this latency is the time taken to traverse the entire process from observing to intervening (see figure 7.1). In systems terminology this is latency within a feedback loop, where observations (in this case primarily blood tests) of the system (patient) are signals that the controller uses to modify the system's controlled inputs (primarily ESA and iron); a perspective proposed for renal anaemia management in a recent analysis of haemoglobin variability (West et al., 2007).



**Figure 7.1 Control loop latency in relation to the clinical process model**

Control loop latency is something that has received very little attention in renal anaemia management. In national guidelines (McMahon, 2008; NICE, 2006a; Renal Association, 2008; US National Kidney Foundation, 2006, 2007), while there are recommendations about testing frequency there are no recommendations about the time taken to review test results or effect adjustments to patient management. However, at the joint Renal Association and British Renal Society's anaemia quality improvement collaborative supported by the NHS Institute (Renal Association, 2007), Roberts (2007) presenting results of a survey of 4 high performing centres recommended that test results be reviewed within days rather than weeks and that patients have their ESA administered on the HD unit. Both of Roberts' recommendations relate to latency, while the latter recommendation may also relate to the reliability with which ESA is administered.

### 7.1.3.2 Haemoglobin variability, latency and interventionism

Within renal anaemia, recent interest in delays has related to *haemoglobin cycling* or variability, as discussed in section 3.3.8 of the context chapter, where patients oscillate above and below the bounds of a haemoglobin target on a regular basis. It has been argued that one of the practices that causes haemoglobin cycling is hyper-responsiveness on the part of clinicians: either being too hasty to make repetitive changes to ESA or an excessive change in dose when haemoglobin takes a long time to respond to a change in treatment (see section 3.3.8). This chapter examines the phenomenon of repetitive changes as *interventionism*, the likelihood of a patient having their dose changed, as well as latency in the control loop. However, the speed with which a dose change is repeated is a different but related measure of latency to that discussed above, as it refers to the time between the enactment of an ESA regime, subsequent tests and a resulting adjustment of that regime, rather than the time between a test and the enactment of an ESA regime. There is a third type of latency alluded to here, that of biological latency described in section 3.3.1, where it can take several months for a new steady state of haemoglobin to be reached given a change in ESA.

The NICE guidelines recommend intervening (changing the ESA dose of a patient) when a patient's haemoglobin level is below 11 g/dl or above 12 g/dl (NICE, 2006a) (see also section 3.3.7, protocols, algorithms and decision support systems). As described in section 3.3.5, guidelines for renal anaemia management, prior to the introduction of a target range (i.e. 10.5-12.5 g/dl) for haemoglobin, the previous standard across the UK was to maintain  $Hb \geq 10$  g/dl. In order to achieve this the approach adopted by numerous successful centres (Leeds and York (Richardson et al., 1999; Richardson et al., 2000, 2001), Bradford (Roberts,

2007), Truro (Benton, 2008)) involved intervening in a patient's ESA dose before their haemoglobin fell to  $\leq 10$  g/dl. In effect, these centres were proactively adjusting treatment to guard against a fall below 10 g/dl rather than reacting to such a fall. Therefore, the policy in these cases and now recommended by NICE is to intervene proactively.

The policy of intervening proactively described immediately above stands in contrast to the argument that excessive intervention may cause haemoglobin cycling. Therefore, it is unclear whether centres will produce better results through tighter or looser patterns of intervention.

### **7.1.3.3 Reliability of administration of ESA**

The existing literature on the reliable administration of ESA is small, with two studies of one aspect, compliance in PD patients in the USA who were self-administering ESA. The two studies available found 35% and 45% non-compliance, (Nicoletta et al., 2000; Wazny, Stojimirovic, Heidenheim & Blake, 2002), suggesting that it could be a significant problem. The most common reasons cited among the 14 respondents in the study by Wazny et al. (2002) were forgetting to administer ESA and finding the injection unpleasant or painful.

### **7.1.3.4 Coordination in renal anaemia management**

There has been great interest in coordination of healthcare in recent years (Bodenheimer, 2008; Keen, Moore & West, 2006; Young et al., 1997; Young et al., 1998) with interest in the mechanisms used and their impact upon performance. Coordination is the management of dependencies between activities (Malone & Crowston, 1994) and is essential to good performance in all organisations (Van De Ven, Delbecq & Koenig, 1976). It is achieved through the sharing of information (feedback) or certainty of process (programming) (Van De Ven et al., 1976). Coordination of healthcare is the harmonisation of multiple care providers for and with an individual and their informal carers (Bodenheimer, 2008; Young et al., 1997). Three formal mechanisms of coordination have been proposed: routines (repeated processes), team meetings and boundary spanners (roles of integration and coordination) (Gittell, 2002). Within healthcare these are care pathways, (multidisciplinary) team meetings and a wide range of roles including care coordinators, general practitioners, etc. respectively. In addition, a fourth and informal mechanism where feedback occurs spontaneously and outside of formal mechanisms is termed relational feedback and is also known as teamwork (Gittell, 2002).

As was discussed in the sections on variety in renal care and impact on outcomes and service delivery for renal anaemia management (sections 3.2.4 and 3.3.4 respectively),

multidisciplinary team care and anaemia coordinators are coordination mechanisms in use within the problem domain, with multidisciplinary care often associated with better outcomes. In addition, in chapter 5 a variety of routines for renal anaemia management in current use were described. However, there is no published work on relational coordination in renal anaemia management.

#### **7.1.3.5 Background summary**

There is little literature on delays in the ongoing control loops of chronic care. While the haemoglobin cycling literature suggests that interventionism may be a cause of haemoglobin variability, the algorithm provided with the NICE guideline encourages a narrow pair of intervention thresholds. It is unclear what degree of interventionism is appropriate to minimise haemoglobin variability. There is also little literature on adherence to ESA or its reliable administration. While MDTs, anaemia nurses and well-codified routines would all be expected to improve coordination (and in the case of MDTs appear to improve renal care), there is no literature on relational coordination in renal anaemia management.

## **7.2 Methods**

Data collection for this study involved participant as observer observation, semi-structured interviews and document sampling as described in chapter 4, methodology. A significant part of the analysis involved familiarisation with the data, development of a coding scheme, descriptive and analytical coding and memoing also described in the methods. In this chapter, factors were analysed with cross-case comparison and comparison between performance groups. In addition, each factor was categorised with respect to being a context, process or outcome and, for contexts, by who controls or owns it. Links between these factors were also explored.

### **7.2.1 Theme selection**

The themes discussed in this chapter relate to the question, ‘how do processes and context influence performance of centres with respect to guidelines for patient indicators in renal anaemia management?’ The themes reported in this chapter are a selection of possible themes and each has been chosen because of its relevance to the question and because it was: mentioned by multiple participants; related to the prior framework; observed and considered particularly striking or interesting; or due to a combination of these. Not all themes analysed are presented here, for example the impact of Payment by Results, part of the financial apparatus of the NHS, that some participants argued affected their ability to choose the best form of iron treatment will not be presented because its link to performance is purely hypothetical, and less likely to explain variation in clinical performance between centres in England, all of which were subject to the same pressures.

### **7.2.2 Ethics**

Because of concerns regarding anonymity raised by the main research ethics committee for this research, the ethical clearance does not allow quotations to be linked to renal centres, despite their pseudonymisation throughout. Therefore, where quotations appear they will not be linked to a specific centre, but may be linked to a group of centres (e.g. high performing).

### **7.2.3 Network of contexts, mechanisms and outcomes**

The analysis described here identified a complex set of interrelated factors that may contribute to the performance of renal anaemia management. In order to capture these

relationships and synthesise the findings of the chapter, a modified version of a diagram known as a Benefits Dependency Network (BDN) (Ward & Daniel, 2005) will be used.

A Benefits Dependency Network (BDN) is an approach to formulating a set of organisational changes designed to achieve certain business objectives developed at the Cranfield school of management (Ward & Daniel, 2005). It is designed to ensure that investments in information technology are viewed in a strategic context as enablers of organisational change, linked in turn to benefits, rather than separately to such objectives. A BDN bears much in common with any causal network, although it does not claim deterministic causality, merely enablement. In a BDN, elements are categorised as one of: IS/IT enabler, enabling change, business change, benefit or investment objective. These categories are based upon the purpose of identifying changes in a single organisation with a focus on IT, rather than exploring differences between organisations. Therefore, in this chapter the categories have been adapted to reflect their new role, while retaining the essence of the components that they include. Context will replace IS/IT enabler and enabling change as states of the organisation or wider systems that enable or disable processes or their features. Process difference replaces business change as the generative mechanism for a result difference. Result difference is used instead of business benefit as an outcome of a process difference with respect to a wider objective. Result is used in preference to outcome or performance because of the traditional association within clinical research of outcomes to patient outcomes and the prevalent use of performance to refer to clinical performance indicators in this thesis. The investment objective simply becomes an objective: *improve performance with respect to the NICE guideline*. Using this approach, the BDN illustrates how context shapes the processes in use and the outcomes achieved, meaning it is an excellent fit with the generative explanations of realism described in section 4.2, research philosophy.

Following the analysis of each major theme, a table will present the elements and links identified and their categorisation according to the scheme described above. In addition to this scheme, each contextual difference will be categorised according to the first level at which it can be influenced, choosing between renal centre, local health economy and government. This is to highlight which contextual enablers may be affected by the renal centre themselves and which require cooperation from other parties.

## 7.3 Findings

### 7.3.1 Latency in the management of renal anaemia

At all high performing centres, multiple participants identified ‘timeliness’ as an important factor in their performance. Similarly, in the two centres where both performance measures were low, ‘delays’ or ‘lags’ were often identified as important contributors to their results. The timeliness or delays relate to the time between a blood sample being taken and a decision based on that sample being enacted (when the patient receives a different dose of ESA).

This section examines evidence gathered on the impact of latency in the clinical process of renal anaemia management on patients’ anaemia and the causes of latency in participating renal centres.

#### 7.3.1.1 Relationship between control loop latency and performance

In order to examine whether there was evidence of a relationship between control loop latency and performance, estimates of latency for each centre were compared with performance as measured by the NICE guideline (Hb 10.5-12.5 g/dl) in the Renal Registry report (Richardson et al., 2008, 2010). Through observations and interviews, I estimated the time taken between a routine (monthly bloods) blood sample being taken from an HD patient to them receiving their first new dose of ESA in the case of a change. Because the latency was markedly variable in several centres, estimates of minimum, maximum and median latency were produced.

For parsimony, I excluded those occasions where a patient was not tested successfully during routine bloods (due to absence or the sample clotting for example) as this may reduce the gap between that patient’s blood sample and their first new dose of ESA, but increase the time taken from routine bloods. I have also excluded situations where a dose change, despite being chosen, did not take place (due to miscommunication or non-adherence for example) as the maximum latency would be infinite in this case. I have assumed that all ESAs act equally quickly to begin stimulating erythropoiesis, a simplification based upon the common mechanism of action and its relative speed (Elliott et al., 2008). Therefore a change of dose with one type of ESA would take the same amount of time to adjust a given haemoglobin as with another and therefore the time when a patient receives their first new dose is an

appropriate measure, independent of ESA type which varies both between and within renal centres.

The estimates are based upon two factors discussed in detail below, the time taken to review anaemia management and the time taken for a patient to receive their new dose. In the first case this was based primarily on observation but also on interview data. In the second case, for centres who did not administer ESA to their patients this was based on interview data, while for the rest a combination of interview and observation data was used. The maximum estimates given for the time taken for a patient to receive their new dose at centres who did not administer ESA were between six weeks and two months. Therefore, a six-week estimate of the maximum was used at all of these centres in order not to overestimate the time taken.

Data are presented without labels identifying centres or labels giving absolute values for performance to maintain anonymity because the performance data are publicly available.

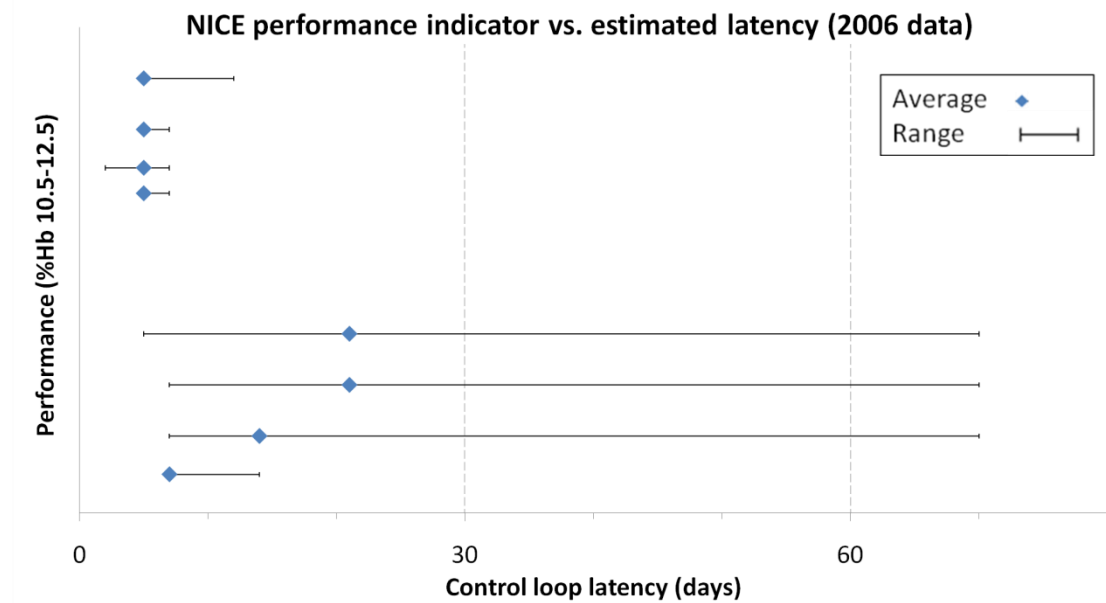
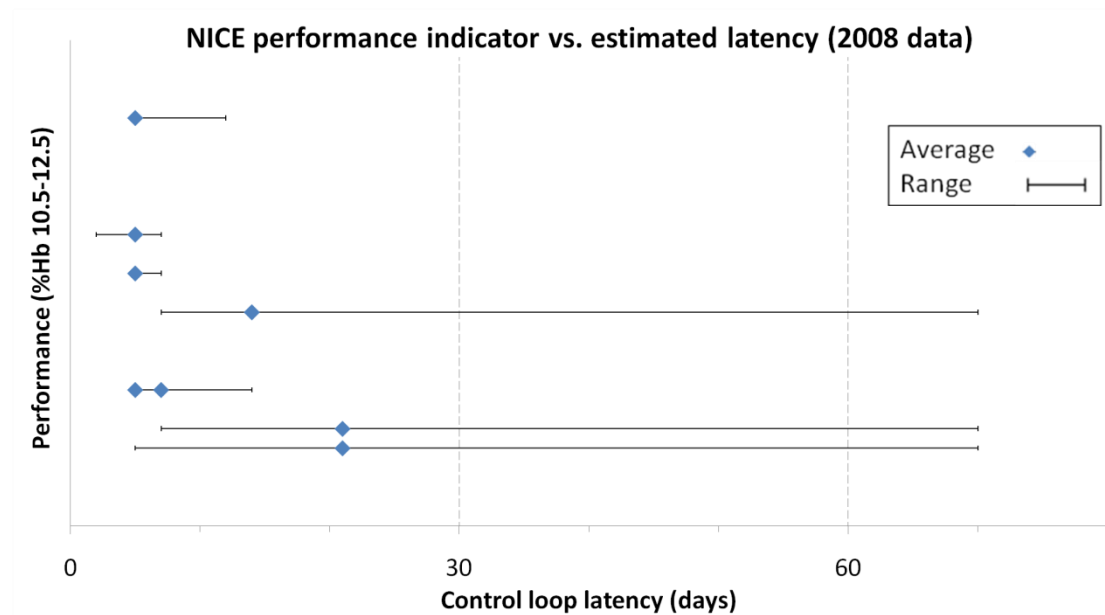


Figure 7.2 NICE anaemia management performance indicator vs. estimated ESA dose change latency for HD patients in 2006.

Figure 7.2 shows estimates of latency for the eight participating centres, compared with performance for 2006, the performance data from which centres were selected. The graph demonstrates that all high performing centres effect changes to their HD patients' anaemia management within 12 days, much faster than three of the four low performing centres (70 days). The median is also slightly faster in all cases for the high performing centres.



**Figure 7.3 NICE anaemia management performance indicator vs. estimated ESA dose change latency for HD patients in 2008.**

The difference in performance between centres is less stark using the latest data (from the end of 2008, published Feb 2010). In particular, the low performers have all improved, some significantly and, although there is steady improvement for three of the four high performing centres, one has dropped by 8%. This means there are now two centres that are fast but relatively low performing (this is discussed in section 7.3.1.4 below).

### 7.3.1.2 The causes of latency in renal anaemia management for HD patients

Because latency appears to be closely related to performance, this section examines the stages at which this arises and the reasons in each case. The contributory factors were identified primarily through interview and where possible their presence was confirmed through observation and interview. There are two key components to the time taken to change anaemia management: the time between test samples being taken and a new decision being made, and the time from that until the patient receives their new treatment. In each case there are a variety of factors that contribute, although in the first these are largely operational factors while in the second case they are largely financial. In figure 7.4, a sequence diagram is used to illustrate one example of a sequence of interactions and some of the entities that that can be involved in the control loop for a haemodialysis patient. The actions, delays and their alternatives, as well as some of their context and motivations are described in detail in the sections below.

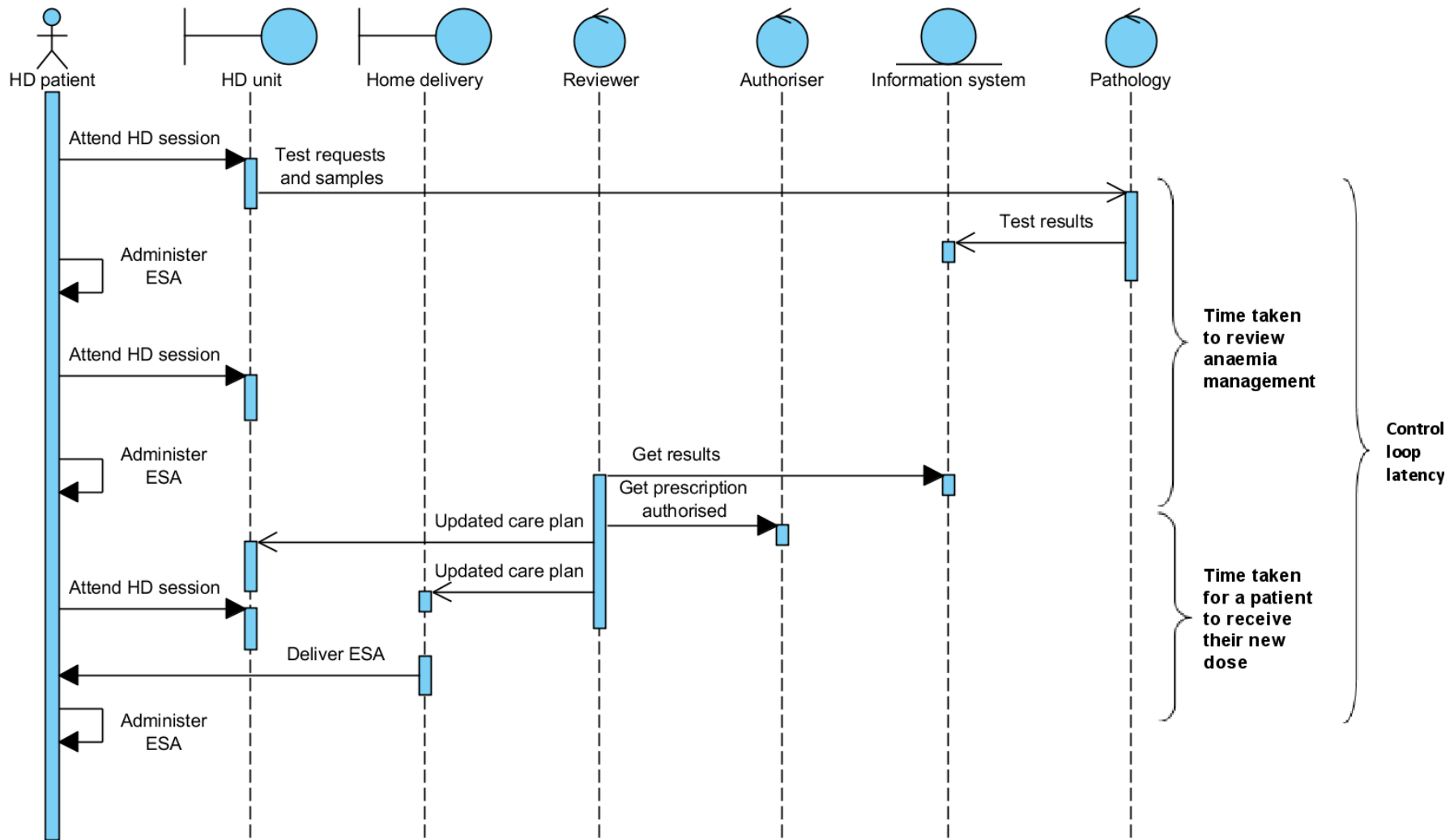


Figure 7.4 Sequence diagram illustrating the parts of control loop latency in an example using a separate reviewer and authoriser, home delivery and a patient who self-administers ESA thrice weekly

### 7.3.1.2.1 Time taken to review anaemia management

Reviews of anaemia management following routine bloods (scheduled testing of a group of HD patients) use a variety of approaches as discussed in section 5.3.3. However, all involve (at least one) batch review of all patients tested. At the three consistently high performing centres (B, D and H), the review began promptly following routine bloods (typically on Thursday and always by Friday, with samples being taken Wednesday and Thursday) and was conducted by an anaemia nurse alone. In contrast, the review began at least one week after routine bloods at three low performing centres (A, C and G) and in some cases this would stretch to two, three or even four weeks on a regular basis. In these three cases, the review took place as part of an MDT meeting. At all but one centre (F) there were MDT meetings to discuss the results of routine bloods but at only four of these had the anaemia management been reviewed separately and more promptly (B, D, E and H).

### 7.3.1.2.2 Time taken for a patient to receive their new dose

The speed with which a change of dose is achieved is affected by the mechanisms for prescribing and supplying ESA. A doctor or nurse prescriber from within the renal centre may prescribe ESA, or it may be prescribed by the patient's GP. When prescribed by the renal centre, ESA may be provided from the haemodialysis unit, via a home delivery service or dispensed by a community pharmacy. When a GP prescribes ESA, it is dispensed by a community pharmacy (see also figure 5.25, p. 92).

Where a patient's ESA is GP prescribed (A, C and previously E), the renal centre has to communicate the required change to them, a process that can take up to two months. Alternatively, where the centre prescribes ESA, three factors may delay a change in treatment: the time taken to authorise decisions, the use of a home delivery service and the frequency with which ESA can be administered. If the anaemia team does not have the right to prescribe and the review did not involve a doctor (as at B, D and E for HD patients), there can be a delay while the prescriptions are signed; this can be further delayed if there are disagreements over the initial decision.

The frequency of administration and its timing in relation to the notification of a change to treatment also contribute to delays. Where ESA is administered at the HD unit and less frequently than dialysis (i.e. not three times a week, therefore not Eprex or neoRecormon), three centres had implemented a specific administration day (D, F and one satellite unit at H). At F and H where Mircera (once monthly administration) is used, this was timed to be within a week following monthly bloods. At centre D, Aranesp is administered weekly on a Monday,

which meant that when a review took longer than five days to complete, all of the patients would have to wait another week before their management was altered.

Stockpiles of ESA associated with community prescribing reduce flexibility, which in turn can increase latency. With either a home delivery service or GP prescribing, the patient will often have a stockpile of ESA in pre-filled (single use) syringes that cannot be exchanged once dispensed. This, in combination with the expense of ESA provides a dilemma for the prescriber: "We've spent the money, we must not waste it" stated one consultant when considering what to do with respect to a patient who had recently received a new supply of ESA. In some cases the decision was to wait until the old supply was used up, up to two months. In others, renal centres would adjust the frequency with which the medication was given or ask that the patient 'waste' part of the dose (eject a portion of the syringe's contents) prior to injection. While it is possible to make quite elaborate changes in the frequency to effect a particular dose change, the approach was sometimes used bluntly, doubling or halving the frequency and therefore the effective dose.

Therefore, in relation to figure 7.4, although a patient could have a different dose delivered to them within a week of their blood test, this rarely occurs because of the time taken to notify the delivery company, the decision not to adjust a dose until a current stockpile is consumed and for the delivery itself to occur. For similar reasons, GP prescribing typically introduces a significant delay. Whereas for unit delivered ESA, the delay following review is composed of the time taken to authorise the decision, notify the unit and then wait for the next administration date.

### **7.3.1.2.3 The origins of community-based dispensing**

As community-based dispensing (whether GP prescribed or home delivery) is the greatest source of delays, further detail was sought on the reasons it was employed in some centres and not others. Responsibility for the supply of ESA has varied historically between localities, in some lying with the renal centre and in others with the GP. Centres are now largely taking control of ESA prescribing but there are still locations where GPs prescribe for some (usually non-dialysis) or all patients. There is also the special case of training patients in self-administration of ESA where at some centres a supply will be provided, although this is a temporary measure in lieu of alternative arrangements.

ESA is an expensive therapeutic agent, although it was considerably more expensive in the late 1980s and early 1990s when it was new to the market. This meant that holding control of its budget was important, as were any methods for reducing its cost. Two of the three

centres for which some ESA was GP-prescribed at the start of this study have negotiated with the PCTs in their area to centralise prescribing, persuading them in part because of the ability to reduce costs through bulk contracts with the pharmaceutical companies.

Where ESA is supplied for use in the community, the value-added tax (VAT) can be deducted from its cost, and this applies to all GP-prescribed ESA and that issued from centres by home delivery or FP10(HP) (hospital issued prescription for community dispensing). VAT, a tax on the consumption of goods and services, is governed in the UK by national and European Union rules. The reason VAT can be deducted from medicine in some circumstances and not others is related to different rates being applicable to prescribed medicine and medical care (HM Revenue and Customs, 2007). Medicines are subject to standard VAT but when dispensed upon a prescription are zero-rated for VAT (VAT is technically applied, but at 0%) while medical care is exempt from VAT. Medicine administered during the course of medical care is considered an inseparable part of that care and therefore also exempt from VAT. Because VAT is chargeable on medicine unless it is dispensed on prescription, the sale of it by a pharmaceutical company to a hospital or community pharmacy attracts VAT. Typically, when goods or services are supplied onward, the VAT paid on their inputs can be reclaimed, but only when these are taxable. Because medical care is exempt from VAT, the VAT paid on its inputs (including medicines) cannot be reclaimed, whereas for prescribed medicine whose supply is taxed at 0%, it can.

