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**CAN A DISEASE MANAGEMENT APPROACH FACILITATE
THE INCLUSION OF HIGH-COST CONDITIONS IN A
BENEFIT PACKAGE?
: THE CASE OF RENAL REPLACEMENT THERAPY
IN THAILAND**

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1

DECLARATION

I, Noppakun Thammatacharee, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signed: N. Thammatacharee

Date: 15 June 2016

ABSTRACT

People access health services to preserve or improve their health status. In some situations, accessing health services can lead individuals to pay relatively high proportions of their available income, which can push many households into poverty. Universal health coverage is a means to provide health coverage to everyone in terms of effective access to required health services with financial protection against catastrophic spending. In Thailand, the Universal Coverage Scheme (UCS) is the largest public insurance scheme. Launched in 2001, it covers 76% (48 million) of Thais. Its members are households mainly in the informal sector, lower socioeconomic groups, the elderly, the disabled, and all children under 12. In 2008, 7 years after its launch, the UCS introduced the renal replacement therapy (RRT) benefit intended to increase access to health services and reduce bottlenecks of treatment for end-stage renal disease (ESRD). Although the UCS exists, there is inadequate health care infrastructure resulting in accumulated patients waiting for many kinds of treatments including RRT. To manage this problem, the UCS has introduced various so-called disease management programmes intended to increase access to high-cost health services.

The purpose of this study is to explore the introduction and functioning of a high-cost health benefit programme of the UCS using the RRT programme as a tracer and assess how a disease management approach facilitated the inclusion of RRT in the benefit package. Its methods involve both qualitative and quantitative techniques to explore different aspects of high-cost conditions and a disease management approach. They are 1) qualitative approaches of document review, semi-structured interview, focus group discussion, and structured observation to explore the rationale of the RRT programme, also how the disease management approach works in administering and arranging the RRT programme; 2) age-period-cohort analysis based on administrative patient data of the National Health Security Office (NHSO) to assess the changing patterns of access to RRT and all-cause mortality of ESED patients; and 3) cost modelling and time-series projection of RRT patient numbers to estimate the long term financial consequences of the RRT programme.

This study found that the RRT programme was the outcome of lobbying by various stakeholders responding to concerns of the burden of ESRD on households and inequitable access to high-cost treatment. Components of disease management, such as evidence-based guidelines and collaborative practice, were crucial to organise the RRT programme and rapidly scale up access to care. The family played an important role in patients' decision making to enroll in the RRT programme. Without family support, patients were likely to not take up the RRT benefit. Introduction of the RRT programme has resulted in a significant increase in access to care and decrease in the rising all-cause mortality rate of ESRD patients. The RRT programme's long term implications involve an increasing number of ESRD patients and growing budget needs for providing care. This study suggests strengthening involvement of various stakeholders, particularly community participation in health care in order to create efficient services that are responsive to the local needs. Locally made medications and budget optimisation and allocation should be put in place to manage the programme's costs.

ACKNOWLEDGEMENTS

Table of Contents

Table of Figures

Table of Tables

ABBREVIATIONS

ACF	Auto Correlation Function
ARIMA	Autoregressive Integrated Moving Average
CC	Capital Costs
CKD	Chronic Kidney Disease
CAPD	Continuous Ambulatory Peritoneal Dialysis
CSMBS	Civil Servant Medical Benefit Scheme
DRG	Diagnosis Related Groups
ESRD	End-Stage Renal Disease
GDP	Gross Domestic Product
GFR	Glomerular Filtration Rate
HD	Hemodialysis
HTA	Health Technology Assessment
ICER	Incremental Cost-Effectiveness Ratios
KT	Kidney Transplant
LC	Labour Costs
MC	Material Costs
NHSO	National Health Security Office
PACF	Partial Auto Correlation Function
PMP	Per Million Population
PD	Peritoneal Dialysis
QALY	Quality-Adjusted Life Year
RRT	Renal Replacement Therapy
SSS	Social Security Scheme
UCS	Universal Coverage Scheme

CHAPTER 1   Introduction

1.1   Background

People access health services to preserve or improve their health status. In some situations, accessing health services can lead individuals to pay relatively high proportions of their available income which can push many households into poverty (Xu, Evans et al. 2003). Renal dialysis is one such example: care costs have been described as catastrophic and can drive a patient into impoverishment (Wyszewianski 1986). Although renal dialysis is used by only a small percentage of individuals, it accounts for a high proportion of overall health care expenditures (Berk and Monheit 1992).

Chronic kidney disease has been increasingly recognised as a global public health problem (Levey, Atkins et al. 2007; Coresh and Jafar 2015; Liyanage, Ninomiya et al. 2015). This is not only because of the rising prevalence across the world but because of widening inequities in accessing the treatment, renal replacement therapy (RRT)[1] (Grassmann, Gioberge et al. 2005; White, Chadban et al. 2008; Coresh and Jafar 2015; Liyanage, Ninomiya et al. 2015). It is estimated that, worldwide, only a half of those needing RRT receive it. Of those receiving RRT, only 7% reside in low- and middle-income countries, yet these people make up 4%-12% of those who need the treatment. In these countries therefore, the low percentage of people accessing treatment is a consequence of the high cost of dialysis. Although the treatment is less expensive than in high-income countries, it is still unaffordable for most people (Jha 2013). Additionally, inadequate infrastructure, or supply of services, may make it impossible to provide quality access to everyone (Mogyorosy, Mucsi et al. 2003).

Governments in many countries have struggled to provide access to essential health services as well as to protect their citizens from catastrophic payments due to health care costs. Within the given national budget, the government

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[1] A term that used to call treatment options for people who are suffering from last stages of chronic kidney disease

needs to contain costs and, at the same time, maximize the health of the population. This commitment may create a significant dilemma for policy makers when making a decision about some diseases that are very expensive to treat and also expensive for patients to pay out-of-pocket. They must decide whether costly treatments should be included in the basic health benefit or not.

Determining health service inclusion based purely on an economic evaluation means that only the most cost-effective treatments are likely to be covered in the benefit package. When comparing RRT with other health care interventions, RRT modalities are usually ranked as providing inferior value for money expressed in terms of incremental cost-effectiveness ratios (ICER) (Chaikledklew 2014). In addition, renal dialysis is less cost-effective in comparison to transplantation (Muirhead 1996), but it is essential to prolong a patient's life, and since organ donors tend to be in short supply transplantation is not available to every patient. Therefore, making decisions on the basis of cost-effectiveness might be a barrier to access to expensive, less cost-effective, but nonetheless essential treatments such as RRT.

Even if expensive treatment is provided universally, this does not mean that everyone in need is able to use the service. This may be because the benefit package does not cover all essential costs of treatment, meaning patients need to pay high amounts out-of-pocket (Himmelstein, Thorne et al. 2009). Limited geographic accessibility to health services may also be a factor which inhibits treatment take-up (Chan, Hart et al. 2006).

Governments in many countries have tried various approaches to balance the dual objectives of cost containment and achieving health outcomes for expensive treatments. Examples of current approaches are: health technology assessment (Ham 1997), strictly controlled payment mechanisms (Dor, Pauly et al. 2007) and price regulation of pharmaceuticals (Sullivan, Peppercorn et al. 2011). Alternatives have focused on reducing demand to control costs of treatment. These include approaches to increase quality of care, such as individual patient chart review, modifying patient lifestyle, and promoting patient health education that aims to slow down the progress of costly diseases.

It is also believed that investment in prevention programmes is cheaper than paying later the full cost of expensive treatment (Sović, Pająk et al. 2012; Png and Yoong 2014).

Disease management involves the use of a number of approaches for identifying and caring for patients with chronic conditions (Bodenheimer and Berry-Millett 2009). By systematically reorganising medical care for chronic illness across delivery systems, disease management aims to improve health outcomes and reduce healthcare costs (Weingarten, Henning et al. 2002; Bodenheimer and Berry-Millett 2009). A range of disease management initiatives have been developed in the US and Europe to cope with growing health care costs and fragmentation in the health system. In the Universal Coverage Scheme (UCS) in Thailand, the disease management approach was adopted, but has been used with different intentions: the approach aims to administer and arrange service delivery and promote patients' access to health services that have accessibility problems and or where treatment is so expensive that it may lead patients into impoverishment.

1.2   What is known?

Disease management programmes target patients with chronic conditions. Despite the promise offered by these programmes, questions remain about their effectiveness and potential for application in large populations or nationwide. Furthermore, disease management programmes can be costly to develop, implement, and evaluate (Weingarten, Henning et al. 2002). Numerous research studies have been conducted to assess the effect of such approaches, yet findings from these studies have been inconsistent in terms of access to care, cost saving, and quality of care (Bodenheimer and Berry-Millett 2009). Another issue is that these studies concentrate mainly on developed countries, and studies from developing countries are underrepresented.

Among existing evidence that describes the applications and effects of the disease management approach in different health systems, there are further challenges for countries using disease management programmes. These include

for example, how to enable everyone who is in need to access their preferred health care; how best to meet the infinite need for health care while health resources are limited, and how a country can sustain essential, high-cost health benefits in the long run.

1.3 Scope of the thesis

The focus of this study is to assess the performance of one approach to managing a high-cost condition in Thailand, a developing country. This study aims to explore the introduction and functioning of a UCS high-cost health benefit programme, using the RRT disease management programme as a tracer. It will then assess how a disease management approach has facilitated the inclusion of RRT in the benefit package.

The thesis has three main objectives. The first objective is to describe the rationale behind the initiation of a high-cost health benefit programme and the application of the disease management approach. It employs qualitative methods to triangulate evidence from multiple data sources to explore the rationale of the RRT programme, and how the disease management approach works in administering and arranging the RRT programme. These qualitative methods include document review, semi-structured interview, focus group discussion, and structured observation. The second objective is to assess the changing patterns of, firstly, in terms of access to RRT services, and secondly, in terms of the mortality of patients who are diagnosed with end-stage renal disease (ESRD). This will be done by using an age-period-cohort analysis. The third objective is to develop long term projections of the RRT programmes' likely number of future patients and estimated budget from the public payer's perspective. It employs methods of cost modelling and time-series analysis. Possible future scenarios were identified to define probable cost drivers of the RRT programme.

Subsequently, combining with reviews of relevant documents, this study conveys the significance of the study and makes suggestions which contribute to debates about how the disease management approach can facilitate access to

high-cost treatments in general, and in developing countries in particular. Although the UCS has many disease management programmes, this study will focus only on the RRT programme, in addition this study neither assessed nor made comparison with the other two public schemes, namely the Civil Servant Medical Benefit Scheme and Social Security Scheme because the NHSO possesses more comprehensive data and better administrative functions. Secondly, the UCS covers 76% of the Thai population. Thirdly, the other two schemes do not provide disease management programmes to their members.

1.4   How the thesis is organised

The rest of this thesis is organised into eight chapters (chapters 2-9), they are structured as follows.

Chapter 2 offers a literature review. It reviews concerns about high-cost treatment from a health policy perspective, beginning with how high-cost conditions link to catastrophic expenditure and impoverishment of patients. Next, the chapter considers evidence as to the benefits of universal health coverage in every country. The chapter then provides a brief introduction to the disease management approach. This section is followed by an introduction to chronic kidney disease, its treatments, and reimbursements for treatments as they were used as this study's tracers to assess effects of high-cost conditions. The gap in knowledge gained from prior studies that lead to this thesis' research question is provided in the final section.

Chapter 3 reports findings from a systematic search on how disease management programmes are arranged and the effects of population-based disease management programmes. The results are reported both at the payer-provider level and the provider-patient level.

The next chapter, Chapter 4, introduces the framework, aim, objectives, and the methodology of the study. The framework emphasises the main factors to be studied and how each of them connects to the others. The methodology section presents the selected study designs, study subjects, how data were collected, analysed, and reported.

Chapter 5 provides in-depth information on the arrangements of the RRT programme. This chapter links the concepts of disease management and the chronic care model to actual services provided by the RRT programme. These components include: delivery system design, resource and policy, decision support, and self-care support. The chapter describes the relation between policy makers, providers, and patients to obtain a better understanding of how these people in different levels of the health system manage and respond to this high-cost condition.

Chapter 6 analyses and reports trends of 1) new registrations into each RRT modality: peritoneal dialysis, hemodialysis, and kidney transplant and 2) death rates in all patients who were diagnosed with end-stage kidney disease and in patients who were maintaining RRT. Age-period-cohort analysis was taken to model the effect of age and time on new registrations and deaths. At the end of the chapter, surrounding factors which might influence the trends of registration and death are discussed.

Chapter 7 estimates the annual cost of the RRT programme from the health care payer's perspective. The autoregressive integrated moving average (ARIMA) model was used to project numbers of RRT patients in the next ten years. Results from these two parts were drawn on to calculate the final result which was the programme's budget needs during such a period.

Chapter 8 draws on results from the analytical chapters and explains how they provide broader knowledge of disease management in the case of a high-cost health benefit. It also discusses strengths and weaknesses of the research design and the methodology employed by the study.

Finally, Chapter 9 provides a conclusion, suggests policy implications, and proposes future research in this area. It identifies how the study contributes to knowledge of disease management in cases of high-cost health benefits.