As ESA had often been prescribed by GPs, when renal centres took control of prescribing they were taking over a supply that had been community based and it was often considered financially necessary to retain this approach, whether by prescription or home delivery. A home delivery service was considered by some renal centres to be a significant improvement by comparison with GP prescribing or issuing FP10(HP)s, which were considered more complex and less convenient for patients. The patient choice agenda and notions of the expert patient, were given by some as reasons for providing ESA to the patient for them to self-administer, although others refuted this. For patient modalities other than haemodialysis, a community-based service is a convenient way of accessing ESA, rather than regularly attending a hospital; the rise in prescribing for non-dialysis patients coinciding with the growth in home delivery services for ESA through the first decade of the 21<sup>st</sup> century. The convenience for the renal centre of having a unified approach to ESA prescribing across modalities was emphasised at centre C, one of the two centres that continues to use a home delivery service for HD patients.

### 7.3.1.3 A mechanism by which latency may impact upon outcomes

An anaemia nurse discussing their former system of GP prescribing described how latency in dose changes could cause confusion in the decision making process:

Before, the patients were not improving and the doctors would be wanting to change the dose up again thinking the patient hadn't responded and we'd be saying no, because you need to find out what's happening. You have to phone the patients and find out whether they've had it, how long they've had the new dose.

Here the decision makers had insufficient information to understand why test results have not responded to an apparent change to treatment. The anaemia nurse also describes a lack of awareness among some doctors that a dose change may take a long time to be enacted, in addition to the time taken for haemoglobin to be altered, a point that was repeated by anaemia nurses at other centres.

### 7.3.1.4 Discussion of latency in the management of renal anaemia

The study highlights a relationship between latency and performance. The primary cause of this latency is the community-based provision of ESA, which for haemodialysis patients is largely due to historical arrangements and financial pressures. Another cause is the time taken to review a patient, which is affected by the choices of individuals and the technology (including processes) in use.

There is an apparent correlation between performance and latency, with high performing centres always having low latency and low performing centres often having high latency, particularly at the maxima. Although the correlation does not mean that low latency directly enables high performance, this was a strong belief of many of the participants and there are good reasons to believe it. The likely mechanisms underlying this relationship are: a delay in managing the peaks and troughs in a patient's haemoglobin and (as described above) greater complexity and uncertainty for decision makers.

In the comparisons of performance and latency (figure 7.2 and figure 7.3) there are centres that are low performing and with low latency; it is important to examine why this may be. If low latency enables high performance, it would not ensure it. In the data from 2006, for the one outlier (centre G) a number of factors could have contributed to low performance, in particular the overlapping but relatively uncoordinated decision making processes for management of patients in the main haemodialysis unit and lack of anaemia coordinator in

2006 (see also the case study in section A.8). Another significant factor may have been one consultant who deliberately targets high haemoglobin levels in patients (13-15 g/dl), which would increase some patients' haemoglobin above guideline targets and therefore reduce the performance measure (percentage of patients with haemoglobin 10.5-12.5 g/dl).

For 2008, centre G remains an outlier and centre F became an outlier. There was a significant change from 2006 for centre G with the introduction of an anaemia nurse. However, this has not had as great an impact on the process for haemodialysis patients as it has for general nephrology and pre-dialysis patients. Centre F has had a number of changes to process that might be expected to improve performance and yet it has reduced (see also the case study in section A.7). Once again, I believe this can be explained by the target haemoglobin aimed for by a consultant, in this case the only consultant to manage haemodialysis patients' anaemia at this centre. The consultant has stated that they consider 10-12 g/dl to be safer and that they are less concerned with haemoglobin under 10 g/dl than over 12 g/dl. Therefore, while the consultant at one centre is aiming to treat patients' haemoglobin to above the NICE guideline performance measure, at the other they are aiming below the guideline. Performance for percentage of HD patients with Hb  $\geq$  10 g/dl corroborates these explanations, with the historically low performing centre (Hb 10.5-12.5 g/dl) (G) achieving over 90% of patients with Hb  $\geq$  10 g/dl, while the newly low performing centre (F) achieves under 85% (also a shift down from 2006). Another possible contributory factor at F is that they measure haemoglobin after the long break from dialysis (on a Monday/Tuesday) rather than mid-week (Wednesday/Thursday) when routine blood samples are typically taken nation-wide (and at the seven other centres). This, holding all other things constant, should cause lower results for haemoglobin as the pre-dialytic sample will be more dilute (dialysis removes excess fluid and the longer patients wait between dialysis sessions the greater their fluid overload). However, participants at the centre did not recall that this is a change of practice since 2006.

The degree of difference between the performance of the renal centres in this study reduced between 2006 and 2008, which is partly because of regression to the mean (see e.g. Campbell & Stanley, 1963), but may also be because the new NICE performance measure was new in 2006 meaning centres had not had long to adjust their management to suit. Therefore, some centres happened to have management strategies that were particularly suited to the new performance measure while others did not. At all four centres that had performed poorly on the new measure, some participants reported conscious efforts to improve their performance score by reducing the number of patients with high haemoglobin (typically > 13 g/dl).

In this section a range of reasons for differences in control loop latency have been described and are summarised in table 7.1. Their relationship to the literature and implications are considered in the chapter's discussion, section 7.5.

**Table 7.1 Categorisation of control loop latency and related elements**

ID	Element	Category	Links	Section
1	Low control loop latency for renal anaemia management	Result difference		7.3.1.1
2	Review anaemia management promptly	Process difference	1	7.3.1.2.1
3	Review anaemia management prior to MDT (if any)	Process difference	2	7.3.1.2.1
4	Test results promptly available to reviewer	Contextual difference (renal centre)	2	7.3.1.2.1
5	Effect change to renal anaemia management quickly	Process difference	1	7.3.1.2.2
6	Provide ESA from dialysis unit to HD patients	Process difference	5	7.3.1.2.2
7	Prescribe ESA promptly following review	Process difference	5	7.3.1.2.2
8	Communicate changes to external actors immediately	Process difference	5	7.3.1.2.2
9	Coordinate review with ESA administration schedule	Process difference	5	7.3.1.2.2
10	Centre responsible for ESA prescribing	Contextual difference (local health economy)	6, 7	7.3.1.2.3
11	No increase in drug cost for use in a medical facility	Context (government)	6	7.3.1.2.3

### 7.3.2 Coordination of renal anaemia management

At low performing centres, there were repeated comments and sometimes complaints about lack of communication or of discrepancies in the records of treatment regime between relevant parties. These were grouped under the theme *coordination*. Coordination of renal anaemia management was reported to be unreliable in two ways: changes to management are made (or at least intended) that are not communicated to other decision makers, or changes are intended that are not successfully communicated to the care team or patient.

The former was particularly the case in centres A, E and G, although it was something that would occasionally occur in other centres, particularly when new staff arrived. In centre A, this could occur when an MDT meeting took place without a member of the anaemia team present, although in these circumstances a consultant or unit manager would often liaise with the team. In centres E and G, these problems centred on junior doctors making changes to patients' medication during ward rounds or consultants making changes at clinics without notifying the anaemia team. At the other centres, anaemia management was relatively isolated from junior doctors' ward rounds, and staff ensured that all decisions about anaemia

management went via the anaemia team, if only for record keeping and the coordination of external partners such as home delivery services and district nurses. Such a setup reduces the likelihood of multiple dose changes occurring in one direction in a relatively short space of time, as was expressed by an anaemia nurse when asked why results were low: "Too many people interfering, making dose changes and not referring, not waiting long enough for a new red blood cell to appear."

Changes that were intended but not successfully communicated to the care team or patient were described at A and C, although again, this was occasionally the case at other centres. At centre A, there were sometimes differences between what the anaemia team, satellite unit and patient believed was the dose for an HD patient. In another case, the GP had a different record of the dose from the patient and anaemia team. For HD patients in centre A, the communication of changes to their anaemia management is supposed to be carried out by dialysis nurses during the HD session, who are supposed to have made notes on these changes as they occur in the MDT meeting. At C, a decision on anaemia management may be made not only at the MDT, but also at the anaemia QA, a monthly meeting of the anaemia nurse and one consultant who takes a particular interest in anaemia. It was reported that the changes made at an anaemia QA would not always be actively communicated to the dialysis team, consultant or patient, although the decision was recorded and any relevant change to the prescription made. At high-performing centres, for HD patients the anaemia team would provide prescriptions to the HD unit, who would administer treatment and update the patient.

### **7.3.2.1 Discussion of coordination of renal anaemia management**

Among low performing centres the communication and coordination of changes to renal anaemia management was reported to be less reliable than was the case at high performing centres. It is possible that mis-communication, non-communication or non-action is occurring to cause this. These were alleged by some participants, although not observed. As was described above, at the high performing centres only the HD unit needed to be informed of a dose change by the anaemia team, because they administered ESA and could inform the patient. This compared favourably with the case at centres A and C where multiple potential lines of communication seemed to result in different records of the prescription. While there are likely to be other approaches that would achieve reliable communication to relevant parties, unit provision of ESA appears to support it.

Where renal anaemia management is insufficiently coordinated, it is likely to result in the wrong dose being administered or inappropriate management decisions, or both. The

successful coordination of ESA dose changes was achieved by informing the anaemia team of any decisions made, who would actively inform the relevant parties. This is summarised in table 7.2.

**Table 7.2 Categorisation of coordination related elements**

ID	Element	Category	Links	Section
12	Reliable communication of changes to renal anaemia management	Result difference		7.3.2
13	Anaemia team informed of or involved in all decisions	Process difference	12	7.3.2
*6	Provide ESA from dialysis unit to HD patients	Process difference	12	7.3.2

\* Element already identified earlier

### 7.3.3 Reliable supply and administration of ESA

The reliable supply and administration of ESA was considered problematic at several low performing centres. Non-compliance or non-adherence is a potential problem where patients self-administer, in contrast to when it is given directly as part of a haemodialysis session. In the three centres where ESA is not provided on the dialysis unit to all HD patients, performance is low. At all centres, non-HD patients treated with ESA usually self-administer. Most participants considered compliance to be a relatively small problem, although at one centre they considered it a major problem. In addition, there were concerns expressed about the processes used to organise the provision and administration of ESA at several centres.

Participants in the present study suggested that where patients did not self-administer all of the ESA prescribed, it was because: they forgot to self-administer; they found the injection painful; they were needle-phobic; they did not understand what was expected of them because of language barriers; they were not collecting their prescription from the GP or their ESA from the pharmacy; they had associated an illness with administration of ESA, which they considered causal; or they were selling their medication.

There were concerns that GP prescribing was an unreliable system for supplying ESA at two of the three centres using this approach (A and E). They claimed this was partly because some GPs issued only small prescriptions lasting one or two weeks, requiring the patient to return regularly. In addition, some pharmacists do not hold stocks of ESA, and these two factors make it less likely that a patient will always have ESA available.

At centre E, they had performed a local audit and had discovered that nurses were often not signing to say they had administered ESA. At this centre almost all patients' ESA was prescribed by their GP, although they were encouraged to bring their ESA in for the nurses to

administer. While they believed the situation was improving, partly because of the awareness following the audit and partly because they were now supplying ESA from the units, non-administration remained an ongoing problem. The reasons given for this were that: nurses forgot to administer ESA, the ESA was not available as it had not been brought in, the nurse had given ESA but did not sign for it, the patient was hypertensive and therefore ESA is contraindicated or that the patient was absent. However, because a reason for non-administration was not recorded, they could not ascertain the extent to which these were problematic.

For in-patients, the reliable administration of ESA was described as problematic at three centres (E, G and H). In-patients are often admitted as an unplanned event and there can be a lack of coordination between their carers. Where the patient is an HD patient, their paperwork is not always transferred from the dialysis unit to the inpatient ward. Some patients continue to dialyse at the same unit while for others the location changes. As a result there can be confusion over whether ESA is meant to be given on the unit or on the in-patient ward.

Uncertainty over the reliable provision and administration of ESA may lead to uncertainty for the decisions makers with respect to the reasons for particular results, both in individual cases and their aggregate performance by comparison to other centres. Where the anaemia team at E suspected patients of non-compliance but this was not substantiated, they treated the patient as compliant. However, where the anaemia team in coordination with the doctors considered it clear that a patient was non-compliant, they would not increase their medication.

### **7.3.3.1 Discussion of reliable supply and administration of ESA**

The reliable administration of ESA is important for renal anaemia management as it increases the likelihood of a patient receiving optimal therapy. This is true both in the short term where missed doses lead to sub-optimal therapy, but also the long term where decision making may be hampered by uncertainty or a lack of information.

GP prescribing was identified by participants at centres A and E as contributory to an unreliable supply of ESA. A range of causes for patients not self-administering were proposed by participants. At centre E, they were aware of problems with their nurses not always administering ESA to HD patients. There were also considerable difficulties noted at several centres in coordinating the ESA therapy of in-patients.

While a minority of patients may forget or choose not to self-administer ESA, there is a set of problems related to the reliability of some systems for supplying and administering ESA that appear likely to produce sub-optimal therapy. Where HD units administer ESA compliance cannot be a problem, although reliable administration still can. The use of GP prescribing for ESA and therefore community pharmacy supply was of concern to some participants, although the extent to which this is well-founded is unclear based on this evidence. Of greater concern was the ability to administer ESA reliably in a secondary care setting. However, missed doses were apparently rare at most centres.

Simplifying the approach to ESA supply and ensuring there are robust procedures for identifying and administering the right dose to the right patient should improve renal anaemia management performance. The factors identified here are summarised in table 7.3.

**Table 7.3 Categorisation of reliable supply and administration of ESA and related elements**

ID	Element	Category	Links	Section
14	Reliable supply and administration of ESA	Result difference		7.3.3
*6	Provide ESA from dialysis unit to HD patients	Process difference	14	7.3.3
15	Coordinate anaemia management for in-patients	Process difference	14	7.3.3

\* Element already identified earlier

### **7.3.4 Interaction, roles and relationship between consultants and the anaemia team**

The interaction, roles and relationships between consultants and the anaemia team appeared different at high performing centres by comparison with low performing ones. This was reinforced by some material from interviews and therefore a review of the data focusing on relationships, atmosphere and social structure at each centre was pursued. This led to further comparison of the approaches to, and roles in, decision making within anaemia management. This is presented in two sections here, relationships and decision making.

#### **7.3.4.1 Consultant – anaemia nurse relationships**

At all centres, there is interaction between the medical staff and the anaemia team. However, at high performing centres the nature of this appeared different. Rather than just referrals or scheduled meetings, there seemed to be far greater informal contact: emails querying what to do with one patient or another, meetings in corridors or popping heads around doors. There was apparently not only mutual respect for each others' skills but also a

willingness to be involved together in the decision making. However, the evidence for these differences was impressionistic rather than systematically collected.

There was evidence of disharmony between some of the consultants and the anaemia team at each low performing centre. For example, having earlier told a consultant that the reason I was at this centre was because of their performance as reported in the Renal Registry I asked:

Interviewer            Can you describe your role in the management of renal anaemia here?

Consultant              Mainly initiation of treatment - deciding who's going to get treatment. Once that decision's been made it's basically a referral to the anaemia management team. Very rarely do I have to change doses unless someone's coming in as an in-patient, so it's all coordinated, not very well from the sounds of things though, cheers me up.

And later:

Interviewer            Is there a way in which you reverse their [the anaemia nurses'] decisions ever or-

Consultant              If I feel strongly about it

Interviewer            In the QA or would it be...

Consultant              Yeah. If I'll say this patient's needs to have a haemoglobin of 13 because they've got bad heart failure and they're 80 and they're going to die and all I want to do is make them symptomatically better, not care about them living a bit longer or a bit less I'll say that and they'll kick a fuss and I'll say tough it's my decision

Interviewer            And would that occur,

Consultant              Not that frequently. We try and resolve it amicably usually,

Interviewer	Sure
Consultant	I'll say [anaemia nurse], I wasn't asking you I was telling you. And then sort of [they] comes up with 'oh okay I agree we need to do this', finds an escape clause, it very rarely happens.

At one low performing centre, I attended a meeting designed to examine the centre's anaemia management that had been called by two of the consultants who claimed they had invited all of their colleagues along. They were the only two consultants who attended and one stated that the meeting had been called because "certain consultants think they can wash their hands of anaemia management" and think "because there are [several] anaemia nurses they don't even need to think about it", while the other consultant made it clear that they were not of that opinion.

At a low performing centre, an anaemia nurse received a slew of emails from a consultant after the team requested that they were kept informed of any changes; they were apparently sending an email after each consultation. The anaemia nurse said to me:

1 <sup>st</sup> anaemia nurse	[The consultant] is being better. [They're] at least letting us know even if [they are] making mad decisions.
2 <sup>nd</sup> anaemia nurse	We've had a few problems with communication from one of the consultants. [They're] putting us in a difficult position when we don't know what [they've] been doing.

At one low performing renal centre the anaemia team believed the introduction of MDTs had improved communication with consultants. However, they were unhappy with the irregularity of some of these meetings. Discussing this with a colleague one anaemia nurse said:

...if they keep chopping and changing them we can't be expected to drop everything. Anyway, the sisters will email us with the changes — and if they change the dates — it's not rocket science really.

Frustration with the irregularity of MDT meetings was expressed at three of the four low performing sites and at two sites was given as a reason for a member of the anaemia team not always attending, as in the quote above.

At one low performing centre, an anaemia nurse stated she was undervalued and undermined:

They (the consultants) don't care about anaemia, they never have. You're perceived as doing nothing, and that's how I got landed with [an additional role], which I was really pissed off about. We have a job plan to work to as a specialist nurse. Doing things non-related to my anaemia role really detracts from your work. [A consultant] is always slagging me off at meetings. They see you in here with no patients on a non-clinical day in front of the computer and they think you Google all day.

Although the same nurse said: "For all my criticism though, they're [the consultants are] extremely supportive."

Relations between consultants and anaemia nurses at these centres were by no means universally tense, unsupportive or unfriendly. Indeed very close or supportive relationships often existed. Similarly, there were tensions in high performing centres, but these seemed to be in the context of a more appreciative relationship. For example an anaemia nurse had recommended a patient should start ESA following a course of IV iron but a consultant said to wait. A month later, the patient's haemoglobin had risen substantially. The anaemia nurse said:

So I bow to [the consultant's] wisdom because [they were] right not to start EPO. But I won't tell [them] that (*smiles*).

Two days earlier a recommendation to start a different patient on ESA was rejected by the same consultant and the schedule for next checking the patient was also modified from 2 weeks to 1 month. The anaemia nurse's response was "I love the way [they]'ll do anything to disagree with me", but this was said in a light voice. These two quotes demonstrate that at this centre, although differences of opinion exist, they are openly expressed and accepted with good humour. At another high performing centre an anaemia nurse said to me:

The thing that makes it work most is the teamwork. Everyone helps out and is approachable. The consultants are pretty good at letting me know when an extra bloods has been done (pause) except one consultant [said in a joking manner as one walked past]. So it wouldn't work if you had unapproachable doctors and nurses who didn't give a monkey's.

This contrasted with the sense that relations between anaemia nurses and some consultants at three of the four low performing centres did not facilitate good communication.

The physical arrangement of the centres also differed in a way that appeared to reflect this. At high performing centres, the anaemia team were located near the 'heart' of the renal centre. In two centres they were between the consultants' offices and the outpatients and dialysis ward areas. In a third they were just outside the main clinic waiting area and in each of these they were co-located with other specialist nursing teams. In the fourth high performing centre the anaemia nurse was physically towards the edge of the centre, although as this was a relatively small centre they were still a short distance from the consultants' offices and the dialysis unit. In the four other centres the anaemia team tended to be in the furthest office possible from the rest of the centre, although again there was one exception: at one of these centres the anaemia team were located in a central position, although in such cramped conditions (they were sharing a small box office with a number of specialist nurses) that they had all moved by the time of my next visit to a peripheral office, now with their own clinic space.

The interviews all contained questions about relationships within the centre, positioned after descriptions of roles and processes to allow participants to relax into the interview. However, problematic relationships between the anaemia team and consultants were never stated here.

#### **7.3.4.2 Responsibility for decision making**

At high performing centres decision making was shared between consultants and anaemia nurses in a pattern that was similar across centres, while at low performing centres a variety of different patterns were found. At the low performing centres, decision making primarily seemed to rest with: (A) the anaemia team alone; (C) led by the consultants and other medics, but multiply and separately; (E and G) a variety of combinations for different circumstances including in some cases both the anaemia team and medics but separately, in some cases jointly and in further cases the anaemia team alone. At high performing centres, the majority of decisions were made by the anaemia nurse, but there was significant involvement with the consultant team. At B, decisions were held for MDTs where the anaemia nurse considered them to be uncertain. At D, the anaemia nurse would send queries to the consultant about less clear-cut cases, even though the anaemia nurse had an opinion on the appropriate course of action. At F and H, there was a meeting between anaemia nurse and

consultant to examine the management of haemodialysis patients: at F for all patients and at H for those outside of the NICE/RA criteria of Hb 10.5-12.5 g/dl.

### **7.3.4.3 Discussion of interaction, roles and relationships**

The interaction, roles and relationships at high performing centres appeared to take a form that may enable good coordination and decision making. The roles taken by anaemia teams differed across low performing centres but were relatively consistent in the high performing centres, providing a balance of independent authority and integrated engagement. The relationships between anaemia nurses and consultants were always respectful at high performing centres, in apparent contrast to low performing centres. The elements are summarised in table 7.4.

As described in the findings, when relationships were discussed directly in interviews they were never described as problematic, although other answers suggested they were. However, during the course of observation a set of evidence was gathered that reflected a range of relationships. This highlights the important role of observation in the study and some of the limitations of interview data. It also suggests that, not surprisingly, participants were protecting both themselves and their colleagues during interviews, but during prolonged observation were less likely to hide such problems.

It would be reasonable to suggest that these differences in interaction, roles and relationship were features that could be afforded at smaller centres and were infeasible in their larger counterparts. Indeed, at the two largest centres in the study the physical location of the anaemia team made them more remote than would have been possible at a smaller centre. However at H, the largest high performing centre (in the 2<sup>nd</sup> largest quintile of English renal centres) there was regular interaction with consultants, largely informally via email or in person, perhaps facilitated by their close location, but also formally in a focused meeting once a month.

It is also possible that this interaction, in particular the good nature of relations between all consultants and the anaemia team is re-enforced by the knowledge that performance is good and seen to be good externally. Similarly, where performance is low, this may inspire doubts in some consultants about the abilities of the anaemia team and this may influence the way they relate and work together.

**Table 7.4** Categorisation of roles, relationships and related elements

ID	Element	Category	Links	Section
16	Good working relationship between anaemia team and all consultants	Contextual difference (renal centre)		7.3.4.1
17	Anaemia team near the 'heart' of the centre	Contextual difference (renal centre)		7.3.4.1
18	Decision typically made by anaemia nurse but shared when borderline	Process difference		7.3.4.2
19	Anaemia nurse role has authority and anaemia team willing to refer	Contextual difference (renal centre)	18	7.3.4.2

### 7.3.5 Degree of interventionism

The prior framework had identified the point at which a centre intervenes in the ongoing anaemia management of a patient as potentially important in their performance, as described in section 7.1.3.2. Through document sampling, observation and interview I attempted to gather data on this. Many decision makers did not wish to couch the reasons for changing a patient's dose in the language of algorithms, pointing to the individuality of each patient and the variety of factors that they would consider in making such a decision in addition to the absolute value for haemoglobin. At two centres that use decision support systems (D and H), they typically adjust a dose at each 1 g/dl increment for a patient's haemoglobin. At the other six centres (A, B, C, E, F and G), while there was less certainty about the point at which they would change dose in the terms given here, they could broadly be generalised as making changes when the patient's haemoglobin is somewhere between 10 and 11 g/dl and then between 12.5 and 13.5 g/dl, although there were individuals who operated different policies to this as discussed in section 7.3.1.4.

To examine the effect of this on the likelihood of a dose change and to examine whether similar policies were having different effects in high and low performing centres I gathered data on the number of HD patients for whom changes were made in a review of routine bloods. These are presented in table 7.5 and figure 7.5.

As can be seen, the two centres with decision support systems intervene in their patients' care almost twice as regularly as the highest of the other centres, among which there is no discernable pattern. It is particularly notable that other high performing centres are included in the group that do not intervene very regularly. In addition, at centre D 10 of the 95 changes made were different from the recommendations of the decision support system. Similar data for centre H was not collected.

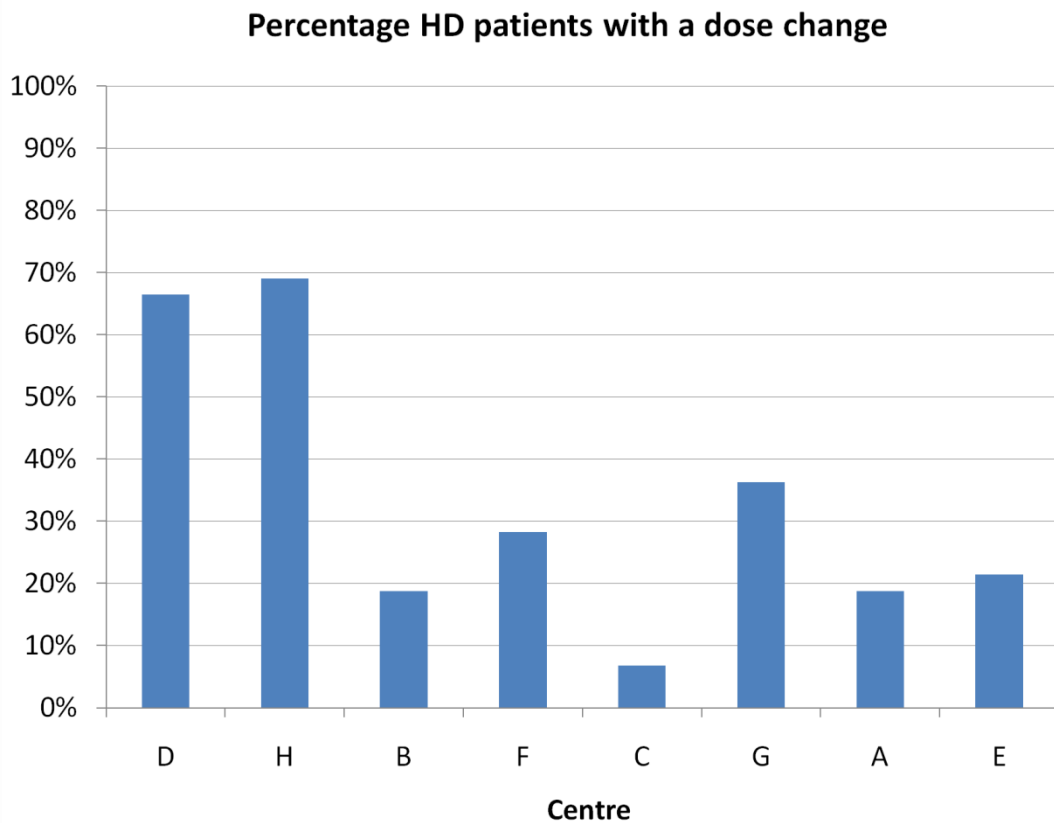


Figure 7.5 Percentage of haemodialysis patients with a dose change in a routine review

Table 7.5 Percentage of haemodialysis patients with a dose change in a routine review

Decision support	Performance group	Centre	No. patients	No. changed	% changed
✓	High	D	143	95	66%
✓	High	H	388	268	69%
	High	B	48	9	19%
	High	F	46	13	28%
	Low-high	C	103	7	7%
	Low-high	G	80	29	36%
	Low	A	64	12	19%
	Low	E	14	3	21%

### 7.3.5.1 Attitudes to decision support in renal anaemia management

Two of the eight centres participating in this study use some form of computer-assisted decision support, where, at least for the haemodialysis population, an ESA and iron dose is recommended by their information system. Both of these centres were high performing and so although such a system is not essential to high performance it may assist. During the first round of fieldwork, negative views were expressed about such systems by some who did not have access to them, although they were popular in both centres that did have them. These

negative views were often based on the notion of an algorithmic decision making system, rather than the type of decision support system observed. For example, “I don't believe in algorithms because everyone's so individual with their co-morbidities” and:

I have some clinical knowledge of these patients. If one has had a bleed then the last thing you want to do is confound things. So it's not all about the numbers, you need clinical knowledge. The algorithm may say to go up but that may not be right, so you need the human intervention.