CHAPTER 2   Literature review

The purpose of this chapter is to provide the context of high-cost conditions and reveal the gap of knowledge on this topic. The chapter first reviews the characteristics of high-cost conditions and their impacts on the health system. Next, it explores why universal health coverage is important to protect patients against the impact of high-cost conditions, and why it is crucial to have universal health coverage in every country. After that a brief introduction of the disease management approach is presented, prior to a more detailed discussion in Chapter 3. The chapter introduces chronic kidney disease as an example of a high-cost condition. This section is followed by a review of reimbursements and the funding of renal replacement therapy (RRT), both internationally and in Thailand. After that, the chapter focuses on the arrangement of the UCS's RRT programme. The next two sections review the methodology on RRT cost modelling and the UCS's RRT programme evaluations. Knowledge gaps in the literature reviews are identified in the final section.

2.1   Literature search and review sources

The review has three key themes: high-cost and catastrophic conditions, universal health coverage, and chronic kidney disease. These themes and their related issues were used as key words in the literature search. The search included both published and grey literature, such as government reports, research reports, books, proceedings, and online articles; from both international and Thai sources. The majority of retrieved articles came from online databases in the following sources.

Online sources of international articles:

- LSHTM databases: http://www.lshtm.ac.uk/library/resources/databases/
- PubMed: http://www.ncbi.nlm.nih.gov/pubmed
- Google Scholar: https://scholar.google.co.uk/

Online sources of Thai articles:

- Health System Research Institute: http://www.hsri.or.th/researcher
- Health Insurance System Research Office:
  http://www.hisro.or.th/main/index.php
- National Health Security Office Library: http://library.nhso.go.th/

In addition, Google was used to search for other online sources, such as WHO, World Bank, European Observatory on Health Systems and Policies.

2.2   High-cost conditions and their impacts

It is important to differentiate between the terms 'high-cost condition' and 'catastrophic spending' since they influence policy formulation in different ways. While there has long been an interest in protecting patients against catastrophic expenditure, policy concerns over high-cost illness are more recent. Focusing on high-cost conditions is more associated with an attempt to contain health care spending of the health system (Wyszewianski 1986).

The term 'high-cost' is taken to refer to a specific treatment, intervention, or a patient diagnosis that incurs high cost to the patient or the insurer. It is generally characterised by expensive medications or procedures. To be more specific, the major cost drivers of expensive treatments seem to be 1) the aging population, 2) the advancement of new technologies such as medicines and laboratory tests, and 3) these last are often accompanied by improper clinical guideline use (Sullivan, Peppercorn et al. 2011). Health spending on a small number of patients with high-cost conditions can account for a significant proportion of national health expenditure (Berk and Monheit 1992; Sullivan, Peppercorn et al. 2011). Conversely, the bottom half of the population (as ranked by health expenditures) can account for just single digit percentages of total health expenditures (Berk and Monheit 1992).

Wyszewianski (1986) reviewed out-of-pocket caps on several health insurance plans in the US in order to develop a definition of a high-cost case. He proposed

that a high-cost case should refer to a patient who consumes total health expenditure of more than US$10,000 annually (1986 prices). The meaning of high-cost in other recent literature has not been later defined.

Rapid increases in health care spending make it important to assess what conditions or what type of patients account for a high proportion of the total health spending. Cohen and Krauss (2003) defined the fifteen most expensive conditions from the total US health spending and a household survey of healthcare expenditure in 1997. Those expensive conditions could be divided into two types based on the condition's onset and recovery period, and acute and chronic conditions. Acute conditions included, for example, trauma, pneumonia, and infectious diseases. Chronic conditions included diseases such as cerebrovascular disease, cancer, and renal disease. While the main cost driver of chronic conditions was hospitalisation, renal disease was unique in that most of its spending was accounted for by ambulatory visits for dialysis, Figure 2-1. Although the total expenditure on kidney disease ranked twelfth out of fifteen conditions, the mean expense per person was the third most expensive, or US$12,476 per year (1997 prices) after cerebrovascular disease and cancer (Cohen and Krauss 2003). While the study did not identify what proportions these fifteen conditions accounted for in US total health expenditure (THE), an earlier study found that 5% of Americans accounted for up to 58% of THE (Berk and Monheit 1992). These findings provided significant insights for policy makers to know what diseases should be targeted and managed in order to control overall health care spending.

Figure 2-1 Selected expensive conditions made up in US total health expenditure 1997

High-cost condition

Acute condition

- Trauma
- Pneumonia
- Infectious disease

Chronic condition

High proportion of inpatient care

High proportion of ambulatory care

- Cerebrovascular disease
- Cancer
- Diabetes
- Mental disorder

- Renal disease
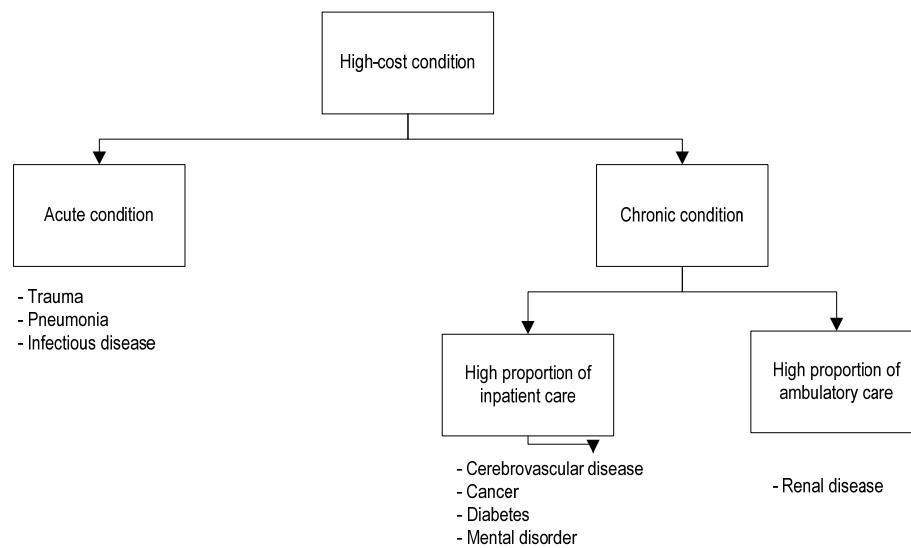
Adapted from: Cohen and Krauss (2003)

2.2.1   Catastrophic health expenditure

Catastrophic health expenditure occurs when a household pays out-of-pocket for health care costs. A financially catastrophic case is a situation where expenditure is overly large in comparison to a household's ability to pay, for example exceeding 15% of family annual income (Wyszewianski 1986). To date, there is still no consensus on the specific threshold for catastrophic expenditure. Most literature, however, agrees to measure catastrophic expenditure relative to patients' capacity-to-pay rather than merely to income (Xu, Evans et al. 2007). The World Health Organisation proposed that catastrophic expenditure should be measured by medical spending greater than 40% of non-subsistence income, which is calculated by annual family income less spending on basic needs. The proposed threshold of 40% can be varied to suit a country's context (Xu, Evans et al. 2005).

A financially catastrophic case can be caused by one-off expensive medical interventions, a relatively small amount of spending but continued over a long time period, or multiple episodes of illness in the household (Wyszewianski 1986). In a situation of financial difficulty, a household may use various coping

strategies; for instance, reducing food consumption, withdrawing children from education, taking out a loan, distress sale of assets, and stopping or delaying treatment, in order to finance health care costs (Russell 1996).

Current measurements of catastrophic expenditure are focused on the impact on individual patients and quantifying proportions of households with catastrophic spending. The intention of these measures is to assess the effectiveness of public health financing in protecting households against impoverishment due to health care costs (Kawabata, Xu et al. 2002).

2.2.2   Relationship between high-cost conditions and catastrophic expenditure

The relationship between catastrophic health expenditure and high-cost conditions is shown in Figure 2-2. A high-cost condition is not always catastrophic (Wyszewianski 1986). For example, if a high-cost illness happens to a member of a well-off family who is able to pay for the treatment, the family will not face financial catastrophe, while in contrast, poor households are less able to cope with any level of health care cost. Even a common disease that is not high-cost, can lead a poor household to catastrophic expenditure.

Figure 2-2   Relations between high-cost and catastrophic expenditure from the household perspective
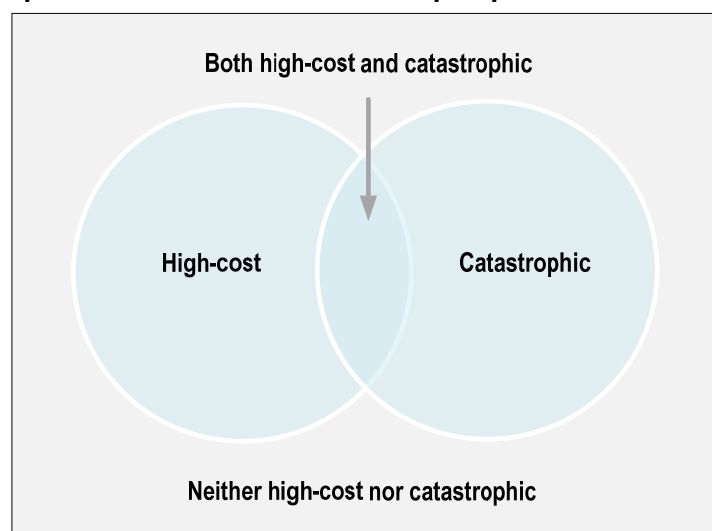
Adapted from: Wyszewianski (1986)

Financial protection plays an important role to prevent individuals with insufficient ability to pay for health care costs from facing financial catastrophe (Table 2-1). A high-cost disease will not cause catastrophic spending if there is financial protection to cover costs of treatment without creating financial hardship to patients (Wyszewianski 1986).

Table 2-1 Relations between high-cost conditions, catastrophic expenditure, and financial protection

	Financially catastrophic		Not financially catastrophic	
	Financial protection	No financial protection	Financial protection	No financial protection
High cost	*Inadequate coverage*	*Insufficient ability-to-pay*	*Adequate coverage*	*Sufficient ability-to-pay*
Not high cost	*Inadequate coverage*	*Insufficient ability-to-pay*		

Adapted from: Wyszewianski (1986)

To date, numerous studies have been conducted to assess to what extent health care financing can protect households from catastrophic expenditure and impoverishment from health spending. Fewer studies, however, focus on high-cost conditions that can lead patients to catastrophic payment and that are of concern to health care payers given their significant effect on total health expenditure.

2.3   Universal Health Coverage

The World Health Report 2010 called for all countries to move forward to universal health coverage. The call was due to evidence that many people are suffering from excessive out-of-pocket payment; in particular, those who rely the most on direct payment[2] to finance health care costs (WHO 2010).

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[2] According to WHO (2010), the term direct payments cover all forms of out-of-pocket payment and informal payment that people pay at the time they use services. Even in a country with universal coverage, people can be required to pay co-payment in various forms, such as co-insurance, co-payment, and deductible.

It was estimated that around 150 million people globally suffer from financial catastrophe and 100 million become poor because of paying for health care costs each year (Xu, Evans et al. 2007). Universal health coverage is a means to provide health coverage to everyone in terms of effective access to required health services including prevention, promotion, treatment, and rehabilitation with financial protection against catastrophic spending (WHO 2010).

When designing universal health coverage, there are three main dimensions that need to be justified. They are: who will be covered, which services will be covered, and to what extent (what price) they will be covered. These dimensions are shown as the three sides of a cube as in Figure 2-3, and are referred to as width, scope, and depth (WHO 2010).

Figure 2-3 Three dimensions of universal health coverage
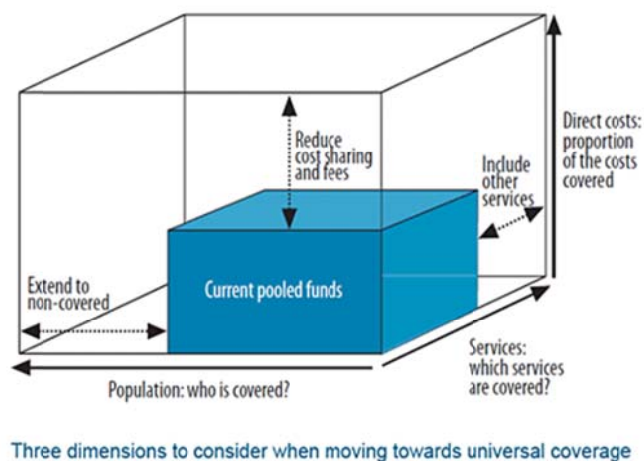
Source: WHO (2010)

2.3.1   Benefit Package

Constructing and maintaining a national benefit package is a large, important part of universal health coverage (Reich 2016). Various terms, such as benefit basket, benefit package, basic package, essential package, and health benefit plan are used to describe a list of various health services offered in the national package. Velasco-Garrido (2006 cited in Glassman, Giedion et al. (2014)) defined a benefit package as *"services, activities and goods reimbursed or directly provided by publicly funded statutory/mandatory insurance schemes or by*

national health services". A benefit package is a starting point to focus on the highest priority services and gives ideas to policy makers on the planning of supply for equipment, human resources, medicine, and medical devices (Bobadilla, Cowley et al. 1994).