I therefore chose to explore the attitudes of decision makers in renal anaemia management to computerised decision support systems during the second round of visits.

As part of the interviews conducted with consultants and anaemia nurses during the second round of visits a set of questions from a questionnaire examining attitudes to computerised decision support systems (Clamp, 1995) were asked (see figure 7.6). The sample was not picked specifically for this purpose and therefore it cannot be assumed that the results generalise to other renal centres, although the results may elicit why relatively few centres have such systems and whether differences in attitude exist between nurses and consultants, high and low performing centres and those with and without existing computerised decision support systems.

Firstly, participants were asked whether they considered five potential benefits and six potential disadvantages would arise as a result of such systems, the benefits and disadvantages having been drawn from a survey of the literature. They were then asked to provide any benefit they would most like to see and disadvantage they would be most worried about before their attitudes to clinical freedom were discussed.

Which of these benefits do you think these may bring about:

- Improved decision making
- Improved quality of care
- Standardisation of medical practice
- Resource savings
- Make practitioners more accountable for their actions
- Other?

What disadvantages might there be?

- Decrease in practitioners' decision making skills
- Increased rigidity of thinking
- Over reliance on a computer
- Increased cost of health care
- Increased legal and ethical problems
- Limit practitioners' freedom of action
- Other?

What one benefit would you most like to see in a computer system designed to help management of anaemia?

What one disadvantage would you be most worried about concerning clinicians' use of such systems?

Clinicians use many different tests and procedures (e.g. blood tests) to help them reach a decision about how to treat a patient. Is a computer system designed to help with decision making different from these other tests? Why?

What do you think about clinical freedom? (i.e. the right of a clinician to manage a patient as they see fit)

Will decision support systems affect clinical freedom? Is this a good/bad thing?

**Figure 7.6 Questions examining attitudes to computerised decision support systems (adapted from Clamp, 1995)**

The answers to the likelihood of the eleven possible benefits and disadvantages were placed into five categories between yes and no (yes (Y), probably (?Y), don't know (DK), probably not (?N), no (N)) from which stacked bar graphs were produced and compared between groupings. In six cases answers were given that could not be placed in these categories and these were excluded. Benefits and disadvantages considered most important were grouped and considered in conjunction with other data gathered throughout fieldwork.

As was described in section 3.3.7, at the renal centre in Leeds St. James's hospital there was a computerised decision support system for managing renal anaemia that has been well publicised. Because this research is based at the University of Leeds, participants often believed that this research was with respect to this particular example, rather than renal anaemia management more generally. This was sometimes mentioned when participants directed their answers towards the problems of an automated decision making process without adequate supervision – apparently a popular interpretation of the process in Leeds St. James's – rather than a process that uses decision support.

7.3.5.1.1 Results

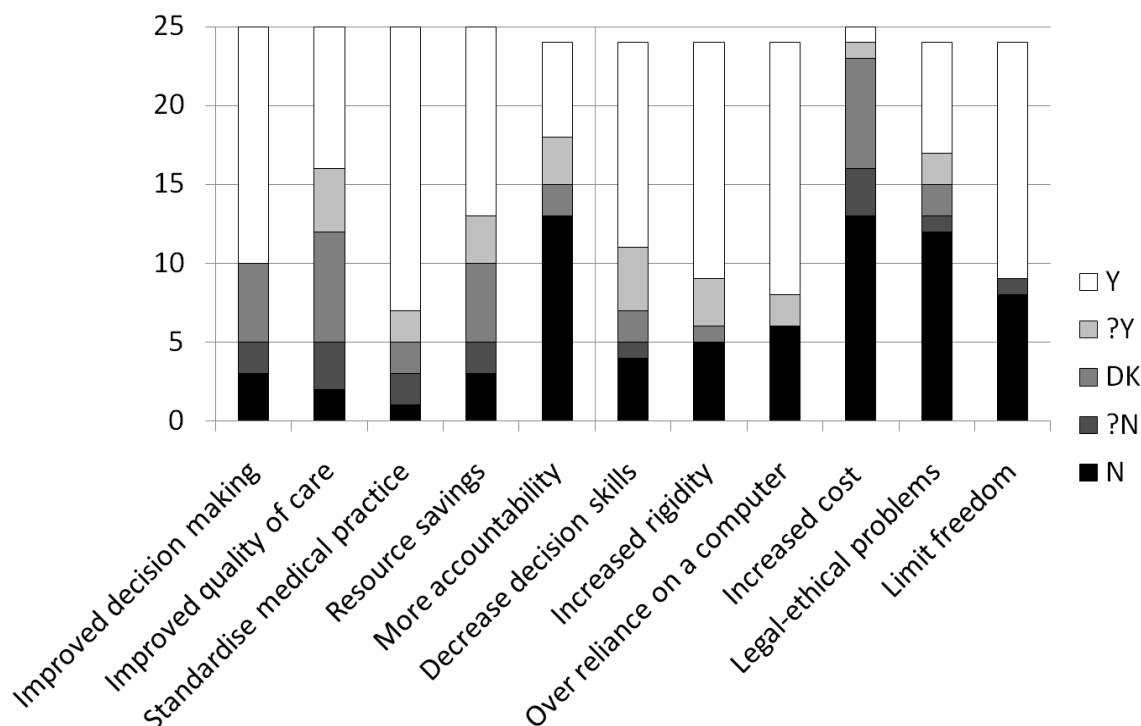


Figure 7.7 Perceptions of advantages and disadvantages of a computerised decision support system among consultant nephrologists and anaemia nurses.

The results of the survey are displayed in figure 7.7. The potential benefits were typically seen as likely, and while many thought the potential disadvantages were also quite

likely, a significant minority explicitly dissented from the view that they were disadvantages. Standardisation of medical practice was considered the most likely benefit, but improved decision making, improved quality of care and resource saving had more positive answers than negative. Of the benefits, only increased accountability was considered unlikely by the majority of respondents. Among the disadvantages, very few considered greater cost likely and some thought there might be legal or ethical problems. However, many participants believed that such systems might bring about a loss of skills, rigidity of thinking, over-reliance on a computer and limited freedom of action for practitioners. There were several occasions when respondents questioned whether some of the potential consequences that were framed as disadvantages were indeed disadvantages: this happened twice regarding a decrease in practitioners' decision making skills and increased rigidity of thinking, and once regarding limiting practitioners' freedom of action. Where explanations were given, these respondents claimed that these consequences were not disadvantages if they improved care. Most of those who felt such a system would not result in over-reliance on a computer qualified their answer with a reference to the existing reliance on computers within renal care and the concept of paperless hospitals.

Comparisons of these answers between groupings of performance, role and use of computerised decision support systems showed few differences, suggesting that the outcomes may have been similar if sampling other members of the renal community. It was apparent that more certain answers were given in the two centres where computerised decision support systems were in place, perhaps unsurprisingly as they were able to draw on this experience rather than hypothesise. However, the extent to which answers were positive or negative showed little difference.

In a system to support anaemia management renal clinicians would most like to see benefits that fell into six themes: better patient outcomes, changes in decision making, improved process flow, good human-computer interaction, audit tools and the means to explain to patients why their anaemia is managed as it is. The focus of anaemia nurses was more on process flow, human-computer interaction and audit tools, while consultants tended to emphasise outcomes and changes to the decision making process.

The aspects of process flow that were mentioned were related to saving time, decreasing delays, improving communication and a range of features related to patient testing: links to primary care test results, identification of new test results and of patients who need a new test performing. For example: "Um, to be able to flag up when results, new blood tests are needed, being able to see computer results from outside the hospital setting..."

Good human-computer interaction was mentioned by several respondents, in terms of the system being straightforward, user friendly and providing graphical overviews of a patient's anaemia management. One anaemia nurse highlighted the general lack of IT training and skills among nursing staff that stands in sharp relief to their routine use of information systems in renal care.

Audit tools that would be valued include the ability to calculate: the percentage of patients within target ranges for haemoglobin; the number of patients in different modalities and which brand of ESA they are on; and average doses of ESA and iron.

There was an apparent desire for many of the participants to clarify the complexity of decision making with respect to renal anaemia management and the large number of alternative causes of anaemia that needed to be considered and ruled out when treating a patient with ESA. Such treatment can mask serious underlying problems including blood loss and cancerous growths. Some respondents expressed this by stating the feature they would most like to see was the ability for a system to take all factors into account or to identify patients with problems. In a similar respect many were keen for a decision support system to consider factors other than haemoglobin and iron-related blood tests, such as infection status, other diseases and lost circuits for haemodialysis patients (when the blood in the lines to the dialysis machine and the machine itself are not returned to the patient).

The greatest worries expressed regarding a system to support anaemia management related to poorer decision making and over-reliance on a computer. In addition, two anaemia nurses expressed concerns over the quality of information within an information system and one consultant believed that managing the change of role for an anaemia nurse would be particularly difficult. Only 1 of the 25 respondents claimed they had no concerns over such a system.

Concerns about poorer decision making were expressed in terms of: only treating the results or numbers rather than the full clinical picture; clinicians accepting recommendations without consideration or 'switching off'; failing to diagnose other illnesses causing anaemia; and unnecessarily high haemoglobin within individual patients. With respect to over-reliance, one consultant expressed concerns that junior staff would not develop the skills to manage anaemia appropriately and may then lack required skills if they moved somewhere else. However, a consultant at another centre where the anaemia team use a computerised decision support system claimed no concern at losing the skill of ESA dosing because the consultant had simply guessed previously (see the following quote).

- Interviewer Over-reliance on a computer?
- Consultant [pause] Well obviously there is over-reliance 'cause if the system broke down or we suddenly discovered that the system wasn't working, would any of us really know what to do? But then we'd only go back to where we were before the computer program was put in place, which was the drug companies sending you charts based on weight as to what to put them on, and when you were converting between brands, and you making a best guess. Cos it is - it was seriously a best guess as far as I was concerned; there was no science in what I did. I'd think oh need a bit more, look at how much they're on, well let's put them up by that much. Need a bit less, oh, look how much they're on, oh drop it to that. I— there was no science as far as I'm concerned [laughs] in my decision making as to what to do with an ESA.

### **Discussion of attitudes to decision support in renal anaemia management**

The results presented here suggest that the majority of nephrologists and renal anaemia nurses believe that computerised decision support systems may improve decision making, improve quality of care, produce resource savings and standardise medical practice, but may also lead to a decrease in decision making skills, rigidity of thinking, over-reliance on a computer and limits to practitioners' freedom of action. However, only one quarter of the centres in this sample used a decision support system. There was also a significant minority who dissented from any notion of benefit. This is particularly important because such systems would typically be conceived of as centre-wide and therefore their introduction would typically require a consensus opinion, imposition on those who do not agree with their use or individualised practices within the centre.

A system to support renal anaemia management should not only be able to demonstrate that it improves outcomes, but should assist with process flow, be easy to use and assist with audit. With respect to process flow, one of the major difficulties faced by anaemia teams is poor communication and coordination with other bodies involved in delivering an anaemia management service. The major concern around such systems was how they would be used in

practice and whether clinicians, particularly junior staff would be sufficiently skilled and confident to over-rule the recommendations.

### **7.3.5.2 Summary of degree of interventionism**

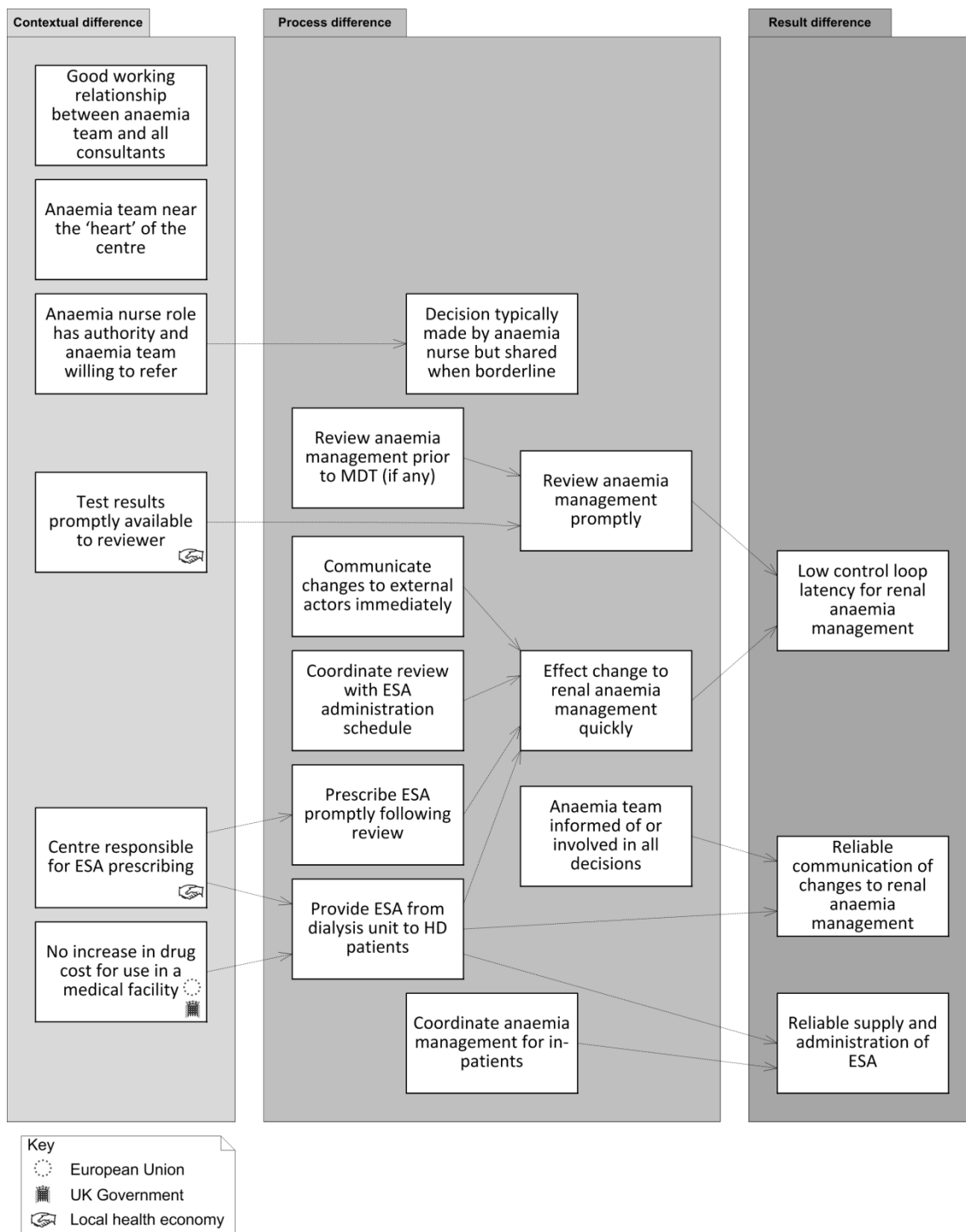
The point in terms of absolute haemoglobin level at which a centre intervenes in a patients ongoing anaemia management appears to have a big effect on the likelihood of a patient having a change of dose, but regular dose changes do not appear to be associated with poor performance with respect to the NICE indicator. However, the use of a decision support system appeared to be driving regular dose changes; the data from D suggesting that while human oversight was being exercised, the decisions were largely in accord with the recommendations. In each case, the measured level suggested month-on-month dose changes were occurring for some patients. It is unclear whether high intervention, use of a decision support system or neither are beneficial for performance and therefore no elements are included in the benefits dependency network.

## 7.4 Network of contexts, mechanisms and outcomes

The network of contexts, mechanisms and outcomes for renal anaemia management (figure 7.8) displays a wide range of contextual, processual and resultant factors, all of which appear to be contributing to the difference in achievement of the NICE guideline according to the findings presented in section 7.3. By displaying the findings graphically, it is possible to see how they are linked and identify those factors where intermediary process or result differences are not identified. For example, although a good working relationship between the anaemia team and all consultants was identified as an important contextual factor, the data itself does not link this to a process or result difference. This means that if it does relate to outcomes, the mechanism that the context affects is unidentified.

The objective of improving performance with respect to the NICE guideline is not shown in the diagram, as for this research it was the objective for which all of the differences were being examined. However, renal centres will be attempting to balance this objectives with other objectives not considered here such as cost or other areas of patient care, some of which may be complimentary but others may be opposing. Moreover, as discussed with respect to the comparison of performance and latency in section 7.3.1.4 this is not necessarily an objective of all renal centres, staff or patients.

While most of the contextual differences are within the scope of the renal centre, two are part of the wider environment. Therefore, while centres may be able to influence some of the barriers to process change, the provision of ESA from a dialysis unit to HD patients is affected by the arrangements in the local health economy and rules that operate at a national and international level.



**Figure 7.8 Network of contexts, mechanisms and outcomes for renal anaemia management based on this research**

## 7.5 Discussion

This study has demonstrated that patient outcomes in renal anaemia management appear to be affected by differences in organisational features, and examined the reasons these differences exist. The use of community-based supply of ESA for haemodialysis patients appears to hamper efforts to manage renal anaemia by increasing latency in the control loop, decreasing the reliability of coordinated anaemia management and supply and administration of ESA and because of these there is increased uncertainty for decision makers. In addition, there was some evidence that a particular role for the anaemia team and good relations between the anaemia team and all consultants may contribute to good performance for HD patients.

### 7.5.1 Strengths, limitations and relation to literature

#### 7.5.1.1 Performance and improvement

The impact of latency on the effectiveness of treatment has interesting implications for concepts of performance. In operations management, speed is typically one of the five aspects of performance (Slack et al., 2004). However, in this case speed can affect another of these aspects, quality. This fits with some definitions of quality from within healthcare, including the Institute of Medicine's (2001) and that given by *The quest for quality in the NHS* (Leatherman & Sutherland, 2003). This interdependency may be true of other services where the context for the service is liable to change over time.

These results are consistent with some of the ideas underpinning lean business process improvement strategies (Womack et al., 1990), which have become the vogue in relation to health service improvement in recent years. The reduced flexibility in stockpiles, found here in relation to ESA held by patients in the community, is one of the reasons behind Just in Time (JIT) approaches to inventory control. More generally, the concept of improving flow through a system appears related to reducing latency.

#### 7.5.1.2 Coordination

Finding that problems with coordination of anaemia management are associated with low performance fits with a wealth of organisational literature identified in section 7.1.3.4, that recognises care pathways, coordinator roles and team meetings as formal mechanisms for coordination. One of the differences that appeared to relate to these problems was not the

presence of the anaemia nurse (coordinator) role (of which there was one at all centres) but the way that it was used and enacted. Unless the anaemia team were informed of problems with patients and decisions made by others, treatment may not be as intended or future decisions could be based on a false view of current treatment. In addition, at high performing centres there were fewer parties that needed informing of the current treatment plan, which presumably made it less likely that errors would occur. The impression that informal interaction was greater at high performing centres also fits well with the notion of relational coordination and its effect on performance (Gittel, 2002; Van De Ven et al., 1976).

The finding that at three of the four high performing centres the anaemia team did not attend an HD MDT meeting appears to contrast with the organisational design literature, where in the face of uncertainty, team meetings would be expected to improve coordination and therefore performance (Galbraith, 1974). However, there were alternative formal coordinating mechanisms that were in place at each of these centres, including a meeting between an anaemia nurse and consultant at two of those three and the authorisation of prescriptions by each patient's consultants at the third.

### **7.5.1.3 Clinical control loop latency**

While previous research has examined the impact of delays due to waiting lists for episodic care (Meier-Kriesche et al., 2000) and delays in medical devices (Bode et al., 2002), none appears to have examined the relationship between delays in a control loop and performance where the clinician is the controller. Such delays would appear to be surprisingly common, for example, follow-up outpatients appointments are often run with a clinician using test results from the previous visit, the patient having left by the time the new test results are available.

### **7.5.1.4 Multi-disciplinary care in CKD**

One of the striking and surprising differences between centres' management of renal anaemia for HD patients was the attendance of anaemia nurses at MDT meetings at low performing centres, but not at three of the four high performing centres. This is apparently in contrast to most studies of the impact of multidisciplinary care in nephrology, where multidisciplinary clinics for pre-dialysis patients (Curtis et al., 2005; Goldstein et al., 2004) and MDT meetings (Plantinga et al., 2004) have been associated with improved mortality and in one case (Curtis et al., 2005), improved haemoglobin levels. However, the care being offered in all of the centres in this study is multidisciplinary, even where there is no team meeting.

Furthermore, two studies have now shown complimentary findings to this study. Plantinga et al.'s (2004) study and two recent publications about one dataset (Spiegel, Bolus, Desai, Zager, Parker, Moran, Bolus et al., 2010; Spiegel, Bolus, Desai, Zager, Parker, Moran, Solomon et al., 2010), the only two studies of MDT meetings for dialysis patients, have found that while MDT meetings are correlated significantly with improved mortality there is no association with improved haemoglobin performance.

The results do not suggest that MDT meetings do not improve care overall, but that for anaemia management they may be unnecessary. This pattern may itself be dependent on appropriate feedback to the anaemia team or another means of accessing relevant information. The results also suggest that waiting for an MDT in order to make a decision can negatively affect the ability to manage a patient's haemoglobin.

#### **7.5.1.5 Performance in renal anaemia management**

The relationship between performance and latency (section 7.3.1) can be explained by control theory and provides a new mechanism to explain intra-patient haemoglobin variability. In control theory, it is well known that time delays in the feedback loop, particularly large ones, tend to reduce stability in the system being controlled (Da, 2006; Hale & Verduyn Lunel, 2001; Han & Xu, 2009). This provides further support for the claim that low latency is an enabler of high performance. It also provides an additional mechanism for the production of cycling within haemoglobin, not yet discussed in this literature.

Finding of high intervention in high performing centres (section 7.3.5) runs counter to most of the haemoglobin variability literature. However, there was also low intervention at high performing centres. It is possible that the high performing centres with decision support are benefiting from the systematic nature of their system but could benefit more if their system had them intervene less frequently. Lindley, Tatersall and Wright (2010) found that adjusting their algorithm to have wider intervention thresholds and not allow month-on-month changes of dose resulted in a reduction in dose changes and reduction in inter-patient haemoglobin variability, suggesting it may also have reduced intra-patient variability.

These findings also disagree with the conclusion of Locatelli et al. (2009) that a computerised decision support system does not affect decision making in anaemia management, with much higher intervention found in the centres that were using decision support. This suggests that it is not the presence of a decision support system itself but the decision to use or trust it that will change practice. That will partly depend upon the fit of the

system with local processes, something that may not be good with a standardised package (Swan et al., 1999).

Finally, these results compare well with a recently published U.S. study (Spiegel, Bolus, Desai, Zager, Parker, Moran, Bolus et al., 2010) that compared survey results of practice across 90 facilities reporting on those with both statistical significance and a statistically medium to large effect size. They found that the presence of an anaemia manager and the frequency, timing and composition of a multidisciplinary team meeting were not significant predictors of haemoglobin performance, which agrees with these findings. However, nurse independence and enthusiasm, nurse manager problem solving and a communal working environment were significantly associated with performance, which may reflect similar organisational aspects to the findings here regarding coordination, interaction, anaemia nurse role and routine decision-making. In addition, the only physician practice their study found to be significant was the frequency of actively informing dialysis staff that an in-patient had been discharged and would resume treatment at the unit, which again emphasises the importance of active coordination. Interestingly a variety of IT and communication related facility characteristics were also statistically significant, although for some (e.g. adequate number of television sets) a reasonable mechanism of action seems unlikely. However, facility use of computers at the dialysis station and access to up-to-date computer systems may again relate to coordination, or perhaps may be a surrogate for resource-based factors.

#### **7.5.1.6 Study limitations**

This study does not solely use direct measures of latency; instead, it relies in part on estimates provided by practitioners. Direct measures would provide greater confidence in the precise minima, maxima and medians for the centres. However, to gain access to such data would have required patients to become participants in the study and, where they self-administered their ESA, record the occurrence of dose changes, which would need to be matched with records of decision making and the blood tests to which they refer. This would have been impractical within the scope of this study (for which patients are not consented), and difficult to link these different actions when further blood tests may have occurred before a dose change or even decision making. In addition, the extent of the difference in maxima is so great that such a degree of accuracy is unnecessary to illustrate the point.

Although latency fits with control theory as an explanatory factor in performance, there are alternative explanations for the relationship. The most significant cause of latency was community-based prescribing and it could be that one or more other mechanisms linked with

this are the actual cause, or at least contributory. Indeed, this chapter's findings included the roles of reliable administration of ESA and the coordination of renal anaemia management, both of which are related to community prescribing, as important factors in performance. However, the logic underpinning the role of latency suggests it should be considered important.

This study uses renal centre staff as its participants and recommends that renal centres prescribe and administer ESA, a recommendation that could result from a biased perspective. However, the recommendation is not based solely upon the responses of interviewees, but the association between performance, estimates of latency and differences in practice. The data from interviews and observation provide possible explanations for why differences in practice may affect performance and why these practice differences exist.

This research does not directly consider the effects of these differences on other aspects of performance for renal anaemia management (e.g. cost) or for other parts of the renal care service. It is plausible that a difference such as the anaemia nurse attending an MDT meeting could affect other parts of renal care. However, it would have been impractical to consider such differences in an exploratory study like this and difficult to select centres on anything other than their publicly available performance data.

## **7.5.2 Unanswered questions and future research**

Further research could examine the generalisability of this group of findings to the wider population of renal centres by operationalising a number of these factors and conducting a survey, the results of which could be compared to public performance data. Alternatively, an action research approach could take the findings of this chapter as a background and attempt to conduct a programme of change within a renal centre. Similarly, as centres make changes themselves (for example a change to delivering ESA on the HD unit), they can attempt to identify the effects of such changes.

The impact of using a decision support system on performance was unclear, with two high performing centres use resulting in a high degree of interventionism, in comparison with the other high performing centres. It is clear that a centre can achieve what is currently regarded as high performance in the absence of a decision support system and with relatively low interventionism. Given the results of Locatelli et al. (2009) it is also quite probable that the successful use of a decision support system is highly contextualised. What is unclear is whether different combinations of interventionism and decision support would result in different outcomes. It seems plausible that a decision support system adds a level of certainty

and therefore reliability to the decisions being made. It may therefore be that high interventionism without a decision support system would demonstrate more of the intra-patient variability discussed in that literature, but that with a decision support system, regular adjustments maintain most patients within a narrow range of haemoglobin. However, whether the current level of interventionism is helping or hindering these efforts is unknown. If the current decision support systems are not suitably characterising each patient it may be that a better long run average dose could be found that would raise performance to levels not currently seen.

The application of control theory to renal anaemia management, while discussed previously (West et al., 2007) deserves further attention. The standard control pattern employed in a variety of situations is known as a proportional integral derivative (PID) controller (Aström & Murray, 2008), which uses a combination of current absolute values, previous response and current rate of change to calculate the response. It is one of the algorithms being used in the development of the artificial pancreas (Renard, 2010) and its applicability to renal anaemia management should be considered.

The degree of interventionism in the two centres with decision support systems could be adjusted in line with the suggestion of Lindley et al. (2010) to limit changes to a minimum of every two months. The change in patients achieving the NICE performance indicator could then be assessed using interrupted time series analysis methods to examine the effect of a reduction in interventionism.

This analysis suggests that latency in the clinical control loop can be harmful to a patient's outcomes, just as delays in the response of an artificial pancreas would lead to excessive periods of hyperglycaemia. Further research could better quantify this effect and examine how it generalises across other spheres of medication management, particularly where patient level data on both outcome measures and latency were available. There was wide variation within those centres that had large latencies, depending on the course of action that was taken and a variety of factors including the size of the patient's existing stockpile, meaning that it may be possible to identify that individuals with the greatest instability or time outside of the target had been subjected to the greatest latency. However, centres may have adaptive responses to such patients meaning any such relationship may be complex.

Further research could examine the generalisability of the association between performance and the pattern for the role of an anaemia team in decision-making described in section 7.3.4.2. If future research finds this to hold true across other renal centres then the generalisability of this pattern to other nurse specialist roles could be considered.

### 7.5.3 Implications for policy and practice

Latency is a recognised problem in other areas of the health service and while the causes will be specific to each area it is likely that other areas of chronic care suffer from similar logistical problems, where patients reside in the community but are managed by specialists located in regional hospitals. Those responsible for managing the delivery of healthcare services should examine whether delays exist in their patients' pathways that could be avoided by adjusting the organisation, its priorities or both. Within renal anaemia management, this includes the mechanisms for delivering results to a clinician, the timing of reviews of those results, time taken to conduct the review and the mechanisms for delivering care to the patient.

Across secondary care, it is worth considering whether MDT meetings should occur in conjunction with more focused and perhaps more timely reviews of patient care than instead of them. As was discussed above, attendance at MDT meetings was not associated with high performance, although this does not mean they should be abandoned or that anaemia nurses should stop attending them. However, it suggests that anaemia can largely be managed as a separate issue from other areas of care, providing the individual managing it is kept aware of anaemia-related problems such as bleeding or the loss of dialysis circuits. There may well be advantages in an anaemia nurse attending an MDT as occurred at one high performing centre, but this was used to identify and manage problem patients, rather than for all. It may be that the lack of focus on anaemia management in a typical MDT meeting, by comparison with an anaemia specific review, has a negative effect on the quality of the decisions made.

Waiting to make decisions at MDTs causes delays in the control loop, as discussed in section 7.3.1.2.1. While at some centres MDTs occur on a predictable basis, at others they are delayed based on the availability of the consultant which, when waiting for the MDT, increases the delay before dose changes can be made.

Although a specified ESA administration day may reduce complexity for an HD unit using weekly, fortnightly or monthly ESA, it needs to coincide with the testing and reviewing process to minimise additional latency. As both testing and reviews of HD patients are currently performed as a batch, batch administration will fit. While Mircera, and to a lesser extent Aranesp, reduce the number of injections for community administered patients, workload for district and practice nurses where they are used and may even improve compliance, as for HD patients timing is crucial.

Renal centres should not be using home delivery services or GP prescribing for ESAs for HD patients. Their use not only causes delays in the control loop, but greater uncertainty over whether treatment has been administered and if so, when. Fortunately, it appears from the renal centres that participated in this study that a move away from this practice is already occurring, with some centres having made the change prior to the study commencing and others now doing so, in part or whole. This is partly due to changes in the cost of ESA and the scale of discount that can be negotiated in a bulk contract, and partly due to a belief that the status quo did not provide the best possible care for their patients.

What is unclear is how renal centres should approach the delivery of ESA for non-HD patients. While the same problems exist with the system, for these patients an obvious alternative that solves these problems is not available. It is possible that with greater synchronisation of the whole system for testing, reviewing and delivering medication that a system more flexible to dose changes could be developed. However, whether the rigidity required in scheduling to produce such flexibility could fit with patients' lives is another matter.

Other healthcare services that use, or are considering adopting, home delivery should consider how it affects their flexibility to adjust treatment, the timeliness with which they can do so and whether alternative arrangements could improve these factors.

There exist significant financial incentives against providing a service that is both effective and efficient at a national level. The current rules for applying VAT to prescribed medicines and medical care have encouraged the use of home delivery services and GP prescribing, apparently at the expense of patients' outcomes (see section 7.3.1.2.3). At the national level with a public health service, the use of a home delivery service for haemodialysis patients should be expected to add costs without benefits. This is because any reductions in tax spend are equivalent to the reductions in revenue, while the additional costs of the delivery service must be borne.

The decision to include prescribed medicines as an inseparable part of medical care for VAT purposes should be re-examined. Guidance issued by the National Home Care Medicines Supply Committee, part of the Purchasing and Supplies Authority (PASA) of the NHS, states that home delivery services should not be used to make VAT savings, but only in the best interest of the patient (Karr, 2007). However, it is unrealistic in a quasi-market to expect this cost not to be considered by the relevant legal entities. Opticians successfully challenged the application of these rules by Her Majesty's Revenue and Customs, with the Commission of the European Community ruling that the sale of prescription glasses (prescribed medical device) were easily separable from the consultation and assessment (medical care) (Terra & Kajus, 2007).

However, they ruled that the UK was right to consider hospital goods that could not be dissociated from the service as exempt from VAT (ibid).

In summary, while a variety of organisational factors appear to contribute to achievement of performance indicators for renal anaemia management, reduction in latency and in particular, the removal of home delivery and GP prescribing mechanisms for HD patients with its associated benefits appear to be the one change most likely to produce significant improvement in performance. However, renal centres may need to work with the local commissioners to achieve this. Furthermore, a change in the application of VAT law may not only improve this situation but similar examples in other areas of healthcare.

## Chapter 8

### Discussion

This research aimed to develop an understanding how the organisation of renal anaemia management influences its performance, with the purpose of enabling improvements to be made. In order to support this aim, future research and performance improvement exercises, a model of the service delivery of renal anaemia management based on the participating cases was developed and reported in chapter 5. In chapter 6, the association of clinical performance with three basic contextual features of the centres involved was examined. In chapter 7, a range of organisational features were considered with respect to performance, based on the extreme performance groups in which the centres had been selected.

#### 8.1 Summary of principal findings

The most important finding is the apparent impact of a community-based prescribing service on performance and the associated problems with latency and coordination (see chapter 7). The finding that MDTs were typically not used for decision making by anaemia nurses at high performing centres was both interesting and provided a slightly different but complimentary angle to the existing evidence that haemoglobin performance was not improved by the presence of an MDT (Plantinga et al., 2004; Spiegel, Bolus, Desai, Zager, Parker, Moran, Bolus et al., 2010) (see chapter 7). Similarly, the importance of a well coordinated service for renal anaemia management fits with the conclusions of Spiegel, Bolus, Desai, Zager, Parker, Moran, Bolus et al. (2010) although the supporting evidence is different (see chapter 7). While resource with respect to anaemia and iron nurses was found to be statistically insignificant at the  $p = .05$  level, it appeared that it may in fact be relevant, as may be expected, and the model fitted the data well (see chapter 6). It also appeared that, as expected, contextual factors outside of the control of the renal centres may be responsible for some of the difference in performance, in particular ethnicity of the patient population that has been shown to be correlated with differences in haemoglobin in large quantitative studies (see chapter 6). The research also produced an original framework describing the organisation of renal anaemia management, which provided a demonstration of the successful use of UML for organisational process modelling within chronic healthcare (see chapter 5).

## 8.2 Implications of the findings

### 8.2.1 Implications for policy

The UK government should re-examine the rules surrounding VAT for prescribed medicines in institutional and self-care settings and reconsider their interpretation. As was discussed in chapter 7, the current rules and their interpretation, set in a context of quasi-markets and financial accountability at a trust level, encourages practice that is costly at a national level and appears to deliver lower quality care. The likelihood is that ESAs are not the only class of drug to use a home delivery service in order to reduce cost, rather than solely for the ease of the patient. Therefore, the effects of a change to this situation are potentially wide-ranging and particularly significant given current budget pressures (Great Britain: H. M. Treasury, 2010; King's Fund, 2009).

### 8.2.2 Implications for practice

For practitioners there are a number of recommendations for change that could be considered as part of an improvement collaborative, as was suggested in section **Error! Reference source not found.**. The key areas for practitioners to consider with respect to their own centre are: latency in the control loop, reliability of ESA supply and administration, reliability of communication of changes to anaemia management, the role for decision making given to anaemia nurses, their resourcing and their relationships with all members of the consultant team (see chapter 6 and chapter 7). Renal centres could use the diagrams presented in chapter 5 as a basis for modelling their own centre's processes for anaemia management. This could be used to understand their current processes better and to consider how they could alter them.

Renal anaemia management should be appropriately resourced to enable high quality management. It appears that, in centres where there are anaemia and iron nurses, the ratio of them to patients may be an important enabler of high performance, although as discussed in section 6.3, with a small sample size this was not statistically significant at  $p = .05$ .

Renal centres and those within chronic care should examine the timeliness with which they enable changes to a patient's treatment. High latency in the control loop for renal anaemia management appears to be a serious confounder of quality (see chapter 7). The most significant contribution to this in the case of maximum latency was the use of community-

based prescribing. However, the time taken to review patients was also important and often most affected by waiting for MDT meetings to make decisions.

Practitioners should consider whether an MDT meeting is the most appropriate setting for routine decision making and whether additional or alternative approaches are apposite. Based on this research and that of others (see section 7.5.1.4) it appears that MDT meetings are not essential to high performance in renal anaemia management. Although some other areas of care appear to benefit from MDT meetings it may be that in some cases this should be an opportunity for coordination and an additional check, rather than the main method for patient review.

## **8.2.3 Implications for research**

### **8.2.3.1 Non-HD patients**

Future research should examine factors that are significant in the performance of the non-HD patients. Because performance data for low clearance and general nephrology patients is not available, this thesis has said little about the factors that may affect performance for them. However, a large amount of data was gathered about them (as is evident in section 5.3.4) and there were many interesting differences in approach that may be expected to influence performance. As was noted in section **Error! Reference source not found.**, the problems with latency are ones that are less easily solved for non-HD patients, their consequences seem likely to be similar and this extends across a range of other factors, including many that are not relevant to HD patients. For HD patients, many of the challenges faced in the management of other chronic diseases relating to interaction between the patient and the service are lessened by the regular contact afforded by the HD session. For non-HD patients, the lack of routine data collection and the increased involvement of the whole local health network make comparisons all the more difficult. However, the models developed in chapter 5, the case narratives reported in Appendix A and the factors identified in chapter 6 and chapter 7 would provide a useful base for future studies.

### **8.2.3.2 Balanced measure of performance**

Future research into renal anaemia management performance could consider a wider measure (or set of measures) of performance, closer to a balanced scorecard approach (Kaplan & Norton, 1992). The evaluation in this study used a single clinical performance measure, the primary measure of anaemia management performance in the UK and one that was readily

available for the purposes of case selection. However, a balanced scorecard approach would advocate inclusion of a range of other measures of quality, customer satisfaction and cost, as well as measures of intra-organisational innovation and learning (ibid). Balanced scorecards have been advocated and used in healthcare (e.g. Chow et al., 1998; Kaatz et al., 2000) and should provide an evaluation that had greater significance for an organisation than one based solely on clinical performance. However, in order to be successful the choice of measures would be critical.

### **8.2.3.3 Comparison with other clinical performance measures**

On a related topic to the balanced scorecard discussed above, future research could examine how the factors identified here may influence other clinical performance measures of relevance to renal anaemia management patients. This research focused on renal anaemia management performance and processes related to renal anaemia management but some of these processes relate to other areas of healthcare. As was discussed in section 7.5.1.6, attendance of an anaemia nurse at an MDT may have significance for other clinical performance measures, even though it appears not to for anaemia management. However, such work would require a different approach to the one taken here in order to encompass a sufficiently large sample size.

### **8.2.3.4 Survey of renal centres**

Future research could operationalise the factors examined here and, following a survey, examine the evidence for the generalisability of the findings here across English, UK and other renal centres. This research has identified a set of factors that appear to relate to performance in these renal centres with mechanisms and contexts that seem likely to generalise across other renal centres but further research that found statistically significant associations between these factors and performance for renal anaemia management would strengthen the claims made here.

### **8.2.3.5 Action research**

Perhaps the most productive piece of research that could be conducted following on from these results would be to use them as the basis for action research, either within one location or as an improvement collaborative between renal centres and their partner organisations. Action research involves working with an organisation to bring about some change based on theory and evaluate its impact on the local context (E. Harris, 2008). An

improvement collaborative involves a group of organisations focusing on improvements to a particular area, making changes, examining the evidence of the effects of those changes and communicating with each other about their successes and difficulties (Øvretveit, 2002). Such an approach would enable these tentative results to be examined in practice, theory being modified as appropriate and hopefully benefit for those involved in renal anaemia management.

#### **8.2.3.6 Comparison with abstract best practices**

Future research could compare the process models developed during this research with abstract models of best practice to consider opportunities for improvement and theory-driven reasons for the current balance of performance. For example, Reijers and Liman Mansar (2005) have gathered a large selection of best practices described elsewhere in the literature and presented them with an appraisal of their expected impact on aspects of performance. This could help identify additional reasons for performance differences between the centres and provide additional support for the theories developed here.

#### **8.2.3.7 Decision support**

Future research could examine the design of decision support systems to produce recommendations more likely to achieve stable haemoglobin levels. This research largely treated decision making within renal anaemia management as a black box, although section 7.3.5 reported attempts to understand some of the basic parameters that shape it. Where decision support systems are in use they currently have relatively simple algorithms for calculating their recommendation, as described in sections 3.3.7 and 7.3.5. These appear to result in relatively high performance by current standards but also relatively high rates of dose adjustment (section 7.3.5). In addition, algorithms (or any other method) do not achieve a target level for all or even close to all of their HD patients, although whether this may ever be possible is unclear.

It is currently unclear whether and to what extent stable haemoglobin levels, haemoglobin levels within a particular target range and stable doses of ESA and iron are causal of mortality and morbidity. However, there are statistical associations with these as described in section 3.3.8 and costs associated with dose adjustment where the patient's ESA is supplied for use in the community (as described in section 7.3.1.2.2). For these reasons, understanding how to achieve a specific and stable haemoglobin level for the individual patient is a valuable

exercise while further evidence is gathered about exactly what anaemia management should be attempting to achieve.

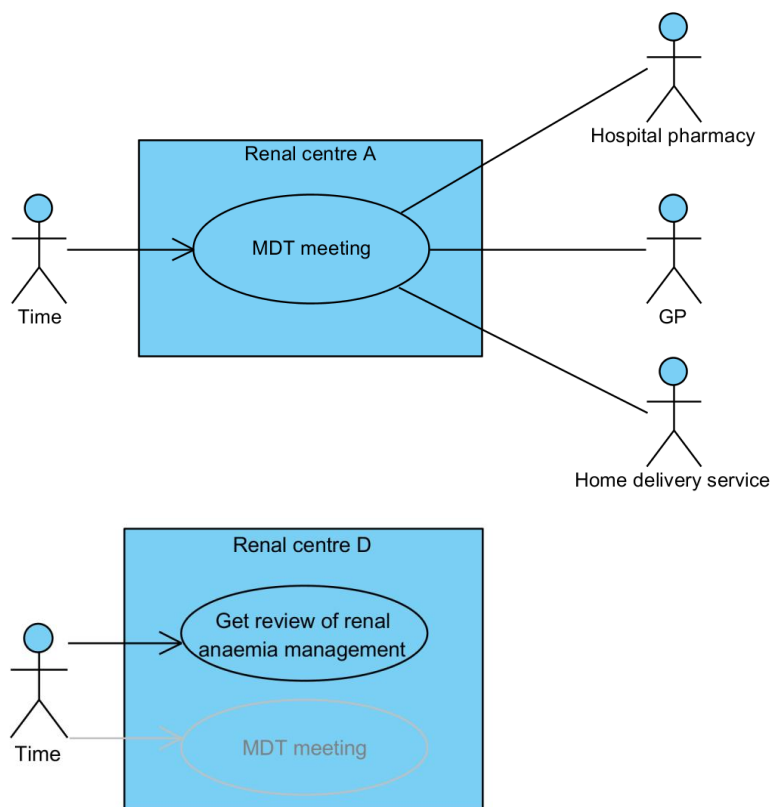
The development of algorithms that include a greater number of inputs and that automatically tailor the response to the patient's responsiveness to ESA should be examined. However, the concerns of respondents to the possibility that sufficiently capable anaemia management decision support could mask underlying diseases should also be addressed by examining changes to patient responsiveness in absolute and relative terms. In that case, such systems could assist with the early identification of underlying diseases rather than risk masking them.

## 8.3 Comparison of the findings with the published literature

### 8.3.1 Chronic care coordination

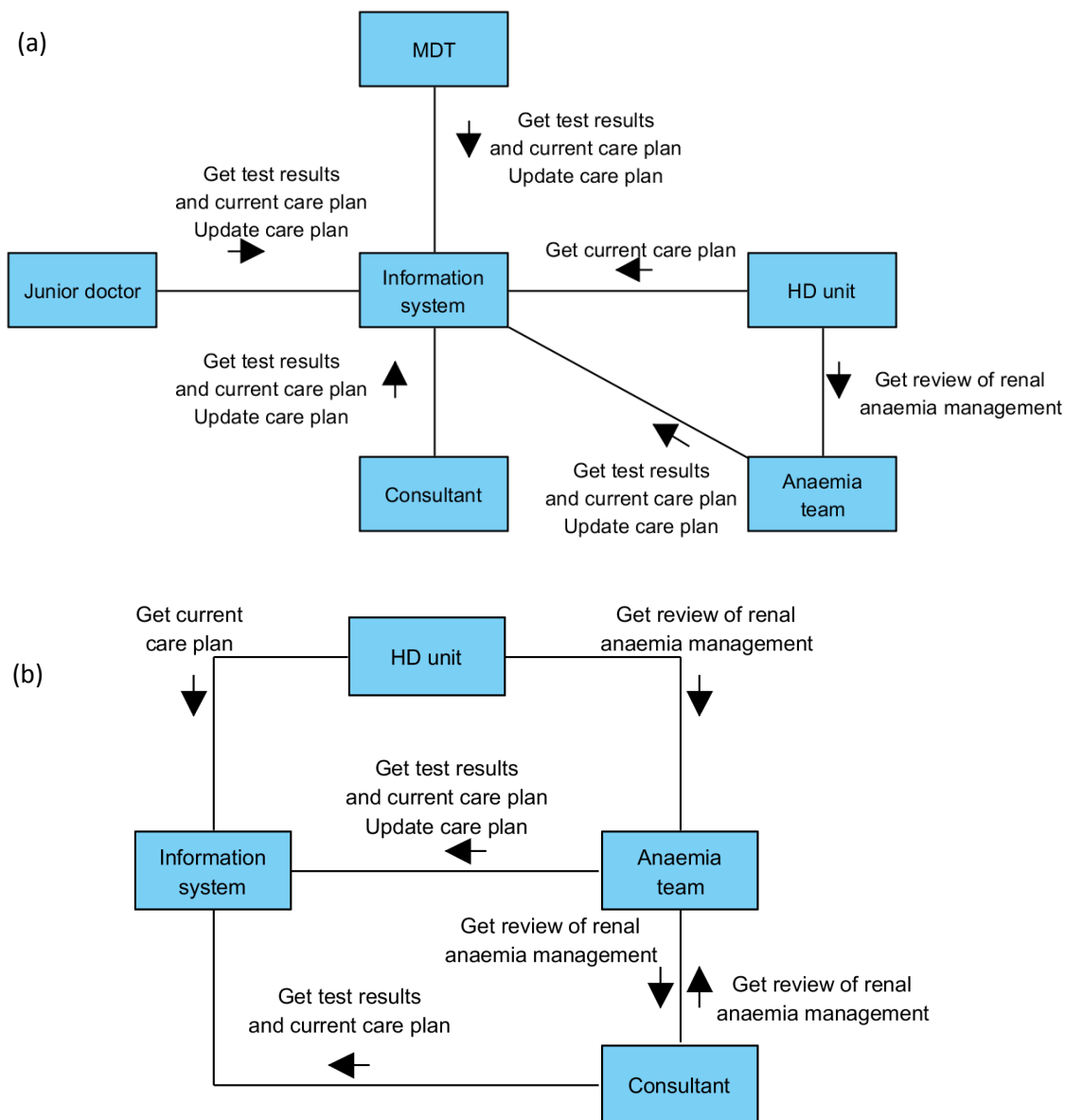
Coordination within and between care providers is vital and there are a number of different mechanisms for achieving this (Gittell, 2002). However, it appears as though different mechanisms suit different problems. For example, while a HD MDT meeting appears important for phosphate control (Casula et al., 2009; Hodsman et al., 2009) and reducing mortality (Plantinga et al., 2004; Spiegel, Bolus, Desai, Zager, Parker, Moran, Solomon et al., 2010), it does not appear to be important for anaemia management (chapter 7, this thesis; Plantinga et al., 2004; Spiegel, Bolus, Desai, Zager, Parker, Moran, Bolus et al., 2010). It may be, as must be presumed by those who advocate strict use of algorithms with a sparse number of inputs for anaemia management, that haemoglobin is relatively isolated from other aspects of patient care by comparison with these other factors. Alternatively, it may be that MDT meetings are not an appropriate environment or mechanism for the type of decision making or even information sharing required for anaemia management of HD patients and that more timely and focused decision making and information sharing are better suited to its needs. The approaches to coordination of renal anaemia management evident in review mechanisms and decision making are characterised below to assist the comparison with the literature.

Figure 8.1 illustrates the different primary mechanisms for reviewing an HD patient's anaemia management following routine bloods and the external parties that may be informed as part of the process in centres A and D, as described in section 7.3, which are typical examples of low and high performing centres respectively. This illustrates both the differences in mechanism for decision making and the external parties with which the centre may have to coordinate. Note that the MDT meeting of centre D is greyed out because although it occurs it is rarely active for renal anaemia management decision making. At centre D there is no need for external coordination, meaning they can focus on internal coordination. In contrast, at centre A the renal centre must update multiple external partners (the pharmacy, home delivery company and multiple GPs for multiple patients) and the internal coordination occurs implicitly as part of the discussions in MDTs.



**Figure 8.1** The main use cases for reviewing an HD patient's anaemia management at renal centres A and D

In chapter 7, sections 7.3.2 and 7.3.4, difficulties with coordination and differences in the patterns for decision making were described. Figure 8.2 presents two communication diagrams illustrating stylised approaches of low and high performing centres to reviewing and altering renal anaemia management for HD patients where the HD unit provides and administers ESA. These are significant characterisations and the reality was much more rich and varied and much less distinct. However, they serve to illustrate the differences. In (a), four different entities are reviewing and adjusting anaemia management. In (b), fewer entities are reviewing a patient's care and, if they believe it should be changed, they request this of the anaemia team, who are the only group to make a change. The latter approach should reduce the likelihood of multiple dose changes being made in a short space of time. It may also improve the decision making because one expert group is making the majority of decisions (although sometimes in collaboration with a consultant). However, it may be problematic if a patient's haemoglobin changed significantly and this was not reported to or noticed by the anaemia team in a timely manner. Given sufficient vigilance by the staff of the HD unit and a robust process for routine bloods and review this should not be problematic.



**Figure 8.2** Two communication diagrams to illustrate the entities and interactions internal to a renal centre that can relate to decision making for a haemodialysis patient's renal anaemia management where (a) characterises a low performing centre and (b) characterises a high performing centre.

Therefore, for HD patients, successful centres appear to improve coordination by reducing the number of parties involved, in particular external partners, and explicitly using the anaemia team to coordinate change, both by directing change to them and in the actions they take (a specific review of anaemia management rather than participation in a general review). In terms of the coordination literature this is a simple reduction in the extent of coordination required and an increase in the use of a boundary spanning role rather than team meetings as a coordinating mechanism. Findings that support and extend the existing literature on MDT meetings for renal care and anaemia nurse coordinators.

### 8.3.2 Appropriate representation of care pathways

The approach to process representation in this thesis has differed from many such models in healthcare by representing more than just activity and sequencing and therefore enabling views that appear better suited to chronic care. Like the LRA, this study has used UML, including use case models. However, in addition state, communication and sequence models were employed. The state diagrams enabled changes in the patient's role with relation to the service to be described, allowing sets of possible interactions to be combined into abstract groupings. Interestingly, this fits with the language that is used by renal health care professionals (different patient modalities) and in the LRA the activities in the overview activity diagram (reproduced in Appendix M) have been grouped similarly, suggesting that these are useful abstractions in chronic care. Similarly, the use of use case models enables elementary business processes to be separated from each other, which is useful because their selection and sequence is typically so variable and determined by so many factors that they cannot be usefully displayed in a diagram. Finally, by remodelling the boundary away from the physical and legal boundaries to a functional boundary the complete collection of use cases were able to be abstracted, regardless of which entity may provide them.