2.3.2   Should high-cost conditions be included in the benefit package?

Some may argue that what is included in the benefit package should be taken on the objective of equity that is inherent in the definition of universal healthcare coverage (Parmar, De Allegri et al. 2014). However, from the payer's perspective, there is constraint in limited resources. These limitations may include financing for the health scheme, numbers of health workers, and health care infrastructure. Designing the benefit package, therefore, always involves priority setting, which happens at many stages of the resource allocation process.

Many countries have established Health Technology Assessment (HTA) agencies and take advice from them to determine which health interventions offer best value for money and at what price these should be covered by the public health care budget. HTA is a key input into the resource allocation process, however it does not mean that decision-making is based solely on the economic assessment. It is evident that even in high-income countries, HTA is used only under certain circumstances and the situation can vary within a country and from one country to another (Paris 2014). This is because in reality, priority setting is primarily a social and political exercise, involving the distribution of benefits and responsibilities to everyone in the nation (Langenbrunner and Somanathan 2011; Glassman, Chalkidou et al. 2012).

Even in a system with well-designed universal health coverage, the rationing dilemma of priority setting may create a conflict over the benefit package, and in particular over expensive therapies (Glassman, Chalkidou et al. 2012). High-cost treatments that can drive a patient into impoverishment often lead to public interest and debate. The issue is how to provide those in need with horizontal equity (equal treatment for equal need) given limited resources (Ham and Robert 2003). In Mexico, the Seguro Popular health scheme has been

praised as an example of best practice: a developing country that has achieved universal coverage and social protection through a comprehensive benefit package (Frenk, González-Pier et al. 2006). While the population covered by the Mexican Social Security Scheme has access to RRT, the Seguro Popular is criticised for failing to reduce inequality in access to health care as it does not include the treatment for end-stage renal disease (Garcia-Garcia, Renoirte-Lopez et al. 2010; Kierans, Padilla-Altamira et al. 2013).

Application of cost-effectiveness principles and a strong cost-containment policy may cause barriers to treatments that are relatively cost-ineffective but essential to prolong patient life and may cause a patient catastrophic spending. A cost-effectiveness league table is one way to provide information to policy makers when determining the economic value of new health care inventions.

Table 2-2 is an example of a league table of health interventions in Thailand. Thailand applies the threshold of 1-1.2 times per-capita gross domestic product (GDP; US$4,800 or roughly 170,000 Baht in 2011) per quality-adjusted life year (QALY) gained to determine whether any health care interventions are cost-effective and should be established in the UCS benefit package (Mohara, Youngkong et al. 2012). The first four treatments in Table 2-2 cost less or approximately equal to the threshold and were covered in the UCS health basket. Peritoneal dialysis and hemodialysis were classified as less cost-effective interventions and were therefore excluded from the benefit package when the UCS was first launched in 2001 but were later included in 2008.

Table 2-2 Cost-effectiveness league table of selected interventions in Thailand

Treatments	Baht/QALY (2009 prices)	UCS coverage
Antiretroviral treatment*	26,000	Yes
Vertical HIV transmission prevention**	25,000	Yes
Cardiovascular disease prevention (generic statins)**	82,000	Yes
Cytomegalovirus retinitis (Gancyclovir)*	185,000	Yes
Antidiabetic drugs: Pioglitazone compared with Rosiglitazone	211,000	No
HPV vaccine at age 15 compared with smear test (women aged 35-65)	247,000	No
Osteoporosis: Alendronate compared with Calcium+Vitamin D	296,000	No

Osteoporosis: Residronate compared with Calcium+Vitamin D	328,000	No
Peritoneal dialysis*	435,000	Yes
Hemodialysis*	449,000	Yes
Osteoporosis: Raloxifene compared with Calcium+Vitamin D	634,000	No
Osteoporosis: Calcitonin compared with Calcium+Vitamin D	1,024,000	No

* = compared with palliative care, ** = compared with do nothing
QALY=quality-adjusted life year, UCS= universal health coverage
Adapted from: Chaikledklew (2014)

2.4   Universal health coverage in Thailand

The Thai government launched the UCS in 2001 to cover previously uninsured citizens that were not covered under the other two existing public schemes, namely, the Civil Servant Medical Benefit Scheme (CSMBS) and Social Security Scheme (SSS). To date, the UCS covers 48 million beneficiaries or 76% of all Thais. The remaining 21% are those government employees, their dependants, and retirees who belong to the CSMBS; and formal employees of the private sector that are covered under the SSS (NHSO 2013).

The UCS uses a contract model with arrangements for private and public competition, although in the early phase most UCS contracting units were public facilities and few private hospitals joined the scheme. The contracting unit of the UCS was called the contracting unit for primary care. These were mainly community hospitals acting as main contractors. They are responsible for arranging primary care (including GP services and dental care) and some types of hospital based care for registered members in their local areas, and they refer patients to a higher level of care if necessary. A closed-end payment system was used to control cost and increase efficiency in the UCS. Preventive and promotive care and outpatient care are paid by capitation. Inpatient services are reimbursed by diagnosis related groups (DRG) with global budget. The UCS tried to split the provider and payer roles by setting up a new organisation, namely the National Health Security Office (NHSO) to be the payer and design the UCS benefit package.

The UCS offers a comprehensive benefit package to every member including essential outpatient services, inpatient services, dental care, accident and

emergency, and prevention programmes (Tangcharoensathien, Pitayarangsarit et al. 2012). All costs of services can be reimbursed in full. Patients are not required to pay any form of co-payment except a voluntary payment of 30 Baht (approximately 60 pence) per visit. In the commencement of the UCS in 2001, so there was a concern on the scheme's fiscal constraints and an unprepared system, UCS policy makers decided to exclude two high-cost treatments: HIV/AIDS and RRT from the benefit package. These two high-cost treatments however have been later added in the benefit package.

2.4.1 High-cost conditions in the UCS

The newly-launched UCS met the immediate problem of a large number of accumulated patients on waiting lists for many kinds of treatments. The main cause of this problem was the inadequacies of the existing health care infrastructure. These inadequacies included insufficient funding; lack of service provision, health care staff, equipment, and medications; and an ineffective monitoring and evaluation system (Tangcharoensathien, Pitayarangsarit et al. 2012).

To relieve the bottlenecks, the UCS has introduced many so-called disease management programmes aiming to promote access to health services and prevent catastrophic payment. Some programmes have their own specific objectives, for example, to promote and expand the use of Thai traditional medicine and Thai herbal medicine. Key activities of most programmes include defining the target population, developing standard protocols linked to a new payment mechanism[3], and arranging a reporting system for reimbursement. All actions are intended to promote increase in service provision or health professionals to ensure access to services. The use of the standard protocol also facilitates quality of care in these programmes, and is occasionally used as a tool to indicate a specific treatment approach. For example, the RRT protocol specifies peritoneal dialysis as the first line treatment option.

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[3] Most disease management programmes in the UCS are reimbursed per case, unlike those services in outpatient and inpatient departments which are paid by capitation and DRG respectively.

Since there is no specific model, each UCS disease management programme may have its own details and process, designed by the central NHSO. Consequently, each programme has a different level of comprehensiveness when compared to the standard disease management approach. Therefore, UCS disease management programmes differ from those in the US and Europe, where disease management programmes commonly focus on chronic diseases. The UCS disease management programme focuses on any diseases or conditions that have low level of access due to limited service provision. The focus of each programme is neither necessarily on controlling cost nor integrating care, but on access to health services. This study viewed the disease management approach as an intervention to increase access to high-cost or hard to reach treatment and it is important to understand how this approach might facilitate the inclusion of RRT in the benefit package.

2.5   Management of high-cost conditions: disease management and the chronic care model

Growing numbers of patients suffering from chronic diseases, and the advancement of treatment and management technologies, have added to the financial burden on countries' health care budgets (Martins, de la Maisonneuve et al. 2006). Disease management is one strategy used to cope with the rapid increase in health care costs (Bodenheimer and Berry-Millett 2009). The idea is to improve quality of care delivered to patients with chronic diseases. By efficient and effective use of health care resources, the application of disease management principles is believed to bring health expenditure down (Geyman 2007).

Disease management comes in various forms and there is a range of terms used to describe interventions to manage patients with one or more chronic conditions. These include: integrated care, managed care, coordinated care, and disease management. All of these programmes share a very similar aim, which is to increase quality of care; however, the contents of these programmes may differ greatly (Ouwens, Wollersheim et al. 2005; Krumholz, Currie et al. 2006;

Hisashige 2012). Note that a systematic search from population-based studies on disease management programmes is provided in the next chapter of this thesis.

The chronic care model is an advanced form of disease management (Krumholz, Currie et al. 2006). It was developed by Wagner (1997) and colleagues by reviewing interventions used in chronic conditions across various settings. This is because many patients confront difficulties (such as symptoms of the diseases, diet and life-style change, and complex drug regimens) without much support from health care professionals, or receive help that fails to meet individual needs. Additionally, current policies focusing on a specific disease do not offer approaches for patients with multiple chronic conditions, and there are no general models applied to management of wide range of chronic diseases. The model, therefore, was designed to cope with common challenges shared by most patients with chronic conditions and their families and was intended to offer a generic model for improving provisions of chronic care (Wagner, Austin et al. 2001).

The chronic care model was designed to be a 'functional blueprint' to improve service delivery systems and patient outcomes, corresponding to the growing demand for chronic care (Wagner 1997). Evidence shows that a combination of six areas constituted in the chronic care model is vital to the success of improving patients' outcomes. They include 1) community resources and policies, 2) health care organisation, 3) self-management support, 4) decision support, 5) delivery system redesign, and 6) clinical information systems (Bodenheimer, Lorig et al. 2002; Epping-Jordan, Pruitt et al. 2004; Ham 2010).

Several countries, such as the US, UK, and Continental European countries, have adopted and adjusted the care model according to induvial countries' health systems and political opinions (Epping-Jordan, Pruitt et al. 2004; Coleman, Austin et al. 2009). However, significant variations still exist among these arrangements to improve the performance of high-cost treatment, both in terms of how these arrangements are applied, and in their successful combination of two outcomes. It remains unclear whether it is consistently possible to improve

patients' health while controlling health care costs (Dor, Pauly et al. 2007; Bodenheimer and Berry-Millett 2009; Knauf and Aronson 2009).

Components of the care model are used in ambulatory care for many chronic conditions such as diabetes, hypertension, asthma, and heart failure. Although they produce mixed results of promising and disappointing outcomes, many review studies on effectiveness of the chronic care model have suggested that a combination of its components are more likely to produce positive outcomes (Bodenheimer, Wagner et al. 2002; Adams, Smith et al. 2007; Ham 2010; Stellefson 2013). For example, using the delivery system design component to redesign the service delivery process promotes self-care management and other desirable clinical outcomes (Ham 2010; Stellefson 2013).

2.6   Chronic kidney disease

This study focuses on high-cost conditions, and the treatment for the last stage of chronic kidney disease, namely renal replacement therapy, was selected to assess the effects of such conditions. This section will start by giving the overview of chronic kidney disease, definitions, and treatment modalities that are important as a basis for a better understanding of end-stage renal disease management.

2.6.1   Overview of the disease

Chronic kidney disease (CKD) is a common condition that raises the risk for other health problems, such as cardiovascular disease, renal failure, and other complications. The National Kidney Foundation of the USA defined CKD as "*the presence of objective kidney damage and/or the presence of a glomerular filtration rate of 60 mL/min/1.73 m² body surface area, or less, for at least 3 months, irrespective of the underlying etiology of the kidney damage*" (The National Kidney Foundation 2002).

CKD is divided into five stages according to kidney function. Early stages of CKD, stage I –II, are characterised by kidney damage[4], associated with the presence of decreased kidney function (measured by glomerular filtration rate -GFR). The late stages, stage III-IV, of CKD are defined by a large decrease of kidney function, regardless of the evidence of kidney damage (Eustace and Coresh 2005). The last stage of CKD, kidney failure, is characterised by either 1) GFR less than 15 ml/min per $1.73m^2$ or 2) a need to start renal replacement therapy (RRT), which is either dialysis or renal transplant (Levey, Coresh et al. 2003), Table 2-3.

Table 2-3 Classification of chronic kidney disease

Stage	Description	GFR, mL/min per $1.73m^2$	Related terms	Action*
-	At increased risk	≤ 60 (with chronic kidney disease risk factors)	-	Screening, CKD risk reduction
1	Kidney damage with normal or increased GFR	≤ 90	Albuminuria, proteinuria, hematuria	Diagnosis and treatment, treatment of comorbid conditions, slowing progression, CVD risk reduction
2	Kidney damage with increased GFR	60-89	Albuminuria, proteinuria, hematuria	Estimating progression
3	Moderate decreased GFR	30-59	Chronic renal insufficiency, early renal insufficiency, early renal insufficiency	Evaluating and treating complications
4	Severe decreased GFR	15-29	Chronic renal insufficiency, early renal insufficiency, late renal insufficiency, pre-ESRD	Preparation for RRT
5	Kidney failure	<15 (or need dialysis)	Renal failure, uremia, end-stage renal disease	Kidney replacement

Adapted from: Levey, Coresh et al. (2003) and The National Kidney Foundation (2002)
*includes actions from preceding stages.
GFR= glomerular filtration rate, CKD= Chronic kidney disease, CVD=cardiovascular disease, RRT=renal replacement therapy

In this study, the term end-stage kidney disease (ESRD) is used to refer to the condition of patients who have kidney failure and are diagnosed with the last stage of chronic kidney disease. However, kidney failure is not always

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[4] presence of abnormalities in blood, urine, or imaging studies

synonymous with ESRD. In the US, while kidney failure refers to the last stage of CKD, ESRD is an operational term without a precisely defined level of kidney function (Levey, Coresh et al. 2003). In the US renal registry and regulation system, it is understood that ESRD refers to a patient who is undergoing or is eligible to receive renal replacement therapy, either by some form of dialysis or transplant (Levey, Coresh et al. 2003; Eustace and Coresh 2005).

2.6.2   Prevalence and incidence

Chronic kidney disease (CKD) is a worldwide public health problem as a consequence of two major factors: 1) increasing aging population and 2) prevalence of diabetes (El Nahas and Bello 2005). A study estimated that the prevalence of people needing RRT ranged from the low figure of 920 per million population in Africa to 2,162 per million in Europe (Liyanage, Ninomiya et al. 2015).

To date, there is still a lack of reliable epidemiological information on the various stages of CKD in the general population, especially in the early stages. This is because CKD is a silent disease: a patient may be living asymptomatically until the condition reaches an advanced stage. Renal registry systems can be used to identify the number of CKD patients, however numbers of ESRD patients in this sense reflects only the portion of CKD patients who receive RRT and cannot be used to represent the entire affected population, or even the number of patients with last-stage CKD (Eustace and Coresh 2005). For many reasons, most available figures are derived by estimation and tend to considerably underestimate the overall number of CKD patients (El Nahas and Bello 2005; Eustace and Coresh 2005). The main limitation of this estimation is that some people may have stable impaired kidney function that does not develop into the advanced stage of renal failure and they are not included in the pool of CKD patients (El Nahas and Bello 2005; Eustace and Coresh 2005). Another limitation is that the estimated prevalence is calculated from a single laboratory measure called serum creatinine level. The measured serum creatinine level can vary due to diverse calibration systems of different

laboratories. Additionally, the formula used has not been fully validated in different population groups and CKD stages (El Nahas and Bello 2005).

2.6.3   Treatment options

Secondary prevention should be provided to patients with risk factors of CKD, such as hypertension, diabetes, and obesity. It includes many forms of lifestyle modification for these patients, including weight reduction, exercise, and dietary changes (El Nahas and Bello 2005). If a patient has developed CKD, early detection and treatment of comorbidities is very important to slow down the disease progression, otherwise it may develop into renal failure.

All patients with renal failure rely on renal replacement therapy, either dialysis or renal transplant, in order to sustain their lives. Renal transplant is the preferred treatment, regarding the patient's outcomes and cost-effectiveness, and is solely a treatment, not a cure. A patient who undergoes a renal transplant can survive almost like normal people, however, they must take immunosuppressive drugs to ensure that the organ is not rejected by the body's natural immune system. Unfortunately, due to the limited number of organ donors, most ESRD patients still rely on regular dialysis for the rest of their lives (Yeun and Depner 2005).

Kidney dialysis can be roughly categorised into two types, hemodialysis (HD) and peritoneal dialysis (PD). For HD, dialysis is performed outside the body starting by the continuous flow of blood along arterial lines to the membrane of an artificial kidney called a dialyser or hemodialyser. Within the dialyser, the blood flows against dialysate, a fluid that removes toxins through osmosis, then returns to the body by venous lines. Dialysis in the PD modality occurs in the body by the peritoneum which acts as a natural semipermeable membrane to perform ultrafiltration of the waste substance. Each patient has a catheter implanted in the lower abdomen and dialysis fluid is infused into the peritoneal cavity. As the fluid is removed from the abdomen, waste substances flow out along with the dialysate. Patients who are undergoing dialysis, both PD and HD, also rely on a medicine called erythropoietin (EPO), a highly expensive drug, to prevent anemia (Nesrallah, Blake et al. 2005).

Both HD and PD are diversified into many subcategories. Variations of HD include conventional HD, high-flux HD, hemodiafiltration, and hemofiltration which are differentiated by their degrees of solvent diffusion. Subtypes of PD are based on this principle, for example, continuous ambulatory PD (CAPD), automated PD (APD), tidal PD, and intermittent PD, which differ by their time to stop and start the dialysis cycle (Mohammed 2007).

A patient who is on CAPD, which is the type of PD supported by the Thai NHSO, has a catheter surgically placed through the abdominal wall into the peritoneal cavity. Every six hours or four times a day, the used dialysis fluid, approximately 2 litres, is drained out of the body and replaced with the new fluid. This process is called an exchange or cycle. It allows removal of the waste product from the bloodstream and takes around 30-45 minutes per exchange.

No dialysis modality is perfect, and each modality has its advantages and limitations (Table 2-4). Ideally, this information should be given to patients before starting dialysis in order to encourage them to select the method that best suits their personal situation (Nesrallah, Blake et al. 2005). Among the various forms of dialysis modalities used in developed countries, only CAPD and in-centre HD are preferred in most Asian countries (Li, Lui et al. 2007).

Table 2-4 Comparison of selected dialysis modalities

Characteristic	CAPD	HD
Frequency	everyday	3 times/week

Duration per session	Every 6 hours	3½-4½ hours
	(APD is performed during bedtime and patient is day-dry)	
Advantage	Home-base, less travel cost	Patients feel safe when health staff manage dialysis
	Can be at work while using dialysis	
Disadvantage	Need carers to help self-management	Need to be absent from work to undergo dialysis
	Might cause infection (peritonitis)	Might cause anemia
Examples of country of popularity	Mexico, Hong Kong	USA, China, Japan

Source: Nesrallah, Blake et al. (2005)
CAPD=continuous ambulatory peritoneal dialysis, APD=automated peritoneal dialysis, HD=hemodialysis, both CAPD and HD are the most popular modalities in Thailand and are available for the UCS's members

2.6.4   Access to ESRD treatment and financial protection

A systematic review estimated that around the world in 2010, there were 9.7 million patients needing renal replacement therapy (RRT) but only 2.6 million patients were able to use it (Liyanage, Ninomiya et al. 2015). As a consequence of the costly treatment, a report (Grassmann, Gioberge et al. 2005) revealed that access to dialysis is significantly different in high income, middle income, and low income countries. Around 80% of patients who are currently on treatment live in Europe, Japan or North America (Grassmann, Gioberge et al. 2005). In other parts of the world, proportions of access to treatment are very different. The proportion of those in need but not receiving RRT ranged from just 5% in North America to 91% in Africa (Liyanage, Ninomiya et al. 2015). Variations among different regions were found to be more associated with supply-side factors (such as macroeconomic, health system, and renal service provision) rather than health status or demographics of the general population (Caskey, Kramer et al. 2011). Therefore, ESRD disparity across countries does not only reflect the difference in underlying disease rates (Levey and Coresh 2012), but also the different priorities for providing access to high-cost health services, as well as an insufficiency of health resources in those countries (Hamer and El Nahas 2006).

For example, Asia has the highest number of ESRD patients in the world, with the proportion of patients receiving this treatment ranging from 17%-36% of

patients with ESRD. Africa has the lowest access to RRT, with only at around 9%-16% of the needy receiving treatment (Liyanage, Ninomiya et al. 2015). The variation in the proportion of patients receiving RRT is a consequence of each country's burden of disease, infrastructure, and financing system (Li, Lui et al. 2007).

In high income countries, ESRD care is publicly financed, and provided to most citizens regardless of how the health care system is financed and organised (Durand-Zaleski, Combe et al. 2007; Fukuhara, Yamazaki et al. 2007; Kleophas and Reichel 2007; Manns, Mendelssohn et al. 2007; Nicholson and Roderick 2007; Pontoriero, Pozzoni et al. 2007). Even in the US, where universal health coverage is inadequate, RRT services have long been provided as a Medicare benefit for all patients based on a patient's medical diagnosis, regardless of age or economic status (Levinsky and Retig 1991). Major problems in those countries involve long waiting lists for dialysis or transplant, and rapidly increasing costs for the health care payer (Levinsky and Retig 1991; Durand-Zaleski, Combe et al. 2007; Fukuhara, Yamazaki et al. 2007; Kleophas and Reichel 2007; Manns, Mendelssohn et al. 2007; Nicholson and Roderick 2007; Pontoriero, Pozzoni et al. 2007).

In contrast, there is greater variation of accessibility to RRT services in low and middle income countries. This includes availability of national data on prevalence and incidence of ESRD (Vazelov, Krivoshiev et al. 2004; Sakhuja and Kohli 2006; Cueto-Manzano and Rojas-Campos 2007; White, Chadban et al. 2008; Odubanjo, Oluwasola et al. 2011), arrangements of RRT service provision (Odubanjo, Oluwasola et al. 2011), and variation in universal public reimbursement for services (Sakhuja and Kohli 2006; Pecoits–Filho, Campos et al. 2009).

In India, for example, most dialysis services are for those who are waiting for renal transplant or have acute renal failure, not for maintenance purposes, and 95% of ESRD patients pay out-of-pocket for dialysis (Li, Lui et al. 2007). Half of that number has to sell their property or take a loan in order to access services, ending up with catastrophic spending and impoverishment (Sakhuja and Kohli

2006). In spite of massive need, there are very few arrangements for RRT in Africa due to the lack of nephrorogists, dialysis centres, and funding for treatment (Abu-Aisha and Elamin 2010; Pozo, Leow et al. 2012; Luyckx, Naicker et al. 2013). In Nigeria, a study found that of those patients who were able to access dialysis, only 5% could afford to continue the dialysis longer than 12 weeks (Luyckx, Naicker et al. 2013).

Evidence of inequalities due to the insurance system exists in Mexico, where only Social Security System beneficiaries (50% of the overall population) have access to RRT benefits (Pecoits–Filho, Campos et al. 2009). Thailand has been able to provide RRT universally from 2008 but is facing challenges regarding access to services and the sustainability of the system (Tantivess, Werayingyong et al. 2013).

2.6.5   ESRD as an example of high-cost and catastrophic condition

End-stage renal disease (ESRD) displays the characteristics of high-cost and catastrophic diseases. Firstly, with only a small number of patients, it nevertheless accounts for a significant percentage of health care costs. In high income countries, it is estimated that around 2%-3% of a country's health care budget is spent on caring for patients with ESRD that constitute less than 0.1% of the population (Lee, Manns et al. 2002; Hamer and El Nahas 2006). For example, new data from the US revealed that 5.6% of the Medicare budget or 28.6 billion US$ was spent on its ESRD programme in 2012. This amount went to treating 525,481 Medicare ESRD patients (United States Renal Data System 2014). In Spain, patients with ESRD constitute around 0.1% of the total population but consume up to 2.5% of the national health budget (de Francisco 2011). In Thailand, a middle income country with a much younger population, the UCS paid 6,023 million Baht (4% of its total health care budget) in 2014 for maintaining patients on RRT that constituted 0.07% of overall UCS members (NHSO 2014).

Costs of RRT including essential medications can drive a patient or household without insurance coverage into impoverishment (Wyszewianski 1986). In India, Pakistan, and Sub-Saharan Africa, provision of renal replacement therapy

is limited and there is an absence of public health insurance support. As a consequence of poor health care and a lack of timely preventive services, patients develop chronic kidney disease at a younger age, ie. in their most productive years, compared to patients in developed countries (Naicker 2009; Jha 2013). In the countries named above, patients rely greatly on treatment obtained on a fee-for-service basis. RRT is very expensive and therefore unobtainable for most patients. In India, with a gross national income (GNI) of US$1,530[5] per capita, costs of two HD sessions per week and three PD exchanges per day were estimated to be US$7,308 and US$7,020 annually (Jha 2013). In Sub-Saharan Africa, where GNI per capita is just US$1,663[6], costs of RRT range from US$7,000-55,000 per year (Abu-Aisha and Elamin 2010).

2.6.6   Disease management in chronic kidney disease

Disease management involves the use of a number of approaches for identifying and caring for patients with chronic conditions. Most chronic kidney disease management programmes aim to 1) identify early patients with chronic kidney disease, 2) slow and minimise the progression of chronic kidney disease to end-stage renal disease, 3) manage the comorbid conditions, and 4) smooth the transition to renal replacement therapy (RRT) or conservative therapy (without RRT) when appropriate (Rastogi, Linden et al. 2008; Rayner, Baharani et al. 2014).

Like other disease management programmes, chronic kidney disease management programmes use combined interventions to deliver care. For example, a chronic kidney disease management programme in the UK incorporates disease management interventions (such as patient identification, routine reporting, use of clinical guidelines, self-care management, and feedback loop among the multidisciplinary team) with other initiatives. These include pre-ESRD multidisciplinary care and conservative management, weekly database searching for patients with low kidney function (estimated glomerular filtration rate: eGFR <15 mL/min/1.73 m^2), and patient empowerment by

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[5] http://povertydata.worldbank.org/poverty/country/IND
[6] http://povertydata.worldbank.org/poverty/region/SSA

sending patients and their GPs a personal report after each consultation
(Rayner, Baharani et al. 2014).