### 8.3.3 Clinical control loop latency

While previous research has examined the impact of delays due to waiting lists for episodic care (Meier-Kriesche et al., 2000) and delays in medical devices (Bode et al., 2002), none appears to have examined the relationship between delays in a control loop and performance where the clinician is the controller. Such delays would appear to be surprisingly common, for example, follow-up outpatients appointments are often run with a clinician using test results from the previous visit, the patient having left by the time the new test results are available.

## 8.4 Conclusion

As healthcare delivery continues to increase in complexity, it becomes ever more important to develop grounded understanding of how and why it is successful or not. This study has identified several candidate mechanisms and contextual features that appear to influence performance in renal anaemia management. This is the first study of the causes of variation in performance in renal anaemia management to use a multiple case studies approach or to use direct observation, rather than surveys or aggregated datasets. In addition, the study has combined existing techniques to produce a more robust and rigorous approach to the development of organisational process models in healthcare. The features identified should be an important input to improving renal anaemia management or redesigning services and may generalise to other areas of healthcare, in particular chronic care.

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## **Appendix A**

### **Eight case studies of renal anaemia management services**

This section explores the anaemia management service provided by eight renal centres as case narratives and the issues each of them perceive. This examination of critical cases enables us to understand how anaemia services are provided and to appreciate issues that may be unique to a set of circumstances.

#### **A.1 Methods**

The centres involved were selected and fieldwork carried out in line with the methods described in chapter 4. Case narratives were synthesised from the field notes, interview transcripts and documents. Each provides a summary of the centre's context, structure, the activities relating to patient monitoring and treatment and the issues that were discussed during the course of the case study. In part it has been necessary to abstract detail from these narratives in order to maintain the anonymity of participating centres and individuals. The study did not receive ethical approval to publish direct quotations that are linked to a specific centre and therefore only summaries of data will be provided in this appendix.

## **A.2 Centre A**

### **A.2.1 Setting**

Based in a large urban area with a wide geographical catchment, the centre is one of the largest in England. The centre's patient cohort includes a relatively high percentage of patients from ethnic minorities (in the top quintile of English renal centres), who are more likely to be anaemic (see chapter 5). Participants also report that communication with those patients for whom English is not a first language can be difficult.

### **A.2.2 Structure**

The centre has seven satellite units external to the main centre and two at the main site. There are fourteen consultants including four academics, thirteen specialty registrars (StRs) of which seven are research registrars and two matrons. The main centre employs just under 200 health care professionals and is divided into: four inpatient wards, the acute renal centre, renal assessment centre, renal outpatients, CAPD (continuous ambulatory peritoneal dialysis) team, renal transplant team, community team, anaemia team, dialysis access team and satellite coordinator.

The centre's anaemia team has one full time nurse graded at band 7 with non-medical prescribing, two band 6 nurses (1.6 FTE), one of whom has non-medical prescribing, and an administrator. The team has changed during the period of study, spending most of the time without an administrator, starting with 1.8 FTE band 6 nurses, then moving to one band 6 nurse and one band 5 nurse before arriving at the current arrangement. The roles within the team have also changed to accommodate the changes in personnel.

The anaemia team are located with some of the other specialist nurses in an office that is in one of the far corners of the renal centre. The consultants' offices are situated around the centre and the main centre itself is located across multiple floors and buildings.

### **A.2.3 Main methods of review**

#### **A.2.3.1 Haemodialysis patients**

The haemodialysis patients' anaemia management is reviewed monthly as part of a series of 'QAs' (quality assurance meetings), with one taking place for each dialysis unit. At the meeting there is usually a consultant, senior nurse for the unit, anaemia nurse, dialysis access

nurse and dietician. These meetings were said to be typically two or three weeks after the patients' blood is taken for testing, although I attended one where the blood results were four weeks old.

Haemodialysis patients also have the opportunity to attend a consultant-led clinic, typically every four months. This was described as significantly more frequent than had been the case a few years ago. The main purpose of this is to take an overview of the patient's management, discuss matters such as transplant listing and other issues. Anaemia is more typically managed in the QA, in the presence of an anaemia nurse.

Patients are routinely assessed as part of their dialysis session. If a dialysis nurse suspects they are anaemic they may take a blood sample for testing and, depending on the result, inform medical staff or the anaemia team.

At each dialysis unit there is at least one anaemia link nurse. This has not always been the case and depends upon individuals who are committed to the role. Typically they review the patients' monthly blood results within a few days of them being produced and will alert the anaemia team or a consultant of any patients whose results show a haemoglobin less than 9 g/dl or greater than 14 g/dl and in the latter case stop further administration of their ESA. They also titrate the patients' iron therapy according to a protocol based upon their ferritin results (and haemoglobin if over 15 g/dl).

### **A.2.3.2 Peritoneal dialysis patients**

Peritoneal dialysis patients at centre A typically attend a clinic every two months and see a consultant every four months. At this, their bloods are taken and these are then reviewed later in the week by the nursing team. The nurses record queries and recommendations for changes to the patient's management and a consultant reviews and authorises these later. The exception to this is anaemia management where the nurse team will request a review of ESA from the anaemia nurse.

### **A.2.3.3 General nephrology, pre-dialysis, home haemodialysis and transplant patients**

A member of the medical team reviews these patients at their clinic consultation. These are typically every 3-6 months but can vary greatly depending upon the condition of the patient and their proximity to treatment (e.g. prior to the start of dialysis or following a transplant).

Patients who are not receiving dialysis and are prescribed an ESA are currently reviewed by the anaemia team monthly for the first six months of their treatment and then on referral or when issuing a repeat prescription. This typically occurs six monthly for home delivery patients (see delivery of treatment below), but does not occur for those prescribed ESA by their GP. This is a change from practice in summer 2008 when all non-dialysis patients on ESA were to be reviewed following their clinic visit. However, at that time there was a waiting time of around seven weeks for that review, which was reported to be similar to the waiting time in 2006.

## **A.2.4 Delivery of treatment**

### **A.2.4.1 ESA**

Either the renal centre or the patient's GP prescribes ESA depending upon their PCT, with an approximately even split between the approaches. In all but one PCT, all outpatient modalities are either renal centre or GP prescribed, in that one HD patients are centre prescribed and all others GP prescribed. Where the centre prescribes to outpatients, they receive neoRecormon via a home delivery service except for HD patients at two dialysis units where they dispense and administer ESA directly. Where the GP prescribes ESA, patients should collect it from a local pharmacy. Many of the patients here have their ESA administered by district nurses or practice nurses; the evidence for this is impressionistic, based on observation and agreed by members of the anaemia team. This is justified by the anaemia team in terms of patient choice and safety – they perceive a lack of contact with the patients they are responsible for and feel security in the knowledge that patients are regularly seeing another health care professional. Where a patient is seeing a district nurse the team typically reduce the frequency of administration to once weekly to reduce the burden upon them.

### **A.2.4.2 Iron**

Venofer is the IV iron used in all but exceptional circumstances by centre A. Haemodialysis patients receive Venofer during their dialysis session while peritoneal dialysis patients attend a clinic and receive iron from the PD team. A new protocol for IV iron introduced in the start of 2008 was reported by PD and HD nurses to have greatly increased the amount of iron being given. General nephrology, transplant and home haemodialysis patients prescribed IV iron usually attend an iron clinic run by the anaemia team although this service has recently changed. Previously the clinic shared space with the PD team, with reported scheduling and capacity difficulties and a waiting list of six to eight weeks. The clinic now has

its own space and increased capacity (from 18 to 23 patients per month) and an additional iron service is now offered from a day case unit in a large acute hospital. The team are hopeful that as a result the waiting list will reduce. However, such is the geographic spread of the centre's catchment that certain patients are not offered IV iron due to the distance they would be required to travel on five occasions in order to receive a typical course of Venofer (one gram of iron). Although the anaemia team state they have made significant efforts to establish an external iron service in this area, including identifying and training willing staff, they claim that financial pressures have blocked it. The team also expressed a desire to provide an occasional satellite clinic for this population using Ferinject (capable of providing one gram in one injection) but haven't yet been able to agree the use of this drug.

### **A.2.5 Problems (as identified by participants)**

There was surprisingly little attempt to blame performance on the circumstances of a large, often inner city population with a large ratio of ethnic minority patients. These factors were often mentioned by participants to state that they didn't consider them to be significant or the major cause, but believed some of their colleagues would. Where the size of the centre was considered significant it was related to the ability to know one's patients or the amount of time available to consider the management of any one patient, but as stated before, these views were not universal. There was also a suggestion from one consultant that their size might make them less innovative or responsive to changes in the guidance or technologies available to them. The large ratio of ethnic minority patients was pointed to as a performance factor by many, citing clinical difficulties (e.g. sickle cell, thalassaemia) and communication problems with those who speak little or no English. This is a particularly important factor when administration of ESA usually occurs outside of the hospital setting.

GP prescribing raised several concerns: primarily relating to lag times in changing prescriptions but also the additional effort required of patients and the possibility of patients going unreviewed for long periods of time. For a GP prescribed patient, a change of syringe type is communicated by letter, a process that can take several weeks before the prescription is issued. Then the patient has to collect the prescription and dispense it at their local pharmacy who often have to order the drug in, creating an additional lag. As stated above, because one of the review mechanisms used by the anaemia team is the request for and issuing of repeat home delivery prescriptions, a patient who is GP prescribed will not receive this review. There was also some concern that the home delivery service could cause delays but it was not considered as significant as GP prescribing.

There were conflicting opinions about how sufficient the human resources available to the anaemia team were. While some thought more staff were needed, either in the centre or stationed around the catchment area, one participant claimed the growth of the anaemia team had outstripped that of the patient population. The current arrangements for monitoring the anaemia management of general nephrology and pre-dialysis patients (a reduction on the previous approach) are because the anaemia team were unable to continue to deliver their previous plan. A suggestion from the anaemia team was to redeploy one of their members of staff as part of a new pre-dialysis team and then rely on that team for routine monitoring of those patients, reducing duplication.

Several participants suggested that haemoglobin cycling (persistently oscillating haemoglobin - see chapter 3) was an issue at this centre because of dose adjustments that were excessive in scale or frequency. However, there were conflicting opinions on who was responsible for this.

It was widely acknowledged that iron had previously been underused and they believed the new protocol would help. There was concern that too many haemodialysis patients' arterial access was with catheters rather than fistulas (a cause of infection and as a result reduced haemoglobin). I was also informed that in comparison to other centres within the region their ESA use was high despite having a relatively low average haemoglobin.

Communication and access to information were highlighted as problems by the anaemia team, in particular, access to blood results. Blood results for any tests not performed at the main centre are not available on their information system, at least for a long period of time. For haemodialysis patients in satellite centres, their results are eventually transferred manually to the information system used at the main centre. For other outpatients any blood tests done elsewhere are not available without contacting the lab where the test was performed or the healthcare professional who requested the test. This takes a significant amount of time, even when all parties are cooperating and as a result many patients are brought into the centre for blood tests.

Communication of any changes to treatment could be problematic for a number of reasons. There were allegations that changes made in clinics would not always be communicated to the anaemia team, which could cause problems with deliveries being made for the wrong amount, a patient not receiving the altered dose or running out of ESA, or further adjustments being made based on inaccurate information. It was also alleged that haemodialysis nurses did not always communicate changes to patients, particularly at one satellite. While I didn't gather evidence to support these specific allegations there were several

occasions when it was apparent that the various parties (i.e. patient, GP, anaemia team, dialysis unit) differed in the dose they believed the patient was prescribed.

There was a suggestion that the new NICE guidelines had affected their centre particularly because they hadn't been too concerned with patients having a haemoglobin up to 14 g/dl and they had wanted to keep their patients higher rather than lower. However, the centre's performance for Hb  $\geq$  10 g/dl was lower than the national average and lower than the recommended achievement of 85% of patients from the previous guidelines. There were concerns too with the way that Renal Registry figures for Hb 10.5-12.5 g/dl are calculated: that patients with a high haemoglobin who aren't receiving an ESA are included in the figures and shouldn't be. It was also suggested that the caterpillar plot presentation was unfair as the differences were exaggerated and people tend not to take into account the size of the errors.

## **A.3 Centre B**

Centre B is located in a relatively rural region with a largely white population. The centre has an average dialysis population size, lying in the middle quintile of English centres.

Centre B has five consultants and two satellite units. At the main centre there is an in-patient ward, dialysis unit, CAPD team, dietetics, transplant team, pre-dialysis nurse and a new post of dialysis access nurse. In addition there is the centre's anaemia team with one anaemia nurse and now a part time iron nurse. The anaemia team do not typically deal with home-based dialysis patients, those patients' anaemia related monitoring and paperwork largely being conducted by the PD team. Specialist nurses are located closely to the registrars and in between the consultants and the chronic dialysis unit, the in-patient ward being on a separate floor.

### **A.3.1 Main methods of review**

#### **A.3.1.1 For haemodialysis patients**

The haemodialysis patients have routine bloods taken every six weeks. This is so that the five teams at the main unit and a satellite unit each take it in turn to go through the process weekly. The anaemia nurse reviews all patients and makes decisions about the ESA and iron doses as well as additional tests required of the majority of patients. These are usually authorised and in place by the patient's next dialysis session (within 48 hours). For those patients the anaemia nurse is unsure about or those who are outside of protocol the anaemia nurse waits for the MDT, which occurs one week following the routine bloods. The MDT is usually comprised of a consultant, dialysis nurse, anaemia nurse, dietician, vascular access nurse, transplant nurse and pharmacist who review the patients' management.

The haemodialysis patients have the opportunity to attend clinic every six months. They are also routinely checked by the nursing staff when they attend for dialysis.

#### **A.3.1.2 For community dialysis patients**

PD and home haemodialysis patients are routinely reviewed in clinic 3-monthly. The CAPD team usually visits these patients at home to take blood samples a couple of weeks prior to a clinic visit. There is also a 2-3 monthly QA meeting with one or two consultants, two CAPD nurses, a dietician and social worker. Any change to treatment will be sent for authorisation to

the consultant in charge of PD and notified to the home delivery service. Repeat ESA prescriptions for CAPD patients are typically issued every 6 months following a request from the home delivery company and review by the CAPD team.

### **A.3.1.3 For general nephrology, pre-dialysis and transplant patients**

These patients are seen at consultant clinic every three to four months if they are considered stable and more frequently if required.

All general nephrology, pre-dialysis and transplant patients who are being treated with ESAs are reviewed monthly by the anaemia nurse. The anaemia nurse sends hospital blood forms to the patients and asks them to attend their GPs for samples to be collected monthly. Patients are also asked to notify the anaemia nurse when they have been tested, in which case they are reviewed as their results become available. These patients are also reviewed prior to issuing a repeat prescription for ESA, which usually occurs on request from the home delivery company every three months.

## **A.3.2 Delivery of treatment**

### **A.3.2.1 ESA**

All patients' ESA is prescribed by the renal centre. The supply of ESA to patients is through the hospital for the haemodialysis population, and via home delivery for community dialysis, conservative care, pre-dialysis, general nephrology and transplant patients. Eprex is used for the haemodialysis patients whereas neoRecormon is used for most home delivery patients. Historically PD patients were supplied Aranesp as their PD supplies were also delivered by Fresenius but new PD patients are now initiated on neoRecormon because it is contracted at a significantly cheaper rate. Home haemodialysis patients are supplied Eprex via home delivery.

### **A.3.2.2 Iron**

Haemodialysis patients receive any IV iron prescribed to them during their dialysis session. The centre is currently running two days worth of iron clinics a week for the non-dialysis patients. This follows approximately one year where these patients were not treated with IV iron. The PD team had previously been delivering all IV iron treatments to non-HD patients but due to the expansion of the CKD population they felt their commitments to their own population were suffering and that they could no longer take on that responsibility. The

centre applied for funding for the additional post that now provides IV iron treatment to non-dialysis patients, which the trust granted. During that year, PD patients continued to receive IV iron as considered necessary. The centre has put forward a business case to introduce Ferinject, particularly for those patients who live furthest from the centre but it has yet to be approved.

### **A.3.3 Issues**

Historically the centre only used TSATs to determine iron dosing, rather than ferritin that is often used elsewhere. They became aware that their patients had higher ferritin levels than their peers and have since taken ferritin into account as a secondary measure, particularly to limit iron provision for those with high ferritin. However, some are unconvinced that the new approach is necessary and would like to see further research conducted on the effect of high ferritin levels. There was also discussion of trialling the use of post-dialysis haemoglobin measures rather than the typical pre-dialysis measures as it might be a better indicator of a patient's inter-dialytic haemoglobin because it would be less affected by fluid intake. The centre uses pre-dialysis haemoglobin but participants joked that it would be much cheaper to dose based on a post-dialysis measure.

As is described above, the centre's non-dialysis population were not offered IV iron treatment for a year as the providers of the service had reached capacity. The centre had placed a business case with the trust at the time of my first visit and when I returned a year later they were operating an iron clinic.

The PD team reported that the review prompted by a request for a repeat prescription can occasionally identify that the dose the centre believe the patient is getting differs from that being delivered. The problem was not blamed solely on the delivery company (it was acknowledged that this would sometimes be down to forgetting to communicate a change of dose to the company) and was estimated to occur once or twice every six months.

## **A.4 Centre C**

### **A.4.1 Setting**

Centre C is situated in a large metropolitan area with a relatively high percentage of ethnic minority groups (in the 4<sup>th</sup> quintile for English dialysis centres). The centre is of average size, in the middle quintile for dialysis centres, and has four satellite units.

### **A.4.2 Structure**

Six consultants run the centre, usually with three or four registrars. There is a haemodialysis ward, an in-patient ward, CAPD ward, chronic renal failure team (pre-dialysis and conservative care), anaemia nurse, transplant nurse and live donor coordinator. The anaemia service is headed by one consultant and largely run by an anaemia nurse. This post has changed hands twice during my study. On my first visit the specialist nurses were located in a very cramped office and borrowing clinic space from the CAPD team. By my return they had moved away from this more central location but now had more suitable office space and their own clinic area.

### **A.4.3 Main methods of review**

#### **A.4.3.1 For haemodialysis patients**

The centre's haemodialysis population are reviewed at monthly QA meetings, which vary in their composition depending upon the site they are for. The timing of each meeting is organised on a monthly basis. The anaemia nurse typically attends meetings out in the satellite units but not for the main centre. Haemodialysis patients are reviewed at a consultants clinic every three to four months and receive a routine check at every dialysis session.

#### **A.4.3.2 For peritoneal dialysis patients**

Peritoneal dialysis patients attend clinic once a month and see a consultant every three months. During the visit blood samples are taken and sent for testing, the results of which are reviewed in the coming days. There is also a CAPD QA meeting that is organised each month, which the anaemia nurse, PD nurses and a consultant attend.

### **A.4.3.3 For general nephrology, pre-dialysis and transplant patients**

The general nephrology and pre-dialysis population are seen in consultant and nurse-led clinics. Those who are having their anaemia managed are routinely brought in to the centre for additional blood tests and review by the anaemia nurse or by a pre-dialysis nurse once they have entered that phase of care. Those reviews (a clinic visit of one sort or another) are typically every two or three months once the patient is established on ESA treatment. For pre-dialysis patients there are two-monthly QA meetings between consultants and pre-dialysis nurses.

### **A.4.3.4 Anaemia QA meeting**

The consultant who heads anaemia management and the anaemia nurse review a selection of all patients in a monthly anaemia QA meeting at which the majority of prescriptions are produced. They work through all patients who are due to receive a new ESA prescription and each month select additional lists such as patients whose haemoglobin is greater than 12.5 g/dl or less than 10.5 g/dl.

## **A.4.4 Delivery of treatment**

### **A.4.4.1 ESA**

The centre prescribes ESA that a home delivery service provides to a large majority of patients, the exception being those that live in one PCT where GPs still prescribe ESA. The exclusive use of a home delivery service for centre-prescribed ESA was only just starting when I first visited centre C in the autumn of 2008; prior to this, the centre issued FP10 hospital prescriptions to either the patient or home delivery service depending upon their PCT.

### **A.4.4.2 IV iron**

The centre administers iron to haemodialysis patients during their sessions. For all other patients IV iron is provided in an outpatient clinic or the home. The CAPD team and pre-dialysis nurses administer IV iron to their respective patient groups while the anaemia nurse will provide iron for the rest.

### **A.4.5 Issues**

As is described above, space was previously a major issue for the anaemia nurse, both for office work and providing clinics.

There were reported to be around 30% of dialysis patients with catheters for access rather than fistulas. Lines result in increased risk of infection and therefore poorer haemoglobin.

Some features of the information management tools were not robust or required the same information to be entered multiple times. For example, the information system was used to print prescriptions at the end of the anaemia QA, a feature not seen in this form at other centres, but sometimes due to paper mis-feeds individual prescriptions would be missing or duplicated requiring a checking process.

There was some tension with the home delivery service that wasn't witnessed elsewhere. The home delivery service was sending requests for repeat prescriptions before they were due, apparently because they were already planning to make a delivery in that area. Because the centre manages the production of repeat prescriptions via the monthly QA they were aware of this and unhappy that they were being tasked to produce prescriptions ad-hoc that weren't due.

## **A.5 Centre D**

Centre D is a relatively small renal centre (2nd quintile of English renal units) in a rural region with a largely white population (1st quintile). The centre has two satellite dialysis units.

The centre currently has four consultants, but had three during my first visit in 2008 and typically has two registrars. At the main centre there is a haemodialysis ward, in-patient ward, home dialysis team, anaemia team, pre-dialysis educator, transplant nurse, vascular access nurse, dietician and renal counsellor. The anaemia team has expanded during the study period from one full time nurse with an iron nurse being employed for one day a week. The anaemia team and other specialist nurses are located in an office in between the consultants' offices and the dialysis unit.

### **A.5.1 Methods of review**

#### **A.5.1.1 For haemodialysis patients**

The centre reviews haemodialysis patients' general care at monthly MDT meetings, three monthly clinics, routinely when attending a dialysis session and informally as part of medical ward rounds. The MDT meeting is not attended by the anaemia nurse, but is attended by a consultant, dialysis nurse and dietician.

Management of anaemia in HD patients occurs once a month following monthly bloods. The anaemia team review the results with the assistance of a computerised decision support system. A recommendation is then passed in the form of a printed prescription to the patient's consultant. Signed prescriptions are then passed to the dialysis unit and new doses are typically administered five days after blood samples are taken. Ferritin is tested every three months and at that point new iron prescriptions are produced. The anaemia nurse has begun training a dialysis nurse at a satellite to perform this review and refer to her as necessary. The intention is that this will eventually be in place for each unit and will not only enable the centre to manage increasing patient numbers but will also improve the ability of the centre to manage anaemia should the anaemia nurse be absent or leave.

#### **A.5.1.2 For other patients**

These patients attend clinic at differing intervals depending upon condition and modality but typically three-monthly. Management of anaemia in these patients occurs as part of a

once weekly batch job. Patients treated with ESA are encouraged to attend their GP for monthly blood tests. The information system gathers blood tests for all renal patients (all blood tests within their catchment area go to the local pathology lab) and enables a list of all patients' latest blood test results to be printed off. The list, containing patient identifiers, the latest haemoglobin, its test date and current ESA dose is examined by the anaemia nurse to identify new results and those patients are reviewed.

## **A.5.2 Delivery of treatment**

### **A.5.2.1 ESA**

The centre prescribes the ESA for all patients. Haemodialysis patients receive their ESA on dialysis while all other patients receive their ESA via a home delivery service. It was claimed that only three to five percent of home delivery patients have their ESA administered by district or practice nurses and that the anaemia nurse takes a hard line with patients about this.

### **A.5.2.2 IV iron**

Iron treatment is provided for some of the non-haemodialysis population in their local district hospitals, while those local to the main centre attend an iron clinic there and those who would require hospital transport are visited by an acute community nursing service. An initial dose is always administered at the main centre. As at other centres, the demand for iron in the general nephrology and low clearance populations has increased substantially over the past few years. As a result a second iron clinic was introduced and a dialysis nurse employed one day a week to cover this. This nurse is also being trained to fulfil much of the anaemia nurse's role as is discussed above.

## **A.5.3 Issues**

There was some concern expressed by consultants at centre D about the extent of their reliance on their anaemia nurse who they considered a significant part of their success. They described how the concentration of knowledge and skills in one individual left them potentially vulnerable should the anaemia nurse leave and that they wanted to ensure that they could continue running in the face of absence. Others expressed concern at the impact of an anaemia team on the knowledge and skills of the ward staff who no longer had to consider anaemia as part of their daily routine. It was suggested by one participant that some of the named nurses would not know their patients' haemoglobin or anaemia treatment off by heart

for this reason. Partly for these reasons and the expansion in pre-dialysis population a haemodialysis nurse is now working one day a week as part of the anaemia team and the plan is to have a nurse at each haemodialysis unit and the peritoneal team take on increasing roles in anaemia management.

There has been significant interest in the decision making process of the anaemia nurse from the consultant body because of their responsibility for prescribing. Concern was expressed by one consultant at the elements of this that were not algorithmic but based on experience. While considering the impact on patients of the status quo to be positive, the consultant wanted to be able to capture that experience explicitly in order to fully understand and document their method. The anaemia nurse has recently gained non-medical prescribing status and will therefore carry this responsibility in the future.

Several changes have been made to haemodialysis ESA prescriptions and the routine around them in the face of errors that have been identified. The patient's name and number are now in a large bold font following a mismatch between patient and prescription. The print-out now marks crosses through the available signing boxes that should not be used to prevent excess doses being given when a patient has fortnightly dosing (most patients are administered ESA weekly). The anaemia nurse also produces a list of patients that is passed with the prescriptions to the dialysis team, which they then mark as they transfer each prescription to the patient's folder to ensure none have been missed.

One consultant expressed concern at the way that information on haemoglobin, other anaemia related test results and treatment are presented in their information system: that the information is distributed over multiple pages and therefore comparisons and trends are harder to make.

## **A.6 Centre E**

Centre E is based in a large metropolitan area and has six satellite dialysis units. The centre is in the quintile of largest renal centres. At the end of 2006, the centre was low performing for anaemia management in terms of both current and old Renal Association guidance. The centre has a large ethnic population (in the largest quintile for renal centres) which they report, in addition to anaemia-specific comorbidities, can make communication difficult and result in compliance difficulties due to increased needle phobia.