2.7 Financing of RRT

In countries where RRT is included under universal health coverage,
governments use various financing strategies to ensure quality of care, contain
costs (Vanholder, Davenport et al. 2012), and promote access to service
(Tantivess, Werayingyong et al. 2013). Most countries finance RRT provision
differently from the normal mainstream to encourage dialysis service provision
and there is a large variation in RRT payment mechanisms across countries
(Dor, Pauly et al. 2007).

For example, Taiwan, a high-income country, was the world's top most country
having highest ESRD incidence and prevalence. Taiwan's NHI programme pays
for dialysis facilities via a global budget. All patients with ESRD are eligible to
receive any kind of RRT without copayment. While the number of patients on
RRT was less than 0.2% of the general population, the RRT cost was over 7% of
total health expenditure (Yang and Hwang 2008). In Malaysia, patients pay out
of pocket, or use private health insurance, or take funding from charity sectors
to undergo dialysis, although they can receive publicly funded services if they
meet the requirements (Lim, Goh et al. 2010). Before 2000, there were
inadequate numbers of public dialysis facilities to serve the high needs of
patients. Consequently, the government adopted a mixed private and public
model for providing and financing dialysis therapy by encouraging the private
sector to provide dialysis services to eligible patients. In this case, engaging the
private sector in dialysis care increased the treatment rate which was
comparable to those in developed countries (Lim, Goh et al. 2010).

Costs and benefits to ESRD patients in different countries also vary. In general,
most countries provide all essential services, including dialysis and medications
for treating anemia, at a predefined bundled package rate (Ponce, Marcelli et al.
2012; Vanholder, Davenport et al. 2012). Laboratory tests and doctor fees may
or may not be included, depending on a country's RRT benefit. In Spain, patients

are paid for transportation costs in addition to all dialysis services and medications (Luño 2007). Patients in high-income countries are well protected from excessive long-term spending, for example through limited copayment levels in Germany (Kleophas and Reichel 2007), exemption from high cost drugs in Japan (Fukuhara, Yamazaki et al. 2007), and entire exemption from copayment in Italy (Pontoriero, Pozzoni et al. 2007) and Spain (Luño 2007).

2.7.1   Bundled payments for renal replacement therapy programme

In line with the increasing numbers of RRT patients, costs of the programme put a large burden on government spending. Various payment strategies have been used to ensure access to service, and at the same time contain costs.

In countries with a national health authority or social security system, ESRD delivery programs are sometimes administered separately from normal mainstream services, or at least have payment rules specific to ESRD care (Dor, Pauly et al. 2007). These countries are moving toward bundled payments as a cost-control initiative to promote the rational use of resources (Vanholder, Davenport et al. 2012). In dialysis, the bundled payment is introduced to pay per treatment which may include, for example medications and fees for physicians, nurses, and RRT units. However, there is a great degree of variation in the design of payment systems and what is included in the bundle between countries.

For example, in the US, a bundled payment for dialysis is paid to dialysis units in an equal amount regardless of dialysis modality and the location where dialysis is performed (at home or in a dialysis centre). This rate also includes payment for injectable drugs, while nephrologists are separately compensated based on the frequency of their presence in outpatient care (Golper, Guest et al. 2011; Iglehart 2011). In Belgium, as hospital HD requires the attendance of medical personnel, it is more costly than alternative dialysis modalities such as self-care HD or PD. The hospital HD is reimbursed with a lump sum plus a physician's fee-for-service per dialysis session. Other dialysis modalities are reimbursed only by means of a weekly lump sum to a hospital (Cleemput and De Laet 2013). Payments for dialysis in the UK and Germany are more complicated. The UK

adopted a mandatory tariff under the system 'Payment by Results'. Dialysis units receive 'Best Practice Tariff' on top of dialysis treatment rates if they reach the target which is set in line with current treatment guidelines (Abma, Jayanti et al. 2014). For example, the Best Practice Tariff is given to NHS Hospital Trusts if they provide an arteriovenous fistula (AV fistula or an AV graft), a vascular access that is believed to give better health outcomes to a patient undergoing hemodialysis (National Health Service 2013). Germany has a wide range of reimbursements such as payments related to type of dialysis, whether the patient is hospitalized, reasons for that hospitalisation, and the region or state (Vanholder, Davenport et al. 2012). In the US, UK, and Germany, nephrologists' salaries are paid separately and not included in the bundle (Vanholder, Davenport et al. 2012).

2.8   Cost of RRT in literature

2.8.1   RRT costing

Numerous research studies have assessed costs relating to dialysis care and kidney transplant. However, cost calculation methods and results can vary depending on the financing system of the country assessed. This is because different systems have diverse payment mechanisms, and different items are reimbursed. The same cost heading may be used in different studies, yet may contain many different parts. For example, 'overheads' in some studies may consist of costs for staff training, education, and research in addition to the cost for hospital administration and housing (Karlberg and Nyberg 1995). Another source of variation is the perspective that is the focus of study. Cost calculations from the funder's perspective usually include only reimbursed items, for example the studies of De Vecchi, Dratwa et al. (1999), Lee, Manns et al. (2002), and Icks, Haastert et al. (2010) while those from the providers' perspective are always through activity-based costing, which accounts for most cost components such as labour costs, material costs, and capital costs, for instance in the studies conducted by Goeree, Manalich et al. (1995) and Baboolal,

McEwan et al. (2008). In studies conducted from the societal perspective, both direct and indirect costs are included (de Abreu, Walker et al. 2013).

2.8.2   Number of patients and cost modelling approaches

Various studies have been conducted to estimate the cost of RRT modalities. Some studies go beyond that, modelling future numbers of patients or financial resource needs of a health care programme. As seen in Table 2-5, these studies used historical data on incidence and prevalence of ESRD to predict future figures.

Table 2-5 Studies on forecasting ESRD patients and cost of ESRD programmes

Authors	Setting	Data sources	Forecast for	Method used	Forecast years
Quinn, Laupacis et al. (2009)	Canada	1999-2005: 1) Billing claims in the Ontario Health Insurance Plan database for identifying numbers of dialysis patients 2) Registered Persons Database for demographic and vital status information and determining the eligibility for the benefit coverage 3) Hospitalisations and kidney transplantation from Canadian Institute for Health Information Discharge Abstracts Database	Incidence and prevalence of chronic and acute dialysis patients	Exponential smoothing model, ARIMA model, stepwise auto-regressive model and exponential smoothing model	2006-2011
Kasemsap, Prakongsai et al. (2006)	Thailand	1) United States Renal Data System annual report 2004 2) National Renal Registry of Malaysian Society of Nephrology 2004 3) Thailand Renal Replacement Therapy Registry report 1997-2000	Dialysis and kidney transplant costs to the Universal Coverage Scheme	Estimations of unit costs of various activities multiplied by expected numbers of patients	1st year to 16th year
You, Hoy et al. (2002)*	Northern Territory, Australia	Patient data from 3 public hospitals, 1996-2000	Numbers of hemodialysis treatments	ARIMA model	2001-2005
Xue, Ma et al. (2001)	USA	United States Renal Data System annual report 1982-1997	Incidence and prevalence of ESRD patients, dialysis patients, functioning transplants, and waitlist patients	Stepwise auto regressive model	1998-2010
Schaubel, Morrison et al. (1998)	Canada	Demographic data, clinical history data, and deaths from the Canadian Organ Replacement Register, 1981-1994	Numbers of ESRD patients by each RRT modality	Poisson and Markov models	1995-2005
Motohashi and Nishi (1991)	Japan	1985-2000: 1) Population profile from Institute of Population Problems 2) Annual Reports on Dialysis Therapy in Japan and vital statistics in Japan 3) Renal transplants from Japanese Society for Transplantation	Numbers of ESRD patients	System dynamics model	1980-2000

Note: ESRD= end-stage renal disease, ARIMA=auto-regressive integrated moving average, *costs of treatment during the studied period were estimated but not projected to the future

While most of the studies forecast numbers of ESRD patients, only the study of Kasemsap, Prakongsai et al. (2006) calculated and projected costs to the NHSO, a health care payer in Thailand.

The study of Kasemsap, Prakongsai et al. (2006) had a specific aim that was to inform policy makers before the RRT programme launched. Back then, the UCS's RRT programme was not in existence, and the authors used the incidence rate from the US renal registry, which was 300 patients per million population, to estimate future numbers of patients and budget needs of the UCS RRT programme. It was predicted that the RRT programme would consume a budget of 14 to 24 billion Baht in 2013 (Kasemsap, Prakongsai et al. 2006). To date, the actual incidence rate is 254 patients per million population. Expenditure of the RRT programme has not reached the estimated amount, however, it has increased substantially and reached £87 million Baht in 2013.

2.9   Renal replacement therapy of the UCS

2.9.1   Background of the UCS RRT programme

RRT was initially excluded from the benefit package when the UCS was launched in 2001 due to fiscal constraints and an unprepared system. Gradually, the NHSO, which was responsible for the UCS, was pressured to expand benefits to include RRT by civil society organisations and patient groups (Tangcharoensathien, Kasemsap et al. 2005). Their justifications for inclusion were that it would save lives and prevent indebtedness and health impoverishment among UCS members.

Before launching the RRT programme, the NHSO commissioned a group of researchers to conduct a set of comprehensive studies relating to RRT situations and the possibilities of an RRT programme for UCS beneficiaries. The intention was to present viable policy options to the NHSO board. Their final decision, supported by the government and the cabinet, was that the RRT would be provided universally regardless of age and socio-economic status (Dhanakijcharoen, Sirivongs et al. 2011).

Despite being cost-ineffective, in 2008 RRT was adopted into the benefit package of UCS. The new health benefit covered RRT services for every UCS member. The justification was to help patients have access to the essential treatment and protect them from catastrophic spending due to health care costs (Kasemsap, Teerawatananon et al. 2006).

The RRT programme is one of the few UCS disease management programmes that has all the basic elements of the disease management concept. The issues about how the RRT programme was established, managed, and linked with the disease management approach are explored in detail in Chapter 5 of this thesis.

2.9.2   Evaluations of the UCS RRT programme

After RRT programme implementation, greatly increased numbers of people accessing UCS-funded RRT of the UCS was a consequence of the large number of patients who had been waiting for the extension of universal health coverage to cover RRT in 2008 (Dhanakijcharoen, Sirivongs et al. 2011). There were two reports that assessed the arrangement of the RRT programme. The first study (Limwattananon and Limwattananon 2013) was about access to RRT services and patient survival rates. Another study (Kasemsap, Limwattananon et al. 2013) evaluated the programme in various dimensions including comparison of care processes among the three public insurance schemes and costs of dialysis care.

Limwattananon and Limwattananon (2013) estimated that the proportion of UCS patients with ESRD diagnoses using RRT services increased rapidly from only 15% in the first year of the RRT programme to 41% in 2010 and 36% in 2012. However, the figures indicated that many patients were still not using dialysis. The study also reported that a half of patients who were able to continuously use RRT survived at least 5 years while a half of patients who did not receive RRT survived less than 20 months (Limwattananon and Limwattananon 2013).

Regarding the low number of patients with ESRD diagnoses with access to the RRT programme, Kasemsap, Limwattananon et al. (2013) clarified that this was

because generally, patients are diagnosed as ESRD when they have eGFR level lower than 15 ml/minute per 1.73 m^2. However according to the Thai Nephrology Society guidelines, patients without signs or symptoms of kidney failure will only be asked to enter the RRT programme once the eGFR level reaches 6 ml/minute per 1.73 m^2. This partly explains why the study of patients with ESRD diagnoses from the database found that many of them had not yet started dialysis.

2.9.3   RRT related costs in Thai literature

In Thailand, most published studies have assessed costs from the health care providers' perspective. From the perspective of providers of HD, Meechai (2002) evaluated costs of hemodialysis in four different sizes of hemodialysis centres. Tisayaticom, Patcharanarumol et al. (2003) used postal questionnaires to calculate costs relating to hemodialysis in 108 public and private facilities across the country. Thanatchon (2012) conducted a cost analysis of hemodialysis in a large-size medical centre. All three studies identified direct costs which consisted of (1) labour costs (LC, including salary, fringe benefits, overtime), (2) material costs (MC, including fluid, drugs, and overheads), and (3) capital costs (CC, including depreciation and maintenance). Apart from the three main categories, Meechai (2002) added indirect costs which were travel costs spent on traveling to dialysis units. Thanatchon (2012) added costs for erythropoietin and indirect costs allocated from hospital non-revenue producing cost centres.

For peritoneal dialysis, Laonapaporn, Punthunane et al. (2014) conducted an activity-based costing of peritoneal analysis in a general hospital. They analysed costs of 13 activities relating to the peritoneal dialysis service. These included the treatment for peritonitis and erythropoietin dispensing in the follow-up process. All activities had three cost categories: labour costs, material costs, and capital costs. For any activity which needed laboratory tests, costs of the test were included.

For kidney transplant, Suksamran, Kongsin et al. (2012) collected data in a large university hospital. They categorised costs into labour costs, material costs, and

capital costs; and separated the material costs into medical care costs and operating care costs for other consumables.

There are three studies (Thanatchon (2012), Laonapaporn, Punthunane et al. (2014), and Suksamran, Kongsin et al. (2012)) that included the cost of medications (erythropoietin and immunosuppressants) in calculations of material costs. In addition, Laonapaporn, Punthunane et al. (2014) took account of laboratory tests in material cost calculations, which may explain the high proportion of these three studies' material costs. Proportions of costs from all reviewed studies are summarised in Table 2-6.

Table 2-6 Proportions (%) of three types of direct costs, indirect costs and the unit cost of RRT

	PD Laonapaporn(2014)	HD			KT Suksamran(2012)
		Meechai(2002)	Tisayaticom(2003)[1]	Thanatchon(2012)	
Labour costs %	25	32	34, 47, 40	18	18
Material costs %	74	42	46, 41, 43	60	79
Capital costs %	1	24	21, 12, 17	13	3
Indirect costs %	N/A	19	N/A	9	N/A
Unit cost (Baht)[2]	45,755	2,328-4,068	1,927, 1,525, 1,708	3,288	388,327

PD=peritoneal dialysis, HD= hemodialysis, KT =kidney transplant
[1] Public, private, and both public and private facilities
[2] Per PD patient·year, or per HD session, or per transplantation

2.10 What is unknown?

Given current studies, little is known about the following issues:

1) While in the international literature, there are many studies conducted to quantify numbers of households with catastrophic spending and numbers of those who are impoverished from health care costs, there has been less study about the effect of providing high-cost health benefits.

2) The number of disease management programmes and their investments are growing, but their effects, both clinical outcomes and cost reduction, are still unclear. Also, a scoping review in Chapter 3 on disease

management found little evidence from low and middle income countries.

3) In Thailand, as a developing country, there is a problem of inadequacy of health care infrastructure. Applications of disease management programmes vary greatly and differ somewhat from the original features of the disease management concept. To date, there has been limited study in Thailand assessing the rationale, process, and performance of these programmes. Additionally, no empirical research connects these programmes to the disease management approach.

4) In cases of high-cost treatment such as RRT, while there is a concern to control programme expenditure, the actual expenditure of the programme is still far lower than the original estimation. Nonetheless, there is no empirical evidence showing what contributed to the lower budget spends. It is unclear whether it is a consequence of the efficient RRT disease management programme, overestimation of expenditure, or poor patient access.

CHAPTER 3   Evidence on Disease Management Programmes: results from population-based studies

The high number of patients suffering from chronic conditions places a significant burden on individuals, society, and health care budgets (Berk and Monheit 1992; Nolte and McKee 2008). These chronic conditions include, for example, coronary heart disease, hypertension, diabetes, and renal disease. One approach to coping with escalating health expenses is to use the disease management approach. This has been developed as a means to improve quality of care delivered to patients with chronic diseases as well as bring the costs down by efficient and effective use of health care resources (Geyman 2007).

Several review studies have described the designs and effects of disease management programmes. However, just a few of them focused on population-based programmes that applied to a wide range of the population. Additionally, there have been a limited number of review studies describing programmes' arrangements both at both the policy and provider level.

This chapter aims to provide the results of a systematic search on the topic of evidence on disease management from population-based programmes where disease management is viewed as an intervention to improve quality of care as well as to reduce health care expenditure. Results are reported in terms of how these programmes are arranged, their effects on patient outcomes, and their effects on cost containment at two levels: funder-provider level and provider-patient level.

3.1   Background to disease management programmes

The concept of disease management was developed in the US in the 1990s as a response to high health care spending (Krumholz, Currie et al. 2006). Although not implemented universally in the country, the Centre for Medicare and Medicaid Services has launched a number of disease management demonstration programmes for its beneficiaries in several states. In the private sector, commercial health schemes and large companies commission private

firms to provide disease management programmes that help individuals manage their chronic conditions. Because of the claim that disease management of high-cost diseases can save more than US$30 billion a year (Mattke, Seid et al. 2007), the disease management industry has grown rapidly. The annual revenue of this sector increased from US$78 million in 1997 to approximately US$1.2 billion in 2005 (Mattke, Seid et al. 2007).

In European countries, the aims of disease management (DM) are different from those in the US. DM is applied as a new model to deliver health services for patients with chronic diseases in response to a set of problems. They include improper utilisation of health care resources, fragmentation of health systems (Busse 2004; Nolte and McKee 2008), poor access to care and catastrophic payment (Stuart and Weinrich 2004; Nolte, Knai et al. 2008). Sometimes, the model is referred to as Chronic Care Model or as integrated care, which is a modified form of disease management. The diverse models applied to manage chronic conditions contribute to differences between health systems. Therefore, what seems to be a successful factor in one health system might give different results in others (Nolte and McKee 2008).

3.2   Definitions and components of disease management

One challenge of disease management implementation is that there is no common definition of disease management, and applications vary greatly (Krumholz, Currie et al. 2006; Schrijvers 2009; Hisashige 2012). Hisashige's systematic review of DM definitions (2012) reported that out of 28 studies, 7 studies use their own definitions, 16 studies adopted the definition of others, and there was no explicit disease management definition in the remaining studies. Despite the inconsistent definitions, a number of key terms were mentioned; they were; comprehensive, systematic approach (and its similarities), population-based, coordinated health care, specific disease, practice guideline, and patient education (Hisashige 2012).

The Disease Management Association of America (DMAA) has provided one of the most frequently cited definitions. Disease management for a specified

disease is defined as *"a system of coordinated health care interventions for a pre-defined group of population with application of evidence-based guideline/protocol, and the monitoring and evaluation process is conducted on a regular basis"* (Krumholz, Currie et al. 2006), Table 3-1.

Table 3-1 DMAA definition of disease management

Disease management:

supports the physician or practitioner/patient relationship and plan of care;

emphasizes prevention of exacerbations and complications through the use of evidence-based practice guidelines and patient empowerment strategies; and evaluates clinical, humanistic, and economic outcomes on an ongoing basis with the goal of improving overall health.

Disease management components include:

- population identification processes;
- evidence-based practice guidelines;
- collaborative practice models to include physician and support-service providers;
- patient self-management education (may include primary prevention, behavior modification programs, and compliance/surveillance);
- process and outcomes measurement, evaluation, and management; and routine reporting/feedback loop (may include communication with patient, physician, health plan, and ancillary providers, and practice profiling).

*Full-service disease management programs must include all 6 components. Programs consisting of fewer components are disease management support services

Source: DMAA (2005) cited inKrumholz, Currie et al. (2006)

A prior scoping review by the researcher found that numerous research studies on DM were conducted at the provider-patient level, looking at various provider disease management approaches and their effects. In addition, most of those studies were carried out on a small scale or a single practice of health care provider. They briefly covered policy interventions given to providers, and therefore little is known about disease management applications and their effects on a larger scale.

3.3 Review questions

A number of questions arise in terms of types of arrangements and their differing effects, especially at the population level. This review sought to answer the questions below. Findings from the review were expected to provide a clearer picture of disease management and its effects, helping to plug knowledge gaps in this area.

1) How are disease management programmes arranged at the policy level, in terms of types, approaches to implementation and enforcement, in different health systems?

2) What are effects on the health system, in terms of costs and quality of care?

3) What are types of disease management content and services provided in health facilities?

4) What are effects on patients, in terms of access to services and clinical outcomes?

3.4   Review methods

Based on the hypothesis that disease management programmes can be sustained by the payment mechanism and enforcement supported at the policy level, this review identified empirical evidence regarding the effect of various incentives or interventions from payers to providers who deliver disease management programmes. This review aimed to explore disease management programmes as interventions to manage chronic conditions and their effects. The effects were examined at two levels. At the payer-provider level, the focus was on costs and quality of care. At the provider-patient level, the focus was on service provision, patient outcomes, and cost containment. Figure 3-1 explains how these interventions work, how they relate to each other, and which effects to be assessed.

Figure 3-1 Framework of disease management to be explored in this review
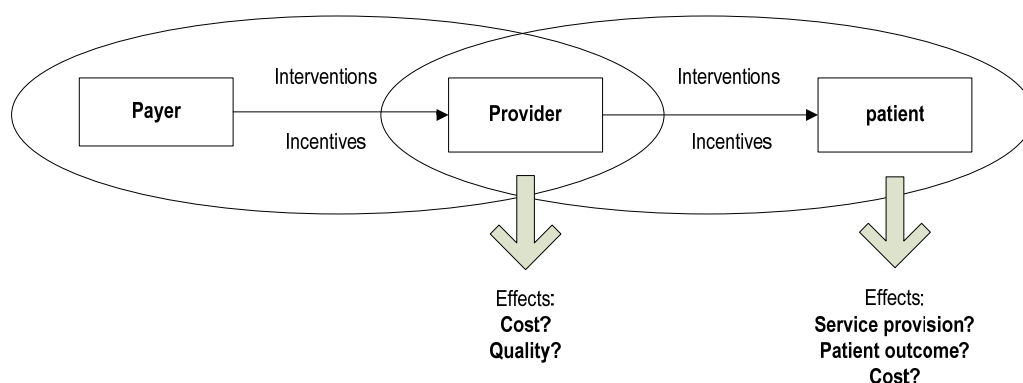
The nature of disease management interventions is diverse, as they are composed of multiple interventions, participants, settings, and outcomes. Because of this diversity, there are no effective formal measures or study designs for a systematic review (Centre for Reviews and Dissemination 2009) and a range of different methodologies have been used to evaluate the effects of DM. This review used the systematic approach to find relevant articles and used narrative synthesis to report the results.

3.4.1 Search strategies for identification of studies

The system of disease management was divided into two levels; payer-provider level and provider-patient level. Each level was considered and reported separately. At payer-provider level, because there was a limited number of research studies exploring the effect at the payer-provider level, most studies were commentaries or descriptive papers. Relevant articles in this part came from both systematic and hand searches. Search terms used for primary research and hand searches included; "disease management", "effect", and "nation or region or county or country or state or decentralize". At this level, studies were identified as relevant and included if they provided sufficient information about the detail of arrangements or interventions of disease management, in terms of types, approaches to implementation and enforcement. Also, these studies measured effects of disease management, for example access to services, quality of care, costs, or patient outcomes.

Results of the effects at provider-patient level were derived from a systematic search of primary studies conducted in a large population group. Trial programmes, demonstration programmes, or non-population based programmes which include only 30-500 participants of patients with high risks were excluded. Search terms for primary research are similar to the payer-provider level. Detailed results for each search term can be found in Appendix 1.

For searching primary research, the review used the Ovid platform to access the EMBASE database. Retrieved articles were first extracted by screening their titles and abstracts. After that, possible relevant articles were then searched to review the full text. Because benefits of disease management programmes are expected to occur over the long term (Lind, Kaplan et al. 2006), this review looked for studies that assessed effects of disease management interventions on patients for at least 12 months. Disease management has multiple components and they tend to be effective when combined. For this reason, any studies which assessed only a single intervention, such as database management or telephone follow-up, were excluded. Also, studies that explored merely attitudes of providers or patients, or provided solely an economic evaluation, were not included in this review.

3.4.2   Inclusion criteria

- Primary research exploring the effect of DM programmes at national, country, state, county, or regional level.
- Patients must be exposed to disease management interventions at least 12 months.
- At least two disease management interventions (such as patient education, provider-patient communication, use of clinical information systems, or use of guidelines) were provided to participants in the study.
- Published in any peer reviewed journal written in English between 2003 and 2015.

3.4.3 Search results of the primary research

The search strategy yielded 768 potentially relevant studies from EMBASE. Of this figure, 284 articles were conference abstracts or study protocols, and 441 articles were irrelevant. Articles were excluded if they were not related to the health system (such as clinical trials, animal or plant studies); not implemented at national, regional, or state level; not a primary study; if the study period was less than 12 months; if it was primarily an economic evaluation; if it duplicated another study. Also, there were many studies (156) that mentioned disease management but did not assess its effects and therefore were excluded. After that, there were 43 potentially relevant articles. It was not possible to retrieve the full text of three articles and 26 articles were removed. The majority of removals were because there were less than two disease management interventions mentioned and used in the study (8 articles), or because there was no description of the disease management interventions studied (8 articles). Some articles were removed for more than one reason, but only the main reason was stated. Finally, there were 14 relevant articles to be synthesised, Figure 3-2.

Figure 3-2 Process of screening for primary study


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┌─────────────────────┐
│  768 potentially    │
│  relevant articles  │
│  for abstract       │
│  screening          │
└─────────────────────┘
         │        ┌──────────────────────────────────────────┐
         │───────▶│ 284 conference abstracts/study protocols  │
         │        │ 441 irrelevant articles removed:          │
         │        │  - not about the health system (133)      │
         │        │  - non population-base programme (12)     │
         │        │  - not focused on DMP interventions (156) │
         │        │  - non primary research (120)             │
         │        │  - short-term study (7)                   │
         │        │  - economic evaluation (8)                │
         │        │  - duplicate (5)                          │
         ▼        └──────────────────────────────────────────┘
┌─────────────────────┐
│  43 fulltext        │
│  articles for       │
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         │───────▶│ 3 unable to retrieve full-text            │
         │        │ 26 irrelevant articles removed            │
         │        │  - non population-base programme (2)      │
         │        │  - not focused on DMP interventions (4)   │
         │        │  - non primary research (1)               │
         │        │  - short-term study (2)                   │
         │        │  - economic evaluation (1)                │
         │        │  - <2 DM components mentioned/used (8)     │
         ▼        │  - no information on DM components (8)     │
┌─────────────────────┐ └────────────────────────────────────┘
│  14 relevant        │
│  articles           │
└─────────────────────┘
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3.5   Results

There were numerous studies about disease management. Using the term
'disease management' in the PubMed database produced the result in Figure
3-3. The term was first mentioned in the 1940s and became of more interest in
the late 1990s. This might be a consequence of the formulation of disease
management concepts followed by the approach to the chronic care model in
this period. After that in 1996, published papers increased considerably. In
2014, the figure rose to 2,725 articles.