The centre has 13 consultants and a number of specialist teams including CAPD, transplant, low clearance, vascular access, dieticians, supportive care and anaemia.

The anaemia management team changed significantly during the study period. There is currently a shared band 7 anaemia nurse post with three full time band 6 anaemia nurses and a half a full time equivalent administrator. However, during the study period and at times before there has been significant understaffing by comparison with what they are funded for. Near the time when the 2006 performance data was recorded, the team was at one stage reduced to 0.6 of a band 7 anaemia nurse.

The anaemia management team are one of a number of nursing groups in the centre attached to a consultant. Physically these teams are located in the outpatients section, separated from the chronic and acute haemodialysis units, inpatient wards and consultants' offices. The anaemia team is in an office separated further by a flight of stairs and the IT department.

The management of anaemia is carefully organised with attention to detail. There are numerous checks in place to attempt to ensure patients are not lost. However, examples arose of such incidents during my two week visit suggesting the well-intended plans are not water tight.

### **A.6.1 Methods of review**

#### **A.6.1.1 For haemodialysis patients**

An HD patient's anaemia management is reviewed following monthly bloods by dialysis nurse, anaemia nurse and at MDT. Dialysis nurses review their patients' results and, as part of the review, titrate IV iron according to a protocol. The anaemia team review results within two weeks of them being taken and prioritise the patients, reviewing those whose haemoglobin is

out of range first. Typically the review begins between two days and a week after blood samples have been taken. MDTs are currently used at all units for centre E, although this only began to happen in 2006. The MDTs are held monthly with the exception of the main site where, due to the volume of patients, only a subset of patients are reviewed each week on a rota that results in a patient being reviewed every 10 or 11 weeks. The timing of MDTs at some satellite units appeared ad-hoc or subject to regular change. The anaemia team intend to attend all HD MDTs but did not during the period of low staffing and do not always when the time for an MDT changes at short notice. Patients are also reviewed when they attend a consultant clinic, typically every six months and have a quick check at every haemodialysis session.

#### **A.6.1.2 For peritoneal dialysis and transplant patients**

These patients are reviewed by their own nurses, typically every six weeks for PD patients and at a variable interval for transplant patients depending upon their health and the proximity to the transplant. The patients are seen at a consultant clinic every two to three months. They are reviewed by the anaemia team both on referral and every three to six months as part of an audit.

#### **A.6.1.3 For low clearance patients**

Low clearance patients are reviewed by their own nurses and consultants at clinic attendances whose periodicity varies widely depending upon the patient's prognosis. These patients' blood results are also reviewed by the anaemia team following a clinic visit.

#### **A.6.1.4 For general nephrology patients**

The general nephrology patients are reviewed at consultant clinic, typically two to six monthly. They are reviewed by the anaemia team on referral.

### **A.6.2 Delivery of treatment**

#### **A.6.2.1 ESA**

The whole centre's population has undergone a change of anaemia supply during the time between accepting an invitation to participate in this research and the follow-up visit of Summer 2009. The patients' ESAs are all prescribed by the hospital now where they were largely GP prescribed previously (hospital prescribing occurred in some cases where GPs

refused to prescribe). This change followed several years of negotiation with the local PCTs and has resulted in unit-based provision of ESA for HD patients and a home delivery service for all others. The centre has retained its approach of using multiple types of ESA, allowing the patients some choice over the product they use and leaving them untied to any one provider.

### **A.6.3 Issues**

The size of the centre's population, their ethnicity, language and deprivation were all cited as problems. The size of the centre was believed to make it harder to have an overview of the centre, a unified approach and close knowledge of the patients. The demographics of the centre's patients would suggest they are more susceptible to anaemia. Where patients spoke little English, communication of treatment changes could be difficult. In addition, it was remarked that among some of the Asian population there was a cultural needle-phobia. Both of these factors are likely to be important where a patient is self-treating with an injection drug. A further factor worth noting, although not considered significant in their overall performance is the difficulties of arranging a home delivery service for persons of no fixed address.

As has been described above, the centre's anaemia team have had extended periods of understaffing. This is considered likely to have contributed to the centre's poor performance as they have had to reduce their monitoring activities during these periods and become more reliant upon the staff in each modality to request changes or reviews of anaemia management.

The centre was reported to have a large number of haemodialysis patients on catheters, which one interviewee stated was due to a lack of access surgeons. Catheters put patients at increased risk of infection than a fistula and patients on ESA have lower haemoglobin if they have an infection. The number of patients with catheters at the centre's satellites was widely variant leading one participant to suggest this related to individual care practices.

Difficulties with the timeliness and details included in referrals were cited as issues for the anaemia team. The anaemia team had previously been told they were not acting upon referrals quickly enough and as a result they began auditing their performance and found they had typically made an appointment for a patient within a week of receiving the referral. The major delay however was between the patient being seen at clinic and the anaemia team receiving the referral, which was variable but often a month. Further delays were claimed to be caused by patient details not yet being recorded on the renal information system making contact difficult and appropriate blood results not being available (typically CRP and ferritin) requiring the patient to have further or repeat tests before treatment begins.

One of the major reasons cited for poor performance by the centre's staff was the GP prescribing system for ESA that had previously been in place. This was believed to introduce large delays in changing treatment (reported as up to six weeks) as well as reduced reliability in acquiring ESA. Any change in prescribing required the centre to write a letter to the GP to enact this. The GP should then issue a prescription which the patient would have to pick up and take to their local pharmacy who would usually have to order the ESA. Then the patient could return to their pharmacy several days later to pick up their supply. Apart from the time lag and coordination difficulties involved, it was reported that some GPs would issue a three month prescription and, if in the interim the renal centre wanted to change a patient's dose, some would object to this wasting of an expensive drug that had already been issued. I was told that alternatively some GPs would issue two week prescriptions and as a result patients didn't always collect their prescriptions.

A further reason given for poor performance was that patients presented later here than at other centres. I was told that 45% of their patients are 'crash landers', which compares with one third nationally according to the renal National Service Framework (Department of Health, 2005), and that it usually takes eight to twelve weeks to correct their haemoglobin levels. However, Renal Registry data excludes incident patient data for three months and therefore the majority of this effect should not be reflected in the data.

There were widely reported problems with the reliability of ESA administration for several reasons. Some patients were suspected of non-compliance with their treatment regime. Where patients were given ESA on an in-patient ward or dialysis unit there was a history of the drug not being signed for. While numerous reasons were given for this including contraindication or the patient not bringing their medication with them, the reason was rarely recorded and it was therefore difficult for the anaemia team to ascertain whether the patient had received their treatment. While the necessity of this recording has now been highlighted to dialysis nurses and provision of ESA directly from dialysis units should remove the problem of availability, interviewees including dialysis nurses considered this to be an ongoing, if improving, problem.

## **A.7 Centre F**

Centre F is a relatively small renal centre (2nd quintile of English renal centres by dialysis population) with a largely white population (1st quintile for % non-white). The centre has two satellite units and four consultants.

The main centre has an in-patient ward, haemodialysis ward, anaemia nurse, CAPD nurse, vascular access nurse and ambulatory care team. The anaemia nurse manages the anaemia of all patients prescribed ESA or IV iron as well as managing the ambulatory care team. That team assists with anaemia management by providing some IV iron infusions.

At centre F the senior nurses had been in post for many years and appeared to have a close working relationship. There was clear respect between the consultants and nursing staff, and an understanding of each others' roles. The centre focused its decision making with the most senior medical and nursing staff.

### **A.7.1 Main methods of review**

#### **A.7.1.1 For haemodialysis patients**

Haemodialysis patients are reviewed monthly by their consultant and four monthly in clinics in addition to the standard checks at each dialysis session. Their anaemia management is reviewed jointly by the anaemia nurse and a consultant, always within a week of blood tests being taken. Patients now receive a once monthly dose of ESA and as a result decisions on haemodialysis patients' anaemia management rarely happen outside of the review between the anaemia nurse and consultant. Previously however, patients received up to three times weekly doses of ESA and as a result decisions were more likely to be made outwith this meeting. Blood samples are typically taken twice a month for the patients here, one set for the majority of tests and another set for anaemia management. This is another change related to the calendar monthly dosing of patients. In addition patients are split into two groups with one half having their tests taken one week and the other half the week after as a method for managing the workload. The anaemia link nurse and anaemia nurse review patients monthly to ensure they are having ferritin tests when required and are receiving the appropriate iron treatment. Named nurses should review their patients' test results, though currently this does not always happen because the haemodialysis ward is understaffed by comparison to what is budgeted for (they have 21.5 FTE but are funded for 29.7 FTE).

### **A.7.1.2 For peritoneal dialysis patients**

PD patients are reviewed at a PD clinic three-monthly with either the PD nurse or the consultant responsible for PD. The blood test results from that are reviewed over the following week by the consultant and PD nurse.

### **A.7.1.3 For low clearance patients**

Low clearance patients are reviewed at clinics by a variety of members of staff and at varying intervals depending upon their disease progression. During the week following the clinic both the consultant responsible for low clearance patients and the anaemia nurse will review blood results and typically the anaemia nurse will have initiated any changes to management. A low clearance MDT takes place a week after the clinic to discuss the patients and their future management.

### **A.7.1.4 For general nephrology patients**

General nephrology patients are seen in a consultant clinic at varying intervals depending on their assessed need. They and low clearance patients who are seen less frequently than two-monthly are brought to an anaemia clinic that serves a dual purpose of reviewing patients anaemia management and supplying ESA. There is both an on-site anaemia clinic and one provided from a satellite unit to reduce patient travel.

### **A.7.1.5 For all patients**

All clinic attendances are preceded by a review of the patient's old blood results by the anaemia nurse. The results and any comments are passed on to the relevant consultant.

## **A.7.2 Delivery of treatment**

### **A.7.2.1 ESA**

For all modalities of patient ESA is currently prescribed and provided by the centre, although at the time of the initial performance data this was not the case. Previously there was both centre-based and GP prescribing. Patients were encouraged to self-administer their ESA regardless of modality or who prescribed or dispensed it. The centre has since taken responsibility for prescribing ESA for all but a handful of patients and dispenses it directly, either by administering it in a HD session or in a clinic setting for other outpatients. They have also transferred all patients to Mircera.

### **A.7.2.2 IV iron**

For non-HD patients IV iron is administered in clinic, either during the week by the ambulatory care team and anaemia nurse or, once a month, on a Sunday where they use the otherwise empty HD ward to treat a large number of patients concurrently. They use Cosmofer at this centre and therefore patients typically need only one dose of iron for a complete course but this takes several hours to administer and therefore has differing resource demands than Venofer.

### **A.7.3 Issues**

An issue that was highlighted to me by a consultant at centre F but was also apparent at other centres was a lack of visibility of a patient's status in the anaemia management process. This was particularly noticed in terms of referrals where the inability of a consultant to know a referral had been received and arrangements made for the next steps in their treatment meant the same patient would often be referred multiple times to ensure that the anaemia nurse attended to them.

In-patient prescribing is a source of potential problems as the majority of in-patient drugs are prescribed on a hospital-wide information system (called EP) but ESA is not. It was reported that sometimes junior doctors will prescribe ESA on EP and that there is then a reliance on in-patient nurses and in-particular the anaemia link nurse to identify this and inform the anaemia nurse.

Several members of staff discussed missed doses of IV iron and missed ferritin tests for HD patients. Although these were not considered systemic, the centre had in place additional checks (performed by a haemodialysis link nurse) not seen elsewhere to identify such occurrences. They had tried different approaches to managing the prescriptions for IV iron but believed their current approach of paper IV iron prescriptions all held in one folder minimised the risk of missed doses. This differs from other prescriptions, which are held on EP or, in the case of ESA, Proton (the renal information system). A particular problem with IV iron administration was not one that was alluded to at other centres although problems with ESA, and as a result special arrangements for ESA prescriptions were. A possible reason this was highlighted as a problem in centre F and not elsewhere is because the use of CosmoFer meant patients typically only received a dose every two or three months rather than weekly as is often the case with Venofer. This would mean that provision of IV iron is not routine in centre F in the way it is at most centres.

Missed ferritin tests were also not mentioned as a significant problem at most centres. Here ferritin tests are taken at different intervals depending upon their previous test result and whether they have recently been treated with IV iron. This is in contrast with other centres where they are done on a routine basis regardless of the patient's condition.

There are additional issues with prescribing and indeed all other information retained on Proton because it is possible for anyone with a log in to alter the data held and there is no audit trail acquired by the software of which identity was used when a change is made. This is a problem in common with some other centres' setup of Proton and provides a potential for abuse that would be difficult to identify.

Downloading test results to Proton occurs in a way that is incomplete and subject to error. Proton takes test result data from the local pathology information system every morning when a query is manually started. The download does not capture all tests performed on their patients at the local laboratory because of the different identifiers used. Instead only the results of tests sent by the renal centre are added to its database. Additionally, tests performed at other laboratories do not get transferred to Proton. This is a problem in common with many renal centres and here as at some other centres they have set up limited access to another pathology lab. However as this spans trusts and therefore legal entities it has been difficult for security, information governance and data protection reasons.

Certain key tests for anaemia management are delayed in their processing by up to three days. Ferritin, serum iron and PTH are held by the laboratory for batch processing (unless marked as urgent). This practice, which I first became aware of at centre F but later discovered was common means that it is unclear when these results will be available and therefore staff can attempt to review the results several times before this component is available to them. Staff that were interviewed about this did not consider it to be a significant impediment or something likely to change due to the cost implications.

The monthly bloods for HD patients at centre F have two features that were unique to them among the centres I visited. They take blood samples for anaemia management after the long break for dialysis and, since the introduction of Mircera, they do this on a separate week than the for the other tests. By taking the samples on the Monday or Tuesday rather than Wednesday or Thursday as at other centres, patients can be expected to be at their most fluid overloaded (dialysis removes excess fluid that non-functioning kidneys cannot) and therefore their blood is more dilute. As a result, measures of a patient's haemoglobin can be expected to be lower after the long break than mid-week. This in turn means that their results are not comparable with those of other centres.

The centre had previously taken their "monthly" bloods on a four-weekly basis and believed this was required by the Renal Registry. To be able to administer Mircera on a calendar monthly basis rather than four-weekly and to have the latest results available to them, the centre decided to separate anaemia related blood tests out from the others. It was considered overly complex to administer Mircera on a four-weekly rather than calendar monthly basis.

The introduction of Mircera and once monthly administration has changed the logistics of anaemia management. For non-HD outpatients a lack of flexibility in changing dose has been identified, while for HD patients, administration has been simplified. Non-HD outpatients attend clinic where they collect their next two months' supply and their blood samples are taken for testing. By the time the results have been returned the patient has left with their ESA, which can be problematic if the centre would like to change the dose. Previously when patients were on thrice or twice-weekly administered ESA it was easier to adjust the dosing schedule than now with the longer gap and lack of familiarity with the product.

For HD patients the introduction of Mircera has simplified the administration of the drug for the dialysis staff. The drug is only given on one dialysis day in the month, shortly after the patient has been reviewed. This makes it less likely that doses will be missed in general, although it does mean that if the patient does not dialyse that day a reminder needs to be set that they have not yet received that month's dose. The consultants appreciated that the once-monthly nature of the drug removed the temptation to tinker with the dose between months and made it easier to audit its administration.

## **A.8 Centre G**

Centre G is based in a large metropolitan area, with a larger than average patient population (in the fourth quintile) and in the second quintile for percentage of non-white patients. It has three satellite dialysis units and nine consultant nephrologists. There are several HD teams, a PD team, transplant team, pre-dialysis team, CKD team, conservative care and the anaemia team.

The centre's anaemia team is currently staffed by one full time anaemia nurse, a part time iron nurse and a share of a full time administrator. In 2006 the centre did not have an anaemia nurse and treatment was to be managed by the responsible clinician in tandem with other management decisions. This followed a period when the centre had employed an anaemia nurse and now, due to dissatisfaction with the absence of the role the post has been re-established.

### **A.8.1 Methods of review**

#### **A.8.1.1 For HD patients**

The haemodialysis population's anaemia treatment is reviewed differently at different sites. However, at all sites patients are assessed by the dialysis staff at each dialysis session and on a monthly basis at a multidisciplinary team meeting (MDT). At the main centre there is a MDT headed by a registrar and attended by the anaemia nurse among others. Decisions about patient management are made here and implemented by the dialysis nurses. Yet, there are a significant number of decisions on anaemia management that are made in between meetings without the involvement or notification of the anaemia nurse. At one satellite the anaemia nurse attends the MDT while at the others the anaemia nurse does not. In addition to these reviews, patients can see a consultant either at clinic or on a ward round, depending upon whose care they are under.

#### **A.8.1.2 For PD patients**

PD patients receive visits at home and attend clinics for review by their PD nurse or one of three consultants. In addition, on a monthly basis one nurse records the latest anaemia related results for all patients into a spreadsheet and makes a recommendation for treatment that is shared with their colleagues. This was done partly because some test results were not

downloading to the renal information system and partly to audit and improve their performance.

#### **A.8.1.3 For CKD and pre-dialysis patients**

CKD and pre-dialysis patients are seen at clinic by a consultant, registrar or nurse. They are additionally reviewed at the end of any course of IV iron.

#### **A.8.1.4 For all patients**

The anaemia nurse reviews all patients who are prescribed ESA on the renal information system between fortnightly and monthly using an extracted spreadsheet. In addition, a request for a repeat ESA prescription results in a review prior to it being produced.

### **A.8.2 Delivery of treatment**

ESA treatment for all HD patients is delivered to and dispensed from the centre. Non-HD outpatients are provided their ESA via a home delivery service. IV iron is administered both at the centre and in several treatment centres that provide a more local setting for the patients. At the centre the PD team provide iron for PD patients while the anaemia team handle all non-HD patients.

### **A.8.3 Issues**

The haemodialysis unit at the main centre is large and has patients who are under the care of many different consultants. As a result, few consultants attend the MDT and decisions are typically made by a registrar. The consultant will then see their patient in clinic and may reverse changes made in the MDT or choose to manage the patient in a way that is not immediately obvious. However, there is little communication between these two decision making bodies and this makes coordination difficult.

The anaemia team were frustrated that outpatients who attended clinic would not always have the appropriate blood tests performed for anaemia management. This would often result in requesting the patient to go to their GP to have the appropriate tests. Where the GP was outside the catchment area they often then had to contact the GP several days later in order to get the results.

Although a detailed protocol for anaemia management is in place, it is not universally accepted by the consultant body. The prevalence of individual policy in an area where decision

making is often devolved to an anaemia nurse or registrar can cause uncertainty as the decision maker attempts to interpret the will of the patient's consultant.

## **A.9 Centre H**

Centre H is a large renal centre in a city with a dialysis population in the 4<sup>th</sup> quintile of renal centres and the central quintile for ethnicity. It has two satellite dialysis units, two local dialysis units and two in-patient wards. There are five consultant nephrologists, a PD team, transplant team, pre-dialysis team, conservative care team and anaemia team.

The centre's anaemia team consists of three nurses, with their usual working time totalling 1.7 FTE. This is a resource increase that occurred during the study period from 1.3 FTE to a flexible allocation of between 1.5 and 1.9 FTE. In addition, one nurse went on secondment and was temporarily replaced. One band 6 nurse is responsible for the iron clinic while two band 7 nurses take on the role of reviewing the population and prescribing therapy. The latter two are also part-time members of the pre-dialysis team and the anaemia team is located in the same office as pre-dialysis and conservative care, at the heart of the unit next to the main outpatient area.

### **A.9.1 Methods of review**

The anaemia team review the centre's haemodialysis population on the Friday following monthly bloods (Wednesday/Thursday) using a print out from the renal information system that includes recommendations for ESA and iron. Prescriptions are printed from the renal information system and passed to the unit by the Monday. In addition, one week after monthly bloods an anaemia nurse and consultant review the management plan for all patients whose haemoglobin is 'out of range' (haemoglobin less than 10.5 g/dl or greater than 12.5 g/dl). General reviews of an HD patient include consultant clinic review, a review of monthly bloods by lead nurse and an assessment at every dialysis session.

#### **A.9.1.1 For CAPD and home HD patients**

CAPD and home HD patients are reviewed monthly at home by a nurse and 3-6 monthly in clinic by a doctor. There are also meetings between the PD nurses and lead consultant for PD where the nurses can discuss any concerns they have. When the PD team want ESA medication altering they do so by referral to the anaemia team.

### **A.9.1.2 For general nephrology and pre-dialysis patients**

The general nephrology and pre-dialysis population are reviewed via several mechanisms. General management is dealt with through consultant clinics as well as nurse-led clinics for pre-dialysis patients. The anaemia team review previous blood results and treatment of patients due to attend clinic and, based upon that may review the patient again following new blood tests in clinic or offer treatment during the visit.

### **A.9.1.3 For all patients**

The anaemia team review all patients prescribed ESA at least every 70 days. They are able to do this because they record a review on their renal system regardless of whether a change was made and in such a way that they can programmatically discover when they last reviewed a patient. Weekly they produce and review a list of patients treated with ESA who haven't been reviewed for 60 days to ensure that no patients are missed.

All patients on the home delivery scheme are reviewed before a repeat prescription is issued. This follows a request from the home delivery company to that effect.

## **A.9.2 Treatment delivery**

Non-haemodialysis patients prescribed ESA are provided it via a home delivery service. IV iron is provided in a clinic ran by the anaemia team alongside the other outpatient clinics for general nephrology and pre-dialysis patients. It is provided by the PD team to PD patients and the transplant team to transplant patients. Home HD patients self-administer iron as part of their dialysis. The conservative management nurse will provide iron to these patients in the community.

### **A.9.3 Issues**

ESA prescriptions for HD patients lack clarity about when the drug should be administered. When the prescriptions are produced, they specify the frequency of administration but there is always room for up to three doses to be signed for per week. The HD team circle the days on which it is to be administered but it was reported that this may be copied from the previous script and that when the frequency changes the old frequency may be copied across. This would be likely to lead to too few or many doses of ESA being administered to the patient.

Reviews by lead nurses on the dialysis ward do not usually occur until two weeks after blood samples have been taken. While blood results have been reviewed by others using the renal information system, lead nurses on the dialysis ward tend to wait for the print-outs of results to come back from pathology.

## **Appendix B**

### **Researcher biography**

The researcher, Tom Crocker, is male, was 26-30 years old during the research project and of white British ethnicity. Born and raised in the North East of England in a middle class environment, Tom's parents separated early in his life and divorced when he was seven. Both parents were self-employed throughout Tom's childhood, his mother a part-time counsellor and life trainer, his father an actor, presenter and scriptwriter. Tom was raised with and developed progressive, left-of-centre and liberal political views. Tom has lived in Sheffield for the past five years with his partner of eight years, Amy.

In higher level education, Tom studied mathematics, physics and computing before moving on to a joint honours degree course of politics and economics. After two of the four years Tom was struggling with politics and dropped this subject, focusing on economics; his dissertation being a quantitative regression analysis of racial and gender discrimination in employment and wages using national survey data. Following this Tom spent 2 years working for BT as a local government credit management agent, during which he developed a database to manage the distribution of the team's workload. Following this, Tom undertook an MSc in multidisciplinary informatics specialising in health, the dissertation for which was a case study of the highly customised clinical information system in the local renal centre. After a year as a research assistant, Tom secured funding for this research project.

Tom has no known family history of chronic kidney disease or any friends who suffer from it. The idea for the project was generated from discussions with his two supervisors at Masters level (Dr Eric Will and Owen Johnson) and with Dr Rick Jones, deputy director of the Yorkshire Centre for Health Informatics and involved with Dr Will in the development of AMIE renal, a renal anaemia decision support tool.

## **Appendix C**

### **Reflections**

#### **C.1 Evolution of the study**

The initial impetus for the project was based on three ingredients, a successful MSc dissertation examining the information system in Leeds St. James's renal centre (Crocker, 2005), the development of the VBP approach (King & Johnson, 2006) involving one MSc supervisor (O. Johnson) and the interest in renal anaemia management and informatics of the other MSc supervisor (E. Will).

Initially the study was focused on the use of the VBP approach (King & Johnson, 2006) as part of the identification of good practice within healthcare. The intention was to develop process models that were representative of particular performance groupings and compare these using a rules-based approach. Early methods examined for the comparison of processes included a variety of quantitative methods (Alves de Medeiros, van der Aalst & Weijters, 2008; Jung & Bae, 2006; Pentland, 2003). However, for a sufficient quantity of high quality data to be gathered to utilise these methods, a standardised data collection tool would have been required, which would have first required the development of an all-inclusive classification of the actions within the processes to be studied. In addition, these methods seemed flawed because for the quantification of the differences between processes to be meaningful, they relied on each action being described at the same level of abstraction and having the same degree of internal variety. This latter problem in particular seemed unlikely to be solvable during the course of the research. The focus of the study on processes alone also appeared premature, when it was organisational rather than specifically process differences that were believed to be relevant. Therefore, alternative techniques to address the evolving aims were sought.

As the review of methods literature progressed, it was increasingly clear that the techniques discussed in process modelling literature were inadequate for a rigorous study of organisational processes and that methods used widely in the social sciences were better suited to this. However, it was also apparent that this did not mean process modelling itself was problematic.

Given these revelations, the plan for the study was adjusted to use appropriate qualitative methods for data collection and analysis, but also to incorporate process modelling techniques. The methods from ethnography, with its extensive use of observation and typically realist epistemology often appeared the most appropriate to the task, although inspiration was drawn from a wide range of sources. The research has not been described as ethnographic for a combination reasons. While the researcher spent two separate weeks in each location, sixteen in the field in total, traditional ethnographies would often have much longer and continuous exposure to a single location, although rapid ethnographies may only last several days. The research was exploring causality and while some ethnographers see this as part of ethnography (e.g. Hammersley & Atkinson, 2007), others are firmly opposed to its inclusion in ethnographic study. In addition, as discussed in the methodology (chapter 4), the observer did not become a full participant as would be typical in an ethnography.

## C.2 Observations and interviews

To my surprise, I was treated with respect and afforded time, honesty and openness by the vast majority of my research participants. I had anticipated that due to my relative youth and lack of clinical training that some participants would consider my research to be a waste of time. I had also expected that at low performing centres they would be understandably defensive, but was impressed by the access I was granted. Participants were typically very willing to discuss operational problems, tasks they believed they should be doing or doing differently and the variety of approaches they had tried to overcome a difficulty, still without success. Within the entire study, I only encountered one particularly defensive interviewee and one dismissive interviewee.

The observations began with a largely open field of enquiry, although with the intention of eventually focusing in on differences that may affect performance. I noticed later in the study the importance of that early openness for sensitising myself as the main research instrument. As I focused in on one particular aspect or another (for example detailed timings of different activities), my ability to observe and record the wider richness or alternative areas of detail diminished. Therefore, if the observation had begun with relatively structured approaches to observation and data recording they would have been conducted in a vacuum to the wider context.