Figure 3-3 Numbers of published articles regarding disease management
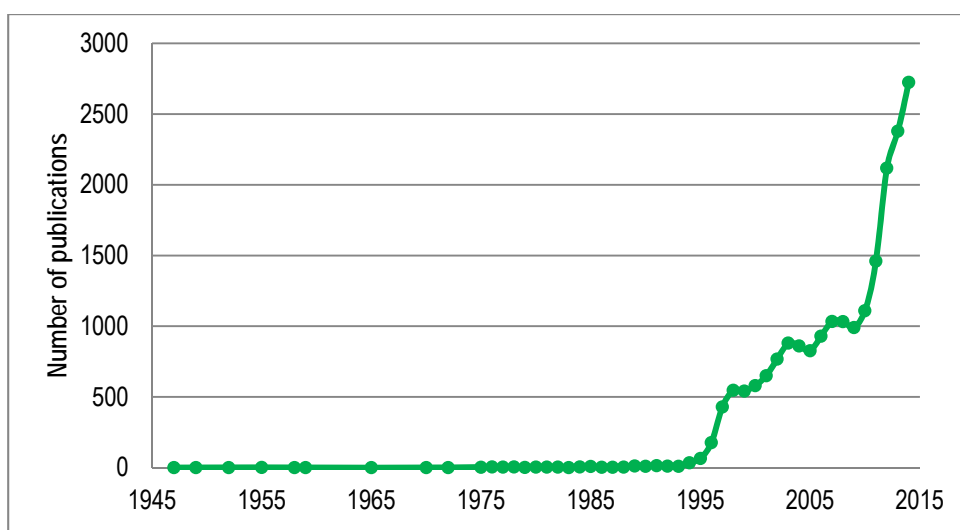
Results are reported at two levels: policy level and provider-patient level. At the
policy level, evidence from systematic and hand searches was described. At the
provider-patient level, findings are reported from the systematic search of
primary studies.

3.5.1   Disease management arrangements at the policy level

3.5.1.1   Types of disease management programmes

There is a large variation in the application of disease management
programmes. It may vary across or within countries. Based on the level of
integration, most disease management programmes can generally be
categorised into two basic types: 1) the chronic care model in which primary
care plays the key role in integrating the programme with other health system

sectors and 2) separately managed programmes for a specific disease without integration or coordination (Geyman 2007).

Examples of the first type are disease management programmes based on the chronic care model. These are used in regions or countries that have strong primary care systems. Primary care acts as a central component, able to coordinate others to connect patients with their specialists or refer the patient from primary care to other sectors, for example, laboratory or x-ray tests, palliative care, or inpatient services (Nolte, Knai et al. 2008). Many disease management programmes in European countries (Nolte, Knai et al. 2008) and non-profit health insurance plans in the US (Group Health Coorperative and Kaiser Permanente) are attempting to move to the chronic care model (Geyman 2007). Aims of these programmes are to improve the quality of health service delivery, control costs, and decrease fragmentation of different health system sectors.

The second type of disease management programmes administers a package of services focused on a single disease. Since this category is often applied where there is a weak primary care system, the coordinating role of the primary care and advocate function of collaborative practice are minimal. Examples of this type are disease management programmes provided by private companies in the US, in which employers, the state Medicaid programme, or health insurance plans commission these companies to provide DM programmes for members suffering from chronic diseases. These programmes are marketed on the basis of cost-containment, with packages focusing on patient education for self-management through systems such as telephone calls, mailing, and online information (Geyman 2007).

3.5.1.2   Approach to implementation and enforcement

Disease management implementation is usually voluntary for providers, and patients can opt out (Busse and Riesberg 2004; Lind, Kaplan et al. 2006; Nolte, Knai et al. 2008). Patients registered with these programmes benefit from disease management services and, depending on their specific programme, exempted or reduced co-payments (Nolte, Knai et al. 2008).

Approaches to disease management implementation can be classified into two types (Gresharp, Baan et al. 2009): top-down approach and bottom-up approach.

i. Top-down approach

The top-down approach is characterised by policy-making at the national level, financing through the national budget, and nationwide regulation and implementation. Notable of this type are England and Germany where purchasers, insurers or providers have financial incentives to set up disease management programmes, generally via additional payment, separate from the normal budget. Support and regulation from the national level mean disease management programmes are implemented quickly, and health care providers have to follow the same standard protocols (Gresharp, Baan et al. 2009). For example, in Germany, sickness funds (health care purchasers) receive higher compensation for setting up certified disease management programmes and recruiting participants with chronic illness. Sickness funds then contract with providers to deliver accredited DM programme packages and enroll as many members as possible (Busse and Riesberg 2004; Gresharp, Focke et al. 2006). As a consequence of strong regulation, although each health insurance company offers its own disease management programmes, most components are applied rather similarly. Patients must consent to enrolment and agree to actively participate in their care according to the requirements of the programme (Stark, Schunk et al. 2011).

The top-down disease management contract models in Germany and the UK provide an incentive to accelerate the implementation of disease management programmes (Gresharp, Focke et al. 2006; Gresharp, Baan et al. 2009; Ham 2009), increasing benefits to family physicians and recruitment of health care staff into the primary care sector (Ham 2009).

Financial incentives of the top-down approach can be categorised into three types according to their purpose; 1) for establishing infrastructure and network, 2) for registering members, and 3) for providing services (see Table 3-2).

Table 3-2 Financial incentives to providers in selected countries

Category	England	Germany
Establishing infrastructure & network	N/A	Earmarked at 1% of total health care budgets at the beginning of nationwide implementation period (2004-2006)
Registering members	Global budget based on the number of registered patients with adjusted weight	Additional compensation for a registered patient
Providing services	Additional pay-for-performance payment for targeted outcomes	Additional flat rate payment for documentation, patient education

Source: Nolte, Knai et al. (2008), Gresharp, Focke et al. (2006), Ham (2009)

Although national funding is a promising sign for the continuity of disease management programmes, large expenditures resulted in criticism of money spent on chronic care programmes (Ham 2009).

ii. Bottom-up approach

The other approach, bottom-up, is characterised by local, state, or regional initiatives within the existing service provision. Although such disease management programmes are developed based on local needs, they are likely to suffer from issues with long term funding. This is because these disease management programmes are mostly financed by time-limited contracts or grants (Gresharp, Baan et al. 2009) or from available regional budgets (Steuten, Palmer et al. 2007). This bottom-up approach frequently reflects the fragmentation within the health system and the government's inability to support integration of chronic care delivery (Lankhorst and Spreeuwenberg 2008). Examples of this type are the asthma management programme in Quebec, Canada, supported by local public-private networks (Boulet, Dorval et al. 2008); the diabetes management programme in Maastricht, the Netherlands, contracted via the health insurance fund (Lankhorst and Spreeuwenberg 2008); and high-cost disease management for Medicaid beneficiaries in many states of

the USA (Martin, Berger et al. 2004; Lind, Kaplan et al. 2006; Zhang, Wan et al. 2008; Katz, Holmes et al. 2009; Coburn, Marcantonio et al. 2012).

3.5.1.1   Effects on the health system: costs and quality of care

A well-functioning primary care provider that can assess patients' clinical outcomes and medication and at the same time, coordinate with other segments (such as specialists), is expected to provide better quality of care and reduce costs by cutting unnecessary medications and utilisation of health care resources (Nolte and McKee 2008). Coordinating mechanisms are, therefore, key to achieving the aims of disease management. Bodenheimer (2009) summarised a number of studies regarding the quality and costs of disease management programmes in the US. They found that disease management based on the primary care function performed better than disease management programmes supported by private companies in terms of quality of care. However cost containment results were inconsistent (Bodenheimer and Berry-Millett 2009).

Coleman et al (2009) reviewed several observational studies which examined the impacts of different components of disease management and chronic care models. Impact was assessed in terms of quality, process indicators (such as coordination and guideline use) and clinical outcomes. They found that the more programme components implemented, the more likely the programme was to gain quality improvements (Coleman, Austin et al. 2009).

The reviewed studies described inconclusive findings on costs and quality of care (Mattke, Seid et al. 2007; de Bruin, Heijink et al. 2011; Hisashige 2012). This was true even in large pilot disease management programmes, such as that of Medicare in the US, which served approximately 300,000 Medicare beneficiaries with chronic diseases. A summary of overall results concluded that these programmes did not show common evidence of improvement in behaviour, compliance to treatment guidelines, or satisfaction of providers or members, although some programmes reported a net cost saving (Bott, Kapp et al. 2009).

While there is inconclusive evidence on the issues of costs and quality, some review studies (Bodenheimer and Berry-Millett 2009; Gresharp, Baan et al. 2009; Nolte, Knai et al. 2012) suggest that there are three possible predictors affecting programmes' success. They include: 1) design of an individual programme, 2) level of integration of primary care and other segments, and 3) policy support at the national level.

3.5.2   Disease management at provider-patient level: results from primary research

What is known about the effect of approaches on disease management is more likely to come from small programmes. These programmes are likely to be non-population based programmes which include only 30-500 participants of patients with high risks, rather than the whole population with a given condition or disease, and short-term studies where length of observation was less than 12 months (Mattke, Seid et al. 2007; Conklin and Nolte 2013). While the results of large, population-based programmes are unclear, this section sought to synthesise effects of disease management that can be generalised to a wider population.

3.5.2.1   Description of included studies

The systematic search of large population-based studies found 14 relevant studies. Studies from the US (7 studies) dominated, while other studies came from Germany, England, Italy, France, and Canada. The studies varied in duration from one year to four years. The majority of the included studies (9 studies) were quasi experimental or observational studies (including pre-post, cohort, and cross sectional studies). Four studies were randomised controlled trials, and one study was a descriptive study. Most of the included studies had control or internal comparison groups (programmes' members receiving usual care or the general population). Only two studies used benchmarks (the general population and targets) for counterfactual comparison. The results of each study are presented in Table 3-3.

3.5.2.2   Service provision

The most common type of disease management service in the US and France were nurse-led clinics or nurse-led disease management services, centralised in the offices of GPs. Nurses acted as a health educators; mentors of patients' monitoring programmes; and coordinators between primary and secondary care systems, and patients and their physicians, either GP or specialist. The level of responsibility of a nurse was based upon agreed protocol (Katz, Holmes et al. 2009; Coburn, Marcantonio et al. 2012; Agrinier, Altieri et al. 2013). In Italy, GPs worked in their own offices and were asked to share clinical experience, adopt clinical guidelines and organise workshops for quality and prescribing assessment with other general practioners in the same group. Other professionals or specialists were not included within the group (Visca, Donatini et al. 2013).

3.5.2.3   Patient outcomes

Since disease management programmes in each study in this review were applied in multiple sites, detailed activities might be varied. However, all programmes were based on patient education for self-care management and follow-up communication. All studies assessed at least one of the following

indicators: patients' access to services, resource utilisation, clinical outcomes, quality of care, and costs.

i. Resource utilisation

Resource utilisation was quantified by a number of measures, such as emergency, outpatient and inpatient use. Results found that disease management reduced emergency visits (Zhang, Wan et al. 2008; Campbell, Ronksley et al. 2012) and hospitalisations (Windt and Glaeske 2010; Campbell, Ronksley et al. 2012; Agrinier, Altieri et al. 2013). However, the effect might not be statistically significant across all diseases if measured in more than one disease.

ii. Clinical outcomes/ quality of care

In terms of health outcomes and quality of care, disease management interventions seemed to be effective at improving most indicators. A number of studies showed statistically significant improvements. These included reductions of the mortality rate (Coburn, Marcantonio et al. 2012), higher rates of receiving proper medical care (Windt and Glaeske 2010; Stark, Schunk et al. 2011), achievement of treatment goals (Gilmer, Philis-Tsimikas et al. 2005; Meng, Wamsley et al. 2010; Stark, Schunk et al. 2011), and better patient quality of life (Zhang, Wan et al. 2008; Meng, Wamsley et al. 2010; Visca, Donatini et al. 2013) in comparison to non-intervention groups. However, results from more than half of studies were mixed, with both positive and negative or insignificant results, within or across providers or disease and regardless of patients' risk levels.

iii. Access to services

By applying collaborative practice, emphasising evidence-based guidelines and feedback reports, a study in Manchester, UK found improvements in the numbers of patients registering with a chronic kidney disease programme. However, levels of improvement varied across providers (Humphreys, Harvey et al. 2012). Disease management programmes might be unable to fully address

existing disparities if they served patients within different socioeconomic status groups. A study in Alberta, Canada found that patients with low socioeconomic status and indigenous patients had higher rates of hospitalisation in comparison to general patients. Also, indigenous patients were less likely to receive specialist care (Campbell, Ronksley et al. 2012).