It was fascinating to administer a set of survey questions as part of a semi-structured interview (see section 7.3.5.1), both because of the richness of the answers but also the disagreement of some participants with the basic categorisation of elements as benefits or disadvantages. Again, this highlights the benefits of different approaches and the kinds of data that can be gathered from them.

With further iterations, it would have been possible to take more of the developing theory back to the participants, including more fully formed process models and areas of theory that developed following the second round of visits. This would have enhanced the validity of the findings and enabled further detail to be sought, no doubt prompting further questions. However, given the timeframe of the PhD it was not possible to do so.

### C.3 Data analysis

Although the data collection and analysis techniques were largely qualitative, the results have often included quantitative elements and graphs. This is an appropriate technique for abstracting and displaying certain types of data, such as time and combinations of qualitative and quantitative methods are often used in case study and ethnographic approaches (Keen, 2006; Pope & Mays, 2006). While numerical evidence has been used to support and contrast with the qualitative data where appropriate, it has not been used as a means of strong simplification. For example, the apparent difference in the place of anaemia team offices between high and low performing renal centres (described in section 7.3.4.1) related to the layout of each centre and the feeling of relative isolation or inclusion. Whereas a metric of distance from the consultants' offices or the dialysis ward to the anaemia team office alone may have shown a correlation but I would argue, would have missed the relevance.

UML provided a discipline to the representation of the ostensive routines in the renal centres. This discipline, combined with data coding and iterative development of models at a case level and abstracted across all cases enabled comparable case and abstract models to be produced with confidence. There are, however, limitations to the use of UML for these purposes. UML, despite its range of perspectives is limited in the views it can represent. In particular, because it is designed for the description of software it lacks the ability to demonstrate a range of features of human organisations adequately. This has been discussed before (e.g. Lindsay, Downs & Lunn, 2003) and in this study meant that the non-deterministic nature of processes, in particular occasional exceptions were difficult to model. In addition, the representation of the relationships between the people who participate in renal anaemia management as simple message passing simplifies reality significantly, which has analytical benefits but also disadvantages. While these had been anticipated, it meant that factors that seemed important to the investigation could not be elegantly included in the models. Nevertheless, the models provided a useful base for understanding and early comparisons, but one that was insufficient for understanding more of the rich web of factors involved. It was therefore essential that other qualitative approaches to analysis were employed.

## Appendix D

### Systematic literature search

#### D.1 Methods for the systematic literature search

To identify keywords to search the literature with the initial thesis title (variety and good practice in long term healthcare) was split into four concepts: *process*, *variety*, *good practice* and *healthcare*. An initial search was conducted using these terms across a range of databases to identify weaknesses in the approach. It became apparent that the terms *process* and *variety* were catching many papers outside of the scope of the thesis and that *process variety* was the relevant concept. In addition, the use of *process modelling* as part of the method of investigation and understanding was considered important and included as an additional concept.

A list of synonyms for each of these concepts was drawn up from Roget's New Millennium Thesaurus (Kipfer, 2007) and the Microsoft Word thesaurus (2007). As synonyms were added to the lists, the words were generalised using appropriate wildcards and truncation. Synonyms were obtained separately for *process*, *variety* and *modelling*. *Good practice* did not have an entry in either thesaurus and its meaning is distinct from the conjunction of synonyms for good and practice. To counter this, a recent systematic review of the literature on adoption of good practice (Leseure et al., 2004) was used as a source of keywords. Domain specialist terms were added to catch papers dealing with renal or anaemia management but not explicitly mentioning healthcare.

For completeness, a sample of the literature was checked for potential keywords for inclusion. To do this a set of ten key pieces of literature were identified and articles making reference to them tracked using the Web of Science cited reference search (Thomson Corporation, 2007). This identified a net total of 174 papers, whose titles, abstracts and keywords were trawled to identify further terms with which to search.

From the lists of synonyms, those considered directly relevant were selected. To join *variety* terms to *process* terms a list of relevant prepositions was gathered from a list of the 51 commonest prepositions (MacFadyen, 2007).

The *variety* terms *vari\**, *differ\**, *divers\** *range* and *simil\** were joined with the *process* terms *process\** *practice\**, *procedure\**, *act\**, *routine\**, *operat\**, *protocol\** and *workflow\** using

the prepositions of, in, between, within and among; resulting in 232 search terms. The *good practice* terms were "good practice\*" OR "best practice\*" OR "process innovation\*" OR "promising practice\*" OR benchmark\* OR pattern\*. The *healthcare* terms were "healthcare" OR "health care" OR "health-care" OR "health maint\*" OR "wellness program\*" OR medic\* OR clinic\* OR renal\* OR nephrol\* OR "anaemia manag\*" OR "anemia manag\*". The *process modelling* terms were "activity model\*" OR "activity diagram\*" OR "activity description\*" OR "process model\*" OR "process diagram\*" OR "process description\*" OR "workflow model\*" OR "workflow diagram\*" OR "workflow description\*". The term *pattern* was later removed as its scope is far greater than good practice and it was retrieving a large number of irrelevant papers.

Thirteen databases that the University of Leeds Library has access to and are relevant were identified by examining lists of subject specific resources and in discussion with librarians. The concepts were searched for as individual sets and combined as clusters of three and all four concepts in the databases.

In three databases it was necessary to reduce the number of terms in the searches to be able to perform them; in two (*Science Direct* and *Compendex and Inspec*) this was achieved using a NEAR or WITHINx function to join *variety* and *process* terms, in the third (*Proquest dissertations and theses, ABI/INFORM Global, Proquest Asian business and reference*) the search could only be performed using topic searches. Within *Web of Science* it was not possible to search for the term "best practice\*" because "best" is a stopword and although several workarounds were attempted no way was found to circumvent the system. Correspondence with Thomson Scientific's technical support team confirmed that the search could not be performed (personal communication, 12 December, 2007).

The results for each search where three or four concept keywords matched were reviewed to remove duplicates and false-positives, where the keyword match was not a concept match. The most regular false-positives were caused by non-organisational processes, such as chemical, biological or psychological processes.

Following this each paper's title and abstract were reviewed and the papers scored against ten factors including domain, location, identification of good practice and expected use in a literature review.

## D.2 Results

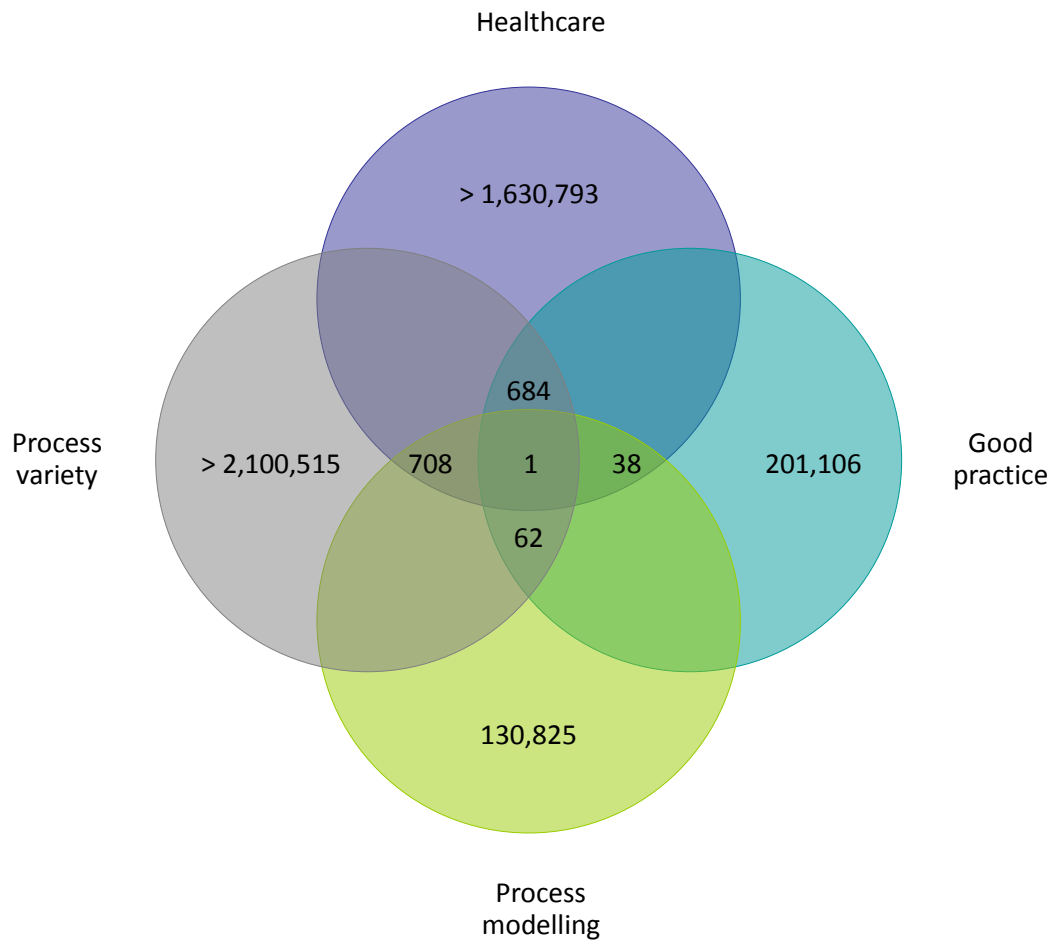


Figure D.1 Results of keyword search (sum of results from databases, figures may include duplicates)

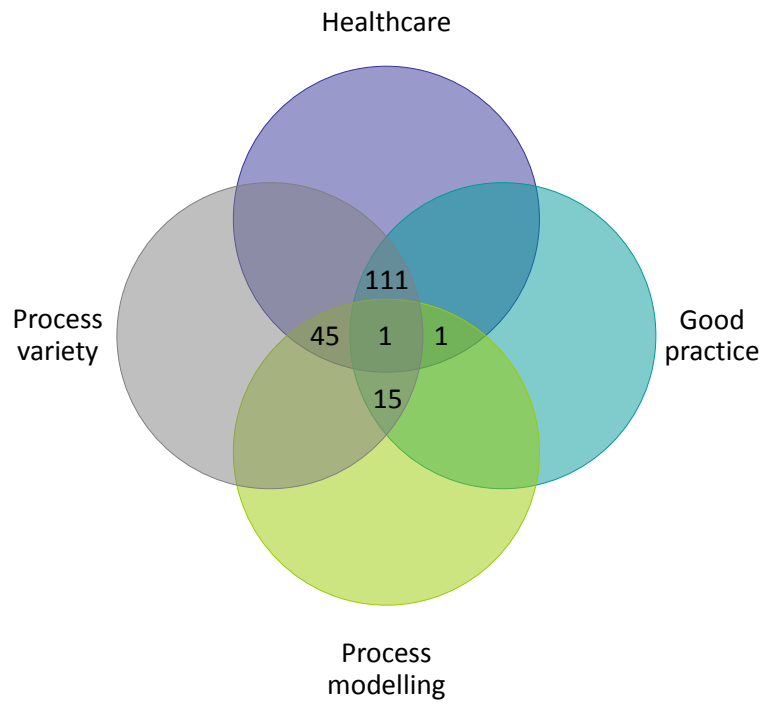


Figure D.2 Results following initial review

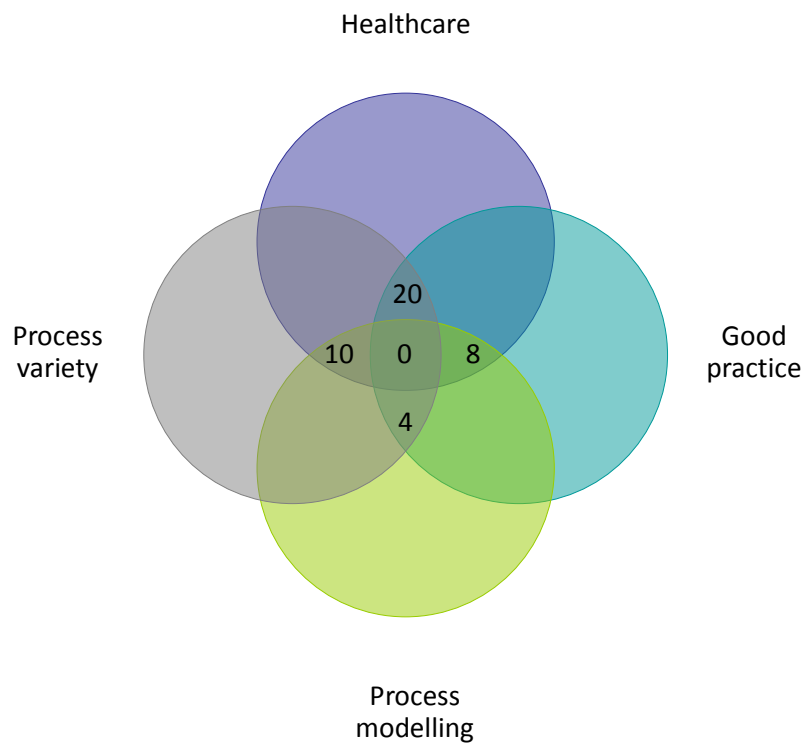


Figure D.3 Papers scoring 4 or 5

### D.3 Discussion

The literature search to identify closely related papers has been conducted in a systematic manner. The results of the search using the selection of terms for individual concepts demonstrate that they are capable of retrieving a large selection of papers. It is also clear that the *healthcare* and *process variety* searches retrieve significantly more papers than the *process modelling* and *good practice* searches. By combining the concepts over 1000 papers related to at least three of the keyword sets were retrieved. These were narrowed down through two exclusion processes to 189 and then 42 papers. Interestingly the scale of reduction was less for those groups with fewer results in the initial search suggesting that they retrieved a greater percentage of relevant papers. The one paper which matched all four concepts in terms of keywords *Requirements engineering practice in pharmaceutical and healthcare manufacturing* (Prakash, Aurum & Cox, 2004) was excluded from the final selection because the process under discussion was a software requirements engineering process, the domain was healthcare manufacturing (products for use in healthcare) as opposed to healthcare provision and the research did not use process modelling meaning too few concepts were well matched. This search has established the existence of similar endeavours within the literature and the originality of the planned research.

The complexity of the search phrases used for each concept, and particularly the combination of phrases made the intended searches difficult in many databases and unfeasible in some. While this could be worked around in most cases without a reduction in the number of papers that would be retrieved this was not possible in the Proquest search engine. Here topic searches were used to enable a search to take place but this may have been relatively ineffective due to a mismatch between available topics and concepts. As this search engine is the only one being used to identify dissertations and theses it increases the possibility that important research has been missed by the strategy. The complexity of the search strategy also made it impossible to use Google Scholar as an additional database to ensure the widest possible coverage.

A comparison of the 189 papers identified following the initial review of results with an existing collection of 519 papers gathered during previous searches for the literature review revealed only 4 matches. While emphasising the importance of this exercise it draws into question the ability to identify all of the relevant literature via this method. This method identifies extremely similar pieces of research but not necessarily the strongest pieces of research, deep theory or most recent developments from within and around the individual

concepts. An examination of the previous collection of papers makes it clear that a large proportion of these fall outside of the scope of this systematic search; however *Using Unified Modelling Language (UML) as a process-modelling technique for clinical-research process improvement* (Kumarapeli et al., 2007) and *Standard, routine and non-routine processes in health care* (Lillrank & Liukko, 2004) show that literature that would have ideally been identified by these searches was excluded. In the case of the former this is because process improvement falls outside of the scope of good practice, and in the latter because process modelling was not explicitly mentioned in the title or abstract (however it is within the body of the paper).

## **Appendix E**

### **Invitation and information sheets**

The written invitation to participate in the study that was sent to the clinical directors of renal centres that the study aimed to recruit is presented on the following page. The information sheets that were given to participants prior to requesting their consent to participate were adapted to include the heading of the local organisation, but the basic version is included here on the pages following the invitation.

Charles Thackrah Building  
University of Leeds  
101 Clarendon Road  
Leeds LS2 9LJ

W [www.leeds.ac.uk/lihs](http://www.leeds.ac.uk/lihs)



**UNIVERSITY OF LEEDS**

[Address]

[Date]

Dear [Name]

I am conducting an investigation into the variations in patient outcomes for renal anaemia. The Renal Registry has shown that there is a wide gap in the performance of renal units in achieving haemoglobin guidelines for their patients but there is insufficient evidence to know why that is.

This research has been designed in consultation with the Renal Registry and aims to identify good practices by investigating the organisation and process of management of renal anaemia in a selection of units. It also forms a major part of my PhD, which is sponsored by the University of Leeds. My aim is that, as a result, improvements in anaemia management will be possible for all of the participating units, who will receive personalised recommendations.

In order to carry out this research I would like access to your unit as one of a set of units that will be my case studies. By allowing me to work with your unit I hope to enable an improved understanding of the way your unit is organised by comparison with your colleagues and how it could be run in the future.

If you would like to pursue this further, I suggest that we have a preliminary discussion during which I could answer your questions and concerns. In the mean time a questions and answers sheet is enclosed for you to browse.

Thank you for your interest, I will contact you in the next few days.

Tom Crocker

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# Examining variety and good practice in renal anaemia management

**Participant Information Sheet: University indemnity v1**  
**Date: 10/07/08**

## Invitation

You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

## Purpose

The aim of this project is to examine the variety in renal units' process and organisation of renal anaemia management and identify good practice which can be spread.

There is a large gap in the anaemia outcomes of patients at different renal units. Previous research suggests this is not just because of differences in patient characteristics or other contextual factors. This research will examine the process (such as what tasks are carried out, when, in what sequence and by whom) and context (such as unit size or patient mix) for managing renal anaemia rather than the specific clinical decisions and actions. This will be undertaken in a number of renal units in order to identify the different ways in which this is organised and the many factors which affect performance. The research will also attempt to identify patterns of good practice and then inform the renal community of these.

This research project is being carried out as part of my PhD.

## Why have you been chosen?

You have been chosen because you are either a participant in or have responsibility for the process for management of renal anaemia in your unit. Your unit has agreed to participate in this research. It was identified as having interesting results in the Renal Registry report 2007.

## Do you have to take part?

It is up to you to decide whether or not to take part. Refusal to take part will involve no penalty or loss of benefits to which you are otherwise entitled. If you do decide to take part you will be given this information sheet to keep (and be asked to sign a consent form). If you decide to

take part you are still free to withdraw at any time, without penalty or loss of benefits, and without giving a reason.

### **What will happen to you if you take part?**

You will be observed playing your part in the process for renal anaemia management and may be asked questions about this during the observation. You may also be interviewed and observed again. The times and locations for observation and interview will be agreed between you and me. You will be asked to examine the models of process and other results to advise whether they are accurate and suggest appropriate changes. Observation will involve me being close by you while you work, noting what you do and usually asking questions about what is observed. Observation will last as long as it takes for you to complete your section of the work, but will typically take between 30 minutes and two hours. Interviews will typically take between 15 minutes and 1 hour and will be audio recorded if you have consented to this. Audio recordings will be stored electronically and encrypted at the end of each day. Interview transcripts will be produced and, where this is carried out by a third party, all references to individuals, locations and other identifiable information will be removed from the audio.

### **What are the possible disadvantages and risks of taking part?**

There are no foreseen possible disadvantages or risks to your participation.

### **What are the possible benefits of taking part?**

Whilst there are no immediate benefits for those people participating in the project, it is hoped that this work will enable improvements to the quality of care received by patients with renal anaemia.

### **What if something goes wrong?**

The University of Leeds has provided indemnity to cover the potential legal liability for harm to you arising from the management, design or conduct of the research.

### **Will taking part in this project be kept confidential?**

Your decision about whether to participate will not be disclosed to anyone outside of the research team, in addition your data will be anonymous in any reporting or publication. You will give your decision in a private location. All participants in the research will be given a research number, which will be used to identify any information you give.

If you decide to participate you will be observed in your role within your typical working environment and therefore your colleagues may see you being observed. To help protect the confidentiality of your decision you are entitled to decline to participate in the research but request to be observed and / or interviewed. The results of any such observations or interviews would be securely destroyed and not included in the research.

If you consent to it, direct quotations could be used as part of the reporting of this research. These will always be checked with you prior to publication.

**Data handling**

All information which is collected about you during the course of the research will be kept strictly confidential. Data from observations will be collected on a computer or paper form. Data from interviews will usually be digitally audio recorded, unless you object, in which case notes will be taken on paper. Your personal details will be stored in a separate note book and a code used to link you to the recorded data. Your personal details will later be copied to an electronic format and stored in a separate and secure location from the research data. All electronic data will be stored in encrypted and password protected files; all physical data will be stored in a secure location. Identifiable data collected during this research will be used for this project alone. As this research is part of a PhD, under exceptional circumstances the university may need to examine identifiable data; this will always be strictly limited to the needs of the examination. The data will be stored securely for a minimum of fifteen years and will be disposed of securely.

**What will happen to the results of the research project?**

The final results of the project are expected to be published in October 2009. A report of the results of the project will be sent to all participants and participating units. The results will also be published as a PhD thesis to be held in the University of Leeds library. It is hoped that the research will also be presented at relevant conferences and published in journals. You will not be identified in any report or publication.

**Who is organising and funding the research?**

The University of Leeds is funding and sponsoring this research.

**Who has reviewed the project?**

This project has been reviewed by the University of Leeds and Cambridgeshire 1 Research Ethics Committee.

**Who should I contact for further information about the research?**

If you have any further questions about, or problems with, the study please contact either the chief investigator or his supervisors (details below)

**Chief investigator:**

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## **Appendix F**

### **Initial concepts to guide observation**

#### **F.1 Generic concepts**

##### **F.1.1 Descriptive observation categories (from Spradley, 1980)**

Space

Object

Act

Activity

Event

Time

Actor

Goal

Feeling

##### **F.1.2 ASME activity types (from Gilbreth & Gilbreth, 1921; Slack et al., 2004)**

operation, inspection, transport, storage, delay

##### **F.1.3 Process chunks**

###### **F.1.3.1 Business use cases**

Value provided outside the renal unit

###### **F.1.3.2 Role use cases**

Value external to the role

### **F.1.3.3 Class transformation**

Process is based around the transformation of a particular class

### **F.1.3.4 Elementary business process (from Cockburn, 2000; Hammer & Champy, 1993; Larman, 2005)**

Analysis should always decompose to this level. This typically involves just one person and takes minutes-hours. It passes the boss test – would my boss be happy if I said I'd been doing these this morning (i.e. not logging on/completing time sheet/navigating system).

## **F.1.4 Process technologies (from Slack et al., 2004)**

### **F.1.4.1 Single unit**

### **F.1.4.2 (Project)**

Undefined actions for the transformation of value (perhaps defined management actions)

### **F.1.4.3 Jobbing**

Variety within actions, variety in sequence and selection of actions, but expect to know the superset of actions and constraints on order

### **F.1.4.4 Multiple units**

### **F.1.4.5 Batching**

Multiple products, one system. (Stream) not iterative and not parallel (system boundary decision)

### **F.1.4.6 Production line**

Multiple products, multiple systems to process. The 'product' moves in a predictable and relatively linear fashion between roles.

#### **F.1.4.7 (Continuous flow)**

Products' emergent properties flow in a continuous (not count) manner and individual bits not the focus of actions, rather the whole flow.

## **F.2 Specific concepts**

### **F.2.1 Modalities**

HD

PD

Home HD

Pre-dialysis

Transplant

### **F.2.2 Activities**

### **F.2.3 Organisational process**

Advise about anaemia

Monitor and manage anaemia

Take blood sample

Send blood sample

Receive test results

Review results and recommend appropriate treatment

Is there an algorithm for general management /starting and for Epo/ iron

Review recommendations and issue treatment plan

Organise treatment delivery

Treat anaemia

Provide ESA

Provide Iron

Provide blood transfusion

Review care (QA) *not expected to be anaemia specific (part of the renal unit system not anaemia management system)*

## **F.2.4 Support activities**

Manage infrastructure

Develop strategy

## **F.2.5 Active classes (Roles & actors)**

### **F.2.5.1 Real roles**

Pathology

Patient

Anaemia team

Anaemia nurse

Multi-disciplinary team

Consultant

GP

Community nurse

Dialysis nurse

Information system

(? Trust/hospital/unit management?)

### **F.2.5.2 Abstract roles**

Care manager

Anaemia advisor/coordinator

Treatment provider

Phlebotomist (sample taker)

### **F.2.5.3 Passive classes (artefacts)**

Prescription

Iron

ESA

Blood transfusion

Test result

Blood sample

Recommendation

Patient record

### **F.2.6 Staff numbers**

How many in each role (FT equivalent?)

### **F.2.7 Information systems**

Which information system?

How long have they had it?

## **Appendix G**

### **Interview topic guide (start of round one)**

Can you give me an overview of the management of renal anaemia?

HD, PD, pre-dialysis

Can you describe your role in the management of renal anaemia?

How many patients anaemia are you responsible for?

How are the patients divided between consultants?

What differences do you see in the management of anaemia between pre-dialysis, PD and HD?

When you issue a prescription for EPO or iron, where does it go to and how does it get there?

Does the unit have any audit meetings?

What happens when you are on leave?

What happens when the anaemia coordinator is on leave?

How often do you make a different decision to the recommendation of the anaemia coordinator or go back and discuss a recommendation?

How does the management of anaemia differ in satellite units?

How has the management of anaemia changed while you have been here?

What features do you think contribute to your centre's performance?

What problems do you think exist with the current system?

What are the layers of management in the trust?

What is the culture like within the centre?

What are relationships like between the anaemia coordinator and: the consultant team, HD team, PD team, pre-dialysis team, transplant team?

Have you worked elsewhere?

- What differences in anaemia management do you recognise between here and there?

Does the unit have a mission statement or any stated objectives?

## **Appendix H**

### **Interview topic guide (round two)**

#### **H.1.1 VAT**

##### **H.1.1.1 Centres with home prescribing for HD patients:**

Is the reason you have home prescribing to save money on VAT?

Do you think that home prescribing impacts upon your patients' care? (how)

##### **H.1.1.2 Centres who used to have home prescribing:**

When you changed from home prescribing to central administration, did you notice any improvement in attainment of targets?

Were you previously on home prescribing to save VAT?

Why did you change to central prescribing?

Does it cost you more now?

#### **H.1.2 Clinic payments and IV iron**

Do you know how much you get paid for an outpatient visit?

Have you considered using Ferinject? What differences would it make to you to be able to use Ferinject? To your patients?

Because of the clinic payments, would you be able to switch to another type of iron than Venofer that took only one visit? Even if it cost as little as Venofer?

*Anaemia team only:*

How much staff time does it take for one outpatient's appointment for IV iron?

What is your DNA rate for your IV iron clinic?

#### **H.1.3 Funding for primary care**

Do you use GPs for blood tests?

How many GPs have refused to provide blood tests?

How many GPs have refused to administer EPO?

How are PNs/DNs paid for?

#### **H.1.4 Payment methods:**

How are payments for patients' pre-dialysis EPO organised? (who and how)

How are payments for EPO on HD made? (in tariff or by use?)

#### **H.1.5 Speed of change**

Are routine bloods always taken on an x weekly or monthly or irregular basis?

Are they taken on a particular day of the week?

Work out my estimates of times and ask for verification

#### **H.1.6 Reliability**

What is in place to stop patients slipping through the net? What ensures that every patient gets reviewed by you?

#### **H.1.7 Systematisation**

How systematic do you think your anaemia management is?

#### **H.1.8 Coordination**

How good do you think the communication is between the anaemia team and the main haemodialysis ward? And the PD team? The pre-dialysis team?

#### **H.1.9 HD blood pressure monitoring (HD team only)**

Do you record reasons when you omit a dose of EPO? What reasons are there?

Do you routinely record the patients' blood pressure? When?

Do you check patients' blood pressure before giving EPO?

### **H.1.10 MDTs**

Ask anaemia nurses the benefit/cost of attending an MDT. Where ANs don't go, how do you keep up to date with the patient – infections, lost circuits etc. Where they go intermittently, do you find you're able to dose if you haven't been there? Where they have no MDT, why? How do you get feedback from the ward nurses? What are the benefits of not running an MDT?

### **H.1.11 Use of graphs (anaemia team)**

You don't seem to use graphs, do you have the functionality available/why don't you use them? Why do you use raw nos. Would you be more inclined to if they were more easily accessible/showed something different (e.g. Hb and dose on same graph) etc.

### **H.1.12 Referrals**

How long does it take to receive / action a referral from a clinic consultation?

How often do you receive referrals where the patient has not been informed of a start of EPO?

How often do you discover that patients have been told they will start or have been started on a ward and you haven't been informed?

Which items do you want to see on a referral and how often are they missing? Hb, ferritin, TSAT, %hypo, CRP, weight, eGFR, etc.

What methods are used for referrals (clinic letter, email, post-it, clinical record, etc.)?

### **H.1.13 'Inbox' for blood results**

Would this be useful? How might it change how you would work?

### **H.1.14 Outlying GP test results (anaemia team and consultants)**

What proportion of GPs' test results are you unable to access / are outside your pathology lab's area? Do you have/your IT system allow you access to other results than those on your local path server?

### **H.1.15 Where algorithm/protocol changed from paper to electronic (anaemia team and consultants)**

What benefits has this had? How much time have you saved do you imagine?

### **H.1.16 Decision support (anaemia team and consultants) (from Clamp, 1995)**

Have you ever had any experience with computer aided decision support systems?

Which of these benefits do you think these may bring about:

Improved decision making

Improved quality of care

Standardisation of medical practice

Resource savings

Make practitioners more accountable for their actions

Other?

What disadvantages might there be?

Decrease in practitioners decision making skills

Increased rigidity of thinking

Over reliance on computer

Increased cost of health care

Increased legal and ethical problems

Limit practitioners' freedom of action

Other?

What one benefit would you most like to see in a computer system designed to help management of anaemia?

What one disadvantage would you be most worried about concerning clinicians use of such systems?

Clinicians use many different tests and procedures (e.g. blood tests) to help them reach a decision about how to treat a patient. Is a computer system designed to help with decision making different from these other tests? Why?

What do you think about clinical freedom? (i.e. the right of a clinician to manage a patient as they see fit)

Will decision support systems affect clinical freedom?  
Is this a good/bad thing?

### **H.1.17 On hold patients (anaemia team only)**

If a patient is referred to you but they don't require anaemia management what do you do?

If you stop a patient's EPO, do you ever stop monitoring their results?

## Appendix I

### UML key

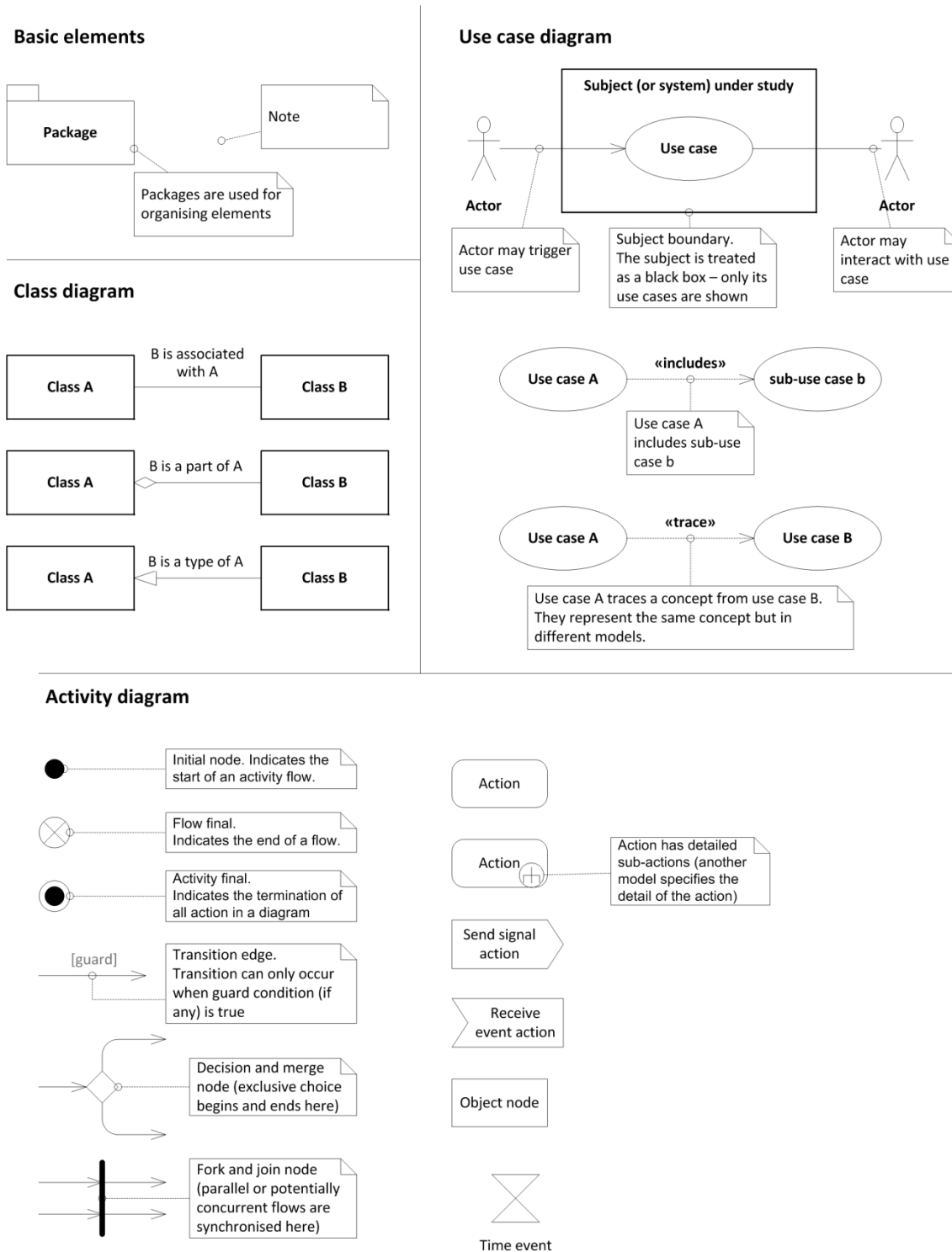


Figure I.1 UML key part 1: Basic elements, use case diagram and activity diagram (for further information see Booch et al., 2005; Object Management Group, 2009)

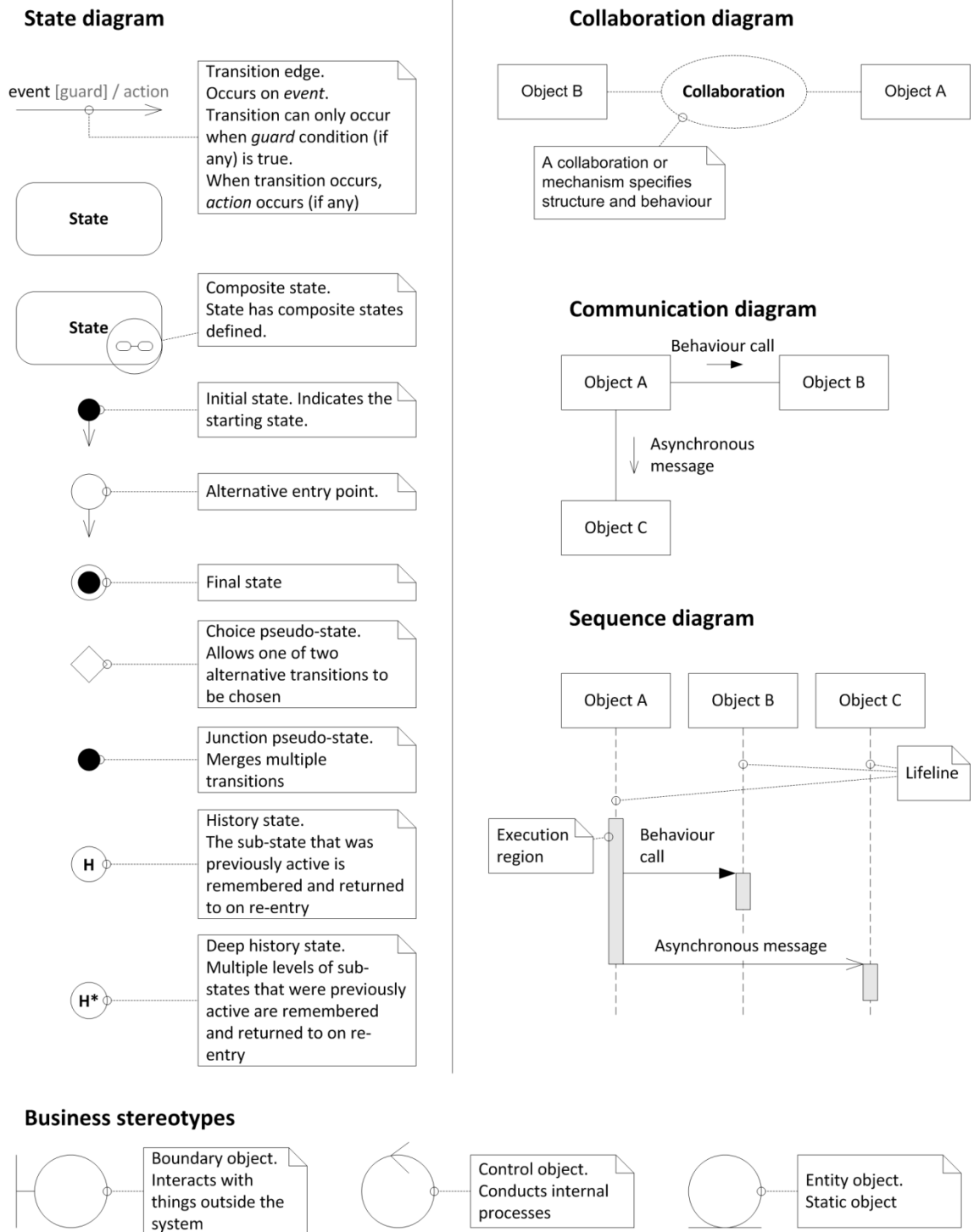


Figure I.2 UML key part 2: State diagram, collaboration diagram, communication diagram, sequence diagram and business stereotypes (for further information see Booch et al., 2005; Object Management Group, 2009)

### Appendix J Detailed ESA patient state diagram

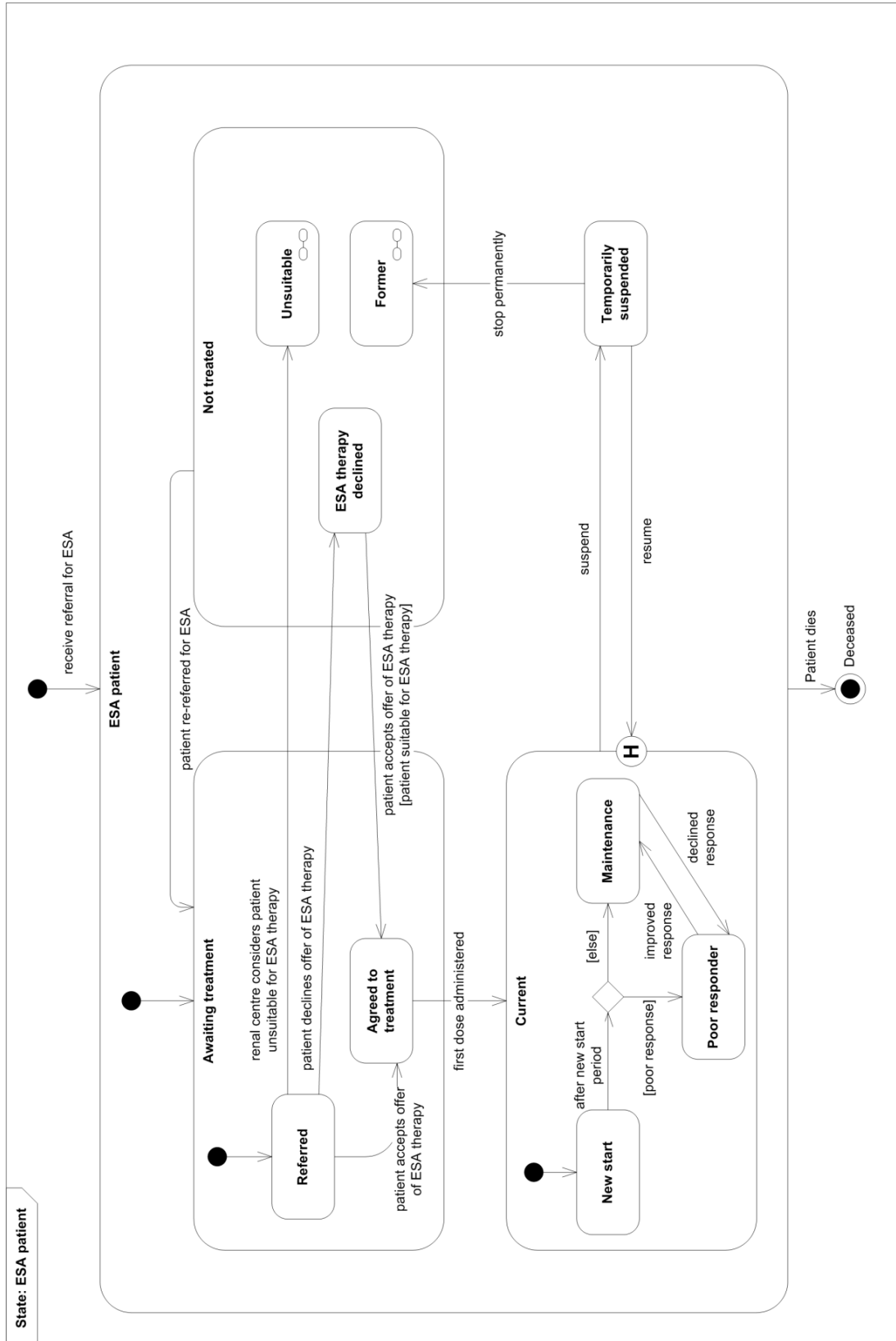


Figure J.1 State diagram for an ESA patient

### Appendix K Detailed IV iron patient state diagram

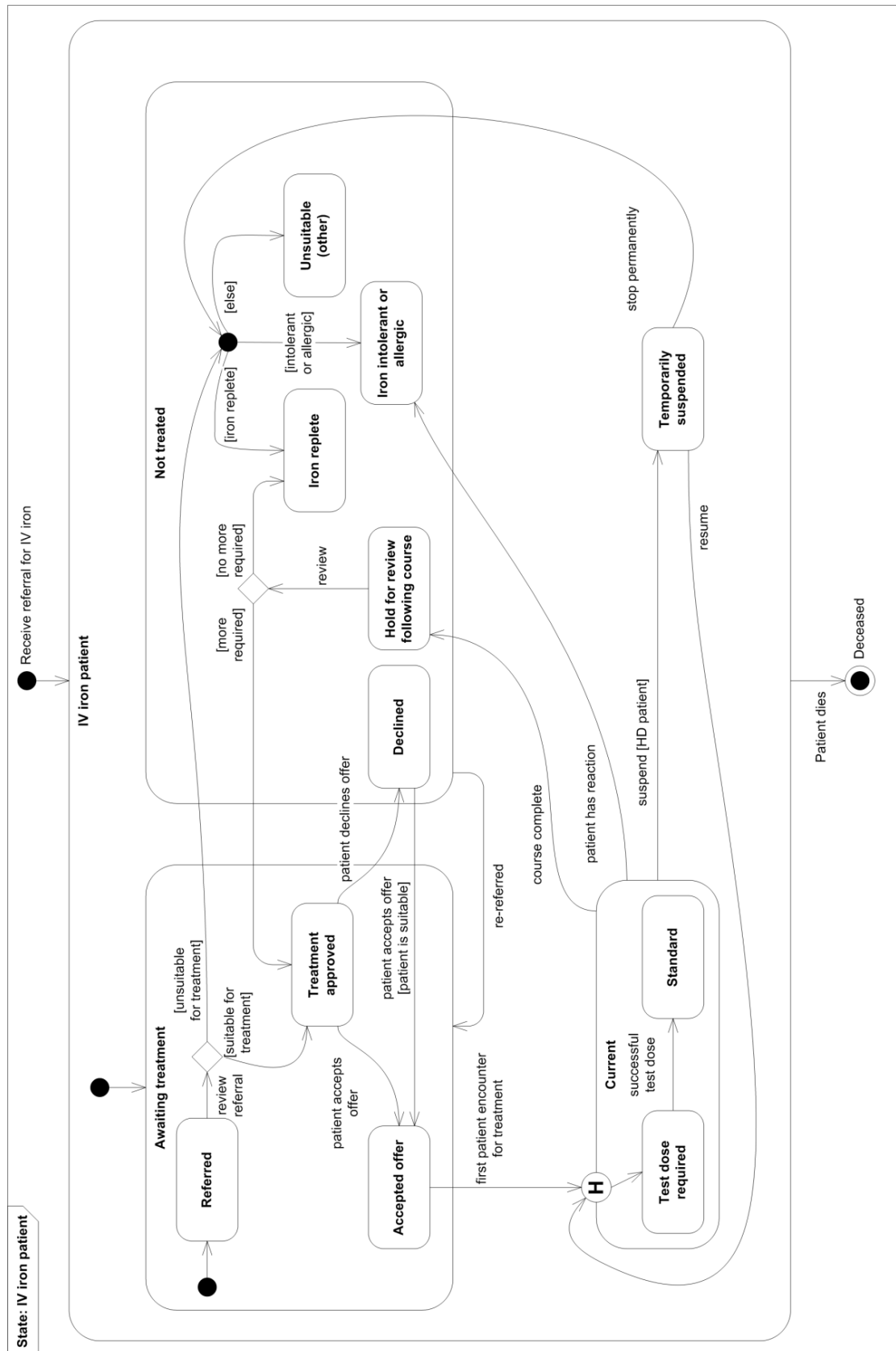


Figure K.1 State diagram for an IV iron patient

### Appendix L Detailed haemodialysis session activity diagram

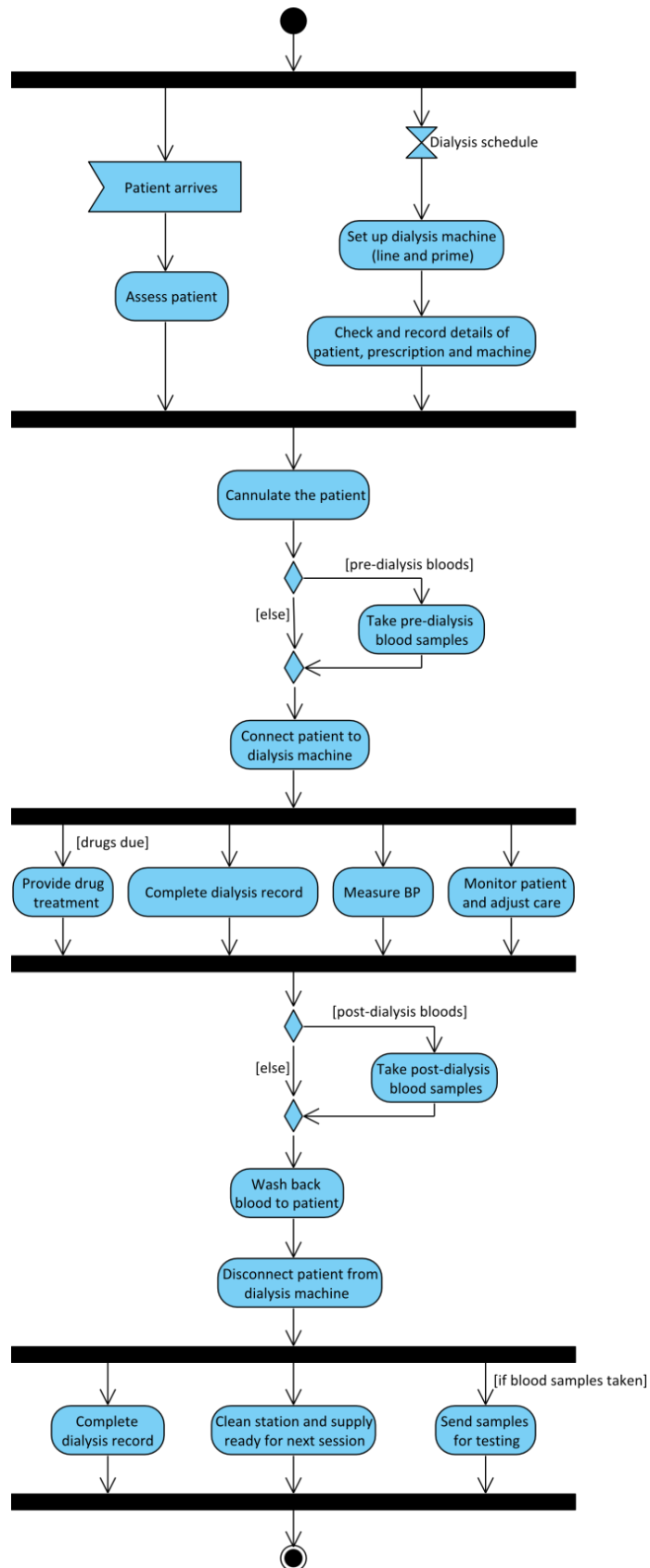


Figure L.1 Activity diagram of the use case attend haemodialysis session (detailed version)

## Appendix M Logical Record Architecture renal stakeholder process model

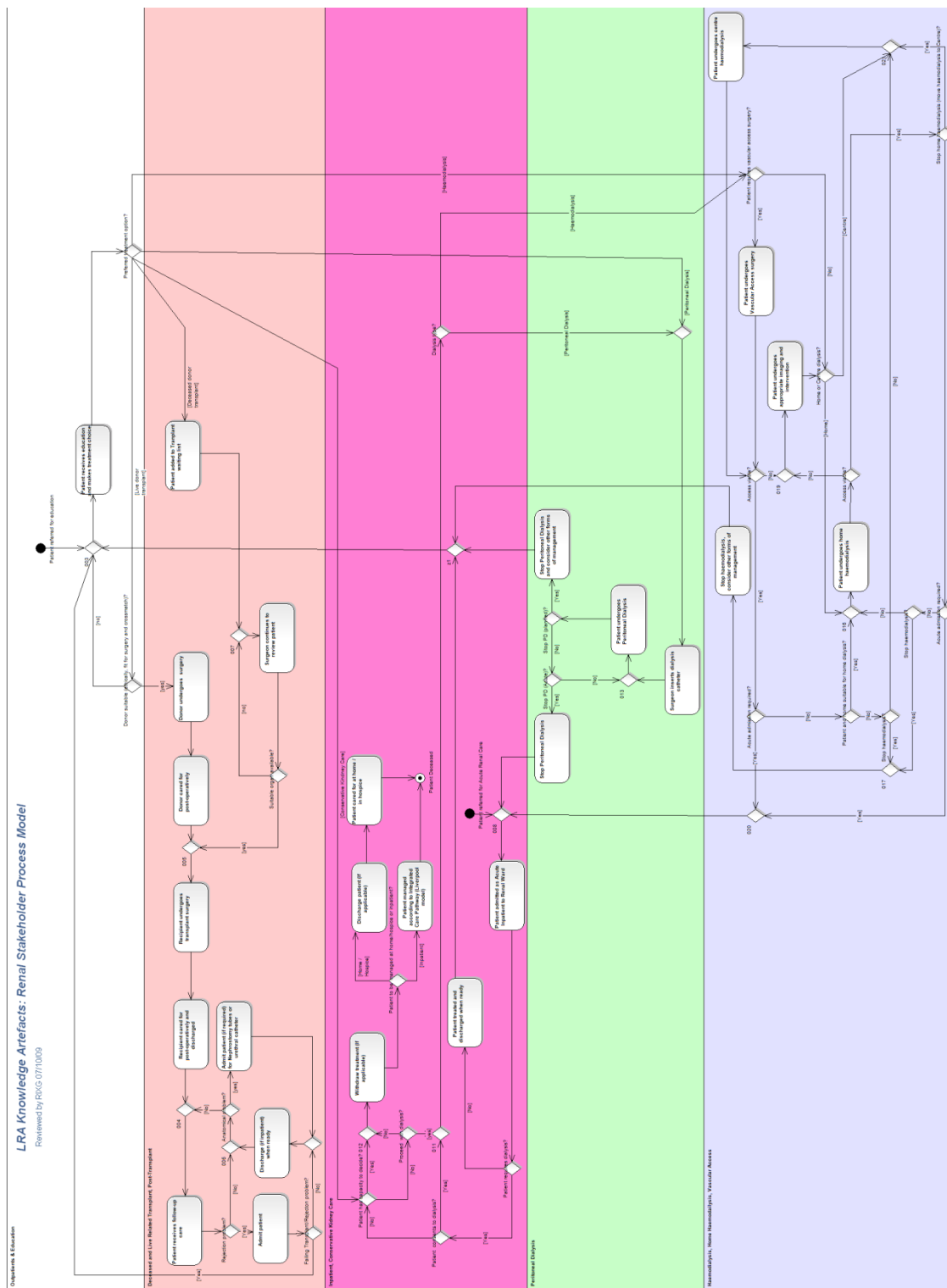


Figure M.1 Logical Record Architecture renal stakeholder process model (reproduced from NHS Connecting for Health, 2010b)