3.5.2.4   Cost containment

Results regarding cost containment of disease management programmes were mixed with statistically significant (Zhang, Wan et al. 2008; Katz, Holmes et al. 2009; Agrinier, Altieri et al. 2013) and not statistically significant results in terms of cost containment (Martin, Berger et al. 2004). In comparison with the usual care group, just two out of five studies assessing the costs of disease management programme (Martin, Berger et al. 2004; Gilmer, Philis-Tsimikas et al. 2005) found significant increases in the cost of disease management arrangements.

Table 3-3 Characteristics and results of relevant primary studies

Author	Setting	Study design	Comparison strategy	Diseases	DM interventions	Study's Measures	Effects
Visca, Donatini et al. (2013)	Italy	Observational, cross-sectional study of general practioners working in teams	Internal comparator: general practioners working in solo practice	Diabetes, CHD, IHD	Policy level: reforms of the primary health care to introduce team practice of GPs. Each GP is paid extra for each patient on top of the capitation. Provider level: clinical practice guidelines and organizing workshops of the GP team for assessment of care quality and appropriate prescribing	Proportions of patients receiving appropriate care	In terms of quality of care, results were mixed and inconclusive.
Agrinier, Altieri et al. (2013)	Lorraine, France	Descriptive and time-series study of patients enrolled in a DMP	Benchmarking: overall French population	HF	Policy level: no detail specified Provider level: home-nurse visits and patient/family education	Number of HF hospitalizations and difference of total cost of operating the DMP and the costs saved by the avoided hospitalizations	In 2010, there was a 7.19% reduction in the risk of hospitalization in the region, estimated net savings associated with the DMP was €1,927,648.
Campbell, Ronksley et al. (2012)	Alberta, Canada	Population-based cohort analysis of patients aged < 65 years	Internal comparator: general population	Diabetes	Policy level: primary care reform by establishing Primary Care Networks funded on a capitated basis to support health services that fall outside the fee-for-service payment. Provider level: multidisciplinary teams and enhancing patient education as a basic	Hospital admissions, physician visits, and emergency department visits	Receiving care in a primary care network was associated with significantly lower rates of all measures and the effects were similar across each population group. The study noted a marked risk of higher hospital admissions and emergency visits of lower income and indigenous groups.
Humphreys, Harvey et al. (2012)	Primary care trusts in Greater Manchester	Descriptive study of patients with	Benchmark: target setting	CKD	Policy level: payment for initiating a DPM, attending training sessions, and	Number of registered patients and level of	Percentage of improvement of both indicators were observed but level of

Author	Setting	Study design	Comparison strategy	Diseases	DM interventions	Study's Measures	Effects
	region, UK	CKD			final payment at the end of the DMP. Provider level: NICE guidelines on the identification and management of CKD, staff training	blood pressure	achievement varied across providers
Coburn, Marcantonio et al. (2012)	Traditional Medicare (administered by federal government) patients in primary care providers in Pennsylvania, USA	RCT of a Medicare demonstration programme	Control group: usual care	HF,CHD, DM, HT, asthma, hyperlipidemia	Policy level: Medicare's FFS coverage and additional fixed negotiated fee per participant per month Provider level: Patient education, coordination mechanism, guideline use (detailed activities were varied across providers)	Mortality rate	Nurse care management associated with reduction of all-cause mortality in chronically ill elderly
Stark, Schunk et al. (2011)	Augsburg, Germany	Cross sectional survey of a DMP	Control group: usual care	Diabetes	Policy level: regulate responsibilities of doctors, patients, and social health insurance companies, as well as set up their treatment goals. Provider level: define eligible patients and regular follow-up, provide health education to patients and health care providers, coordination of complex medical care, and other support	Patient's self-care management, body examination, and other laboratory tests for diabetes	In comparison to the usual care group, patients in DMP were more likely to received anti-diabetic medications, more frequent medical examination, diabetes educations, and achieve blood pressure goals. Both groups had satisfactory HbA1c but poor low-density lipoprotein levels.
Meng, Wamsley et al. (2010)	Medicare patients in New York, West Virginia and	RCT of a Medicare demonstration	Control group: usual care	Disability	Policy level: no detail specified Provider level: patient education, individualised health promotion and	Body mass index and dependence in Activities of Daily Living	DM interventions were statistically associated with less worsening in disability of

Author	Setting	Study design	Comparison strategy	Diseases	DM interventions	Study's Measures	Effects
	Ohio, USA	programme			disease self-management coaching, medication management, and physician care management.		participants in normal weight group, but not in underweight, overweight, and obese groups
Windt and Glaeske (2010)	Germany	Quasi-experimental study of participants of the nationwide DMP	Before and after launching a DMP	Asthma	Policy level: DMPs were introduced by the Act to Reform the Risk Structure Compensation Scheme in Statutory Health Insurance (SHI). Sickness funds received higher payments if they set up certified DMPs and motivated patients to enroll. Provider level: The Act provides recommendations on how to conduct a DMP and its preferred components.	% of hospitalisation, risk to hospitalisation, and a set of prescription drugs for asthma	Effects of DMP on patients' outcomes were weak, no statistical difference observed on hospitalization or high risk for future emergency care. However, the DMP group had more statistically significant numbers of patients with prescriptions of corticosteroid inhalers which these drugs are recommending in the asthma guideline.
Katz, Holmes et al. (2009)	Indiana, USA	Quasi-experimental study of Medicaid members	Matched comparison group (without interventions)	Diabetes, CHF	Policy level: Indiana Office of Medicaid Policy and Planning (OMPP) introduced the Indiana Chronic Disease Management Program to eligible Medicaid participants with diabetes and/or CHF. The OMPP is also responsible for hiring and training of personnel, and coordination of physicians and eligible Medicaid members. Provider level: nurse care management, clinical guidelines for physicians,	Costs of paid claims	Claim data showed slight improvements in cost control but results were statistically significant only in some sectors and regions.

Author	Setting	Study design	Comparison strategy	Diseases	DM interventions	Study's Measures	Effects
					collaborative groups for primary care practice. An individual patient's risk was assessed for predicting annual health care claims.		
Gapp, Schweikert et al. (2008)	Beneficiaries of Statutory Health Insurance, Germany	Cross-sectional study of insured patients with a history of AMI	Internal comparator: usual care	AMI	Policy level: Sickness funds are obligated to provide and evaluate DMP. They receive higher payment for a DMP enrollee. Provider level: patient education, programme review and assessment	Quality of services (medications and counseling)	The study was unable to conclude major health outcomes. Findings suggested no statistical differences in quality of life and body mass index, and only a minor reduction in smoking.
Zhang, Wan et al. (2008)	State managed Medicaid DMP, Virginia, USA	Controlled quasi experimental study of Medicaid beneficiaries	Matched comparison group (without interventions)	Diabetes, HT/CHF, GERD, PUD, asthma/ COPD, depression, and co-morbidity of these diseases	Policy level: Medicaid FFS, no detail specified Provider level: monitoring, assessments, and interventions for patient self-management by trained physicians and pharmacists.	HRQoL questionnaire, medical utilization, drug utilization, adverse drug events and cost of average amount paid per member per month	There were reductions in costs, utilisation, and adverse drug reaction among patients receiving interventions but results were inconsistent across all disease groups, especially in patients with co-morbidity
Vickrey, Mittman et al. (2006)	Southern California, USA	RCT of elderly Medicare patients	Control group: usual care	Dementia	Policy level: no detail specified Provider level: collaborative care planning with carers, carer's self-management support, ongoing follow-up, and provider education	Physicians' adherence to clinical guideline, obtaining community services/resources, and patients and carers' health and quality-of-care measures	Participants in DMP group had higher scores of most measurers than the usual care group except HRQoL of carers which were comparable between the two groups.

Author	Setting	Study design	Comparison strategy	Diseases	DM interventions	Study's Measures	Effects
Gilmer, Philis-Tsimikas et al. (2005)	San Diego County, CA, USA	Non experimental pre-post study of Medicaid beneficiaries	Matched comparison group (without interventions)	Diabetes	Policy level: County Medical Services contracted with Project Dulce to provide diabetes DMP for adults Provider level: trained nurse and other diabetes related health worker to use guideline protocols, patients' self-care management, and trained peer educators recruited from the patient population to provide the training programme	Diabetes related laboratory tests and project management costs	The intervention group was related to significant improvements in HbA1c, both systolic and diastolic blood pressure, total cholesterol, and LDL-C. Expenditures for medicine and DMP arrangements increased. There was probability of reductions in hospitalisation costs within the first year after implementation.
Martin, Berger et al. (2004)	HMO managed Medicare network in Pennsylvania, USA	RCT of Medicare beneficiaries	Control group: usual care	CHF, falls, Diabetes, depression, and nutrition	Policy level: no detail specified Provider level: patient education for self-care management, patient health assessment, physician education, medication review, and coordination with community service	SF-36, satisfaction, paid claim costs, utilization, and mortality	Except for satisfaction that favoured the intervention group, most results from intervention and control groups showed difference but not statistically significant. Health care costs rose considerably in both groups but not statistically significant difference.

AMI= acute myocardial infarction, BP=blood pressure, CHD=coronary heart disease, CHF= congestive heart failure, CKD=chronic kidney disease, COPD=chronic obstructive pulmonary disease, DMP=disease management programme, FFS=fee-for-service, GERD=Gastro-esophageal reflux disease, HF=heart failure, HMO=Health Maintenance Organization, HRQoL=health-related quality of life, HT=Hypertension, IHD=ischemic heart disease, PUD=peptic ulcer disease, RCT=Randomised controlled trial, SF-36=Short form health survey

3.6   Discussion and conclusions

Disease management has been widely adopted as a tool to control health care costs and increase quality of care, in particular in North America and Europe. However, the approach puts challenges to implement, and also ways to evaluate such types of programmes.

Because of the blurred definitions and boundaries of disease management, great variations in practice exist across disease management programmes. Of those six components referred to in the DMAA definition, a study (Weingarten, Henning et al. 2002) found that patient education was the most frequently used component among disease management programmes (78%). The other popular components were provider education (40%), and provider feedback (27%). This current review, however, argues that there are three basic components needed for setting up a disease management programme, namely; predefined population group, evidence based protocols and guidelines, and routine reporting. Although most disease management programmes use patient education as a means to promote self-care management, without the three basic components, a disease management programme cannot be differentiated from the regular health care delivery.

Considerable attempts have been put in action on design and development of disease management programmes. Nevertheless, some characteristics of the health system might impede DM programmes from their aims and so findings from one country might not be relevant to another. Examples from this review include strong segment separation in Germany, making the programmes hard to integrate (Busse 2004). Fee-for-service payment of traditional Medicaid and Medicare programmes make it difficult to control costs, since this method tends to lead to escalating health care costs (Gottret and Schieber 2006). Application of disease management programmes needs to be tailored to patients with various health care needs or diverse socioeconomic statuses.

An interesting issue emerged from the review of primary studies that used the RCT method (blind and randomised allocation of patients to control and intervention groups). These studies are questionable, given that it is difficult to

control the numbers and quality of interventions given to the patients. In particular, interventions such as giving patient education, counselling, and treatment, depend on individual medical and communication skills. The quality of these interventions, therefore, is likely to be diverse across providers. Interpreting results from such study designs in any disease management programme evaluations should be done with caution.

Disease management is an appealing approach to help patients and health care providers manage high-cost conditions. If a disease management programme achieves its goals by providing a better quality of care and reducing costs, it could be a powerful tool. To date, findings from disease management evaluations are still inconsistent, particularly in terms of net cost savings, which might stem from the difference in study settings. Additionally, disease management service delivery relies heavily on investment in programme set-up and administrative functions, especially in the initial phase. Therefore a new disease management programme might not be cost-saving during the initial phase (Burns and Pauly 2012).

One source of variation in the results from population-based disease management evaluations is differences in study designs. In practice, controlled trials have difficulties in randomly assigning subjects to the control and intervention groups and providing the same interventions to individuals, and this might lead to an ethical issue of giving interventions to just one group but not to another (Conklin and Nolte 2013). This is the reason why many population-based disease management evaluations are not randomised controlled trials and have moved towards more practical study designs such as various types of non-experimental study designs. These study designs have a number of limitations, in terms of controlling for possible biases and confounders. Combining with multifaceted interventions of the disease management approach, this could lead to mixed and inconclusive results in programme evaluations.

All reviewed studies used a comparison strategy to interpret results, whether disease management interventions are effective and produced positive results. Apart from controlled trials, a comparator group (internal, external, or general

population) and benchmarks (general population or target) were used in weaker, non-experimental and descriptive studies.

From this review, results from studies in low and middle income countries have been found to be lacking. This may be a consequence of limited numbers of population-based disease management programmes and their evaluations applied in these countries. Future research should: bring about experiences from more diverse health systems, in particular low and middle income countries, identify disease management approaches which are most suitable for each context, and assess whether disease management programmes provide desired outputs or outcomes. Selected evaluation methods should fit best to each system's available resources and produce minimum biases which could lead to an issue of the validity of results.

CHAPTER 4   Aims, objectives, and methodology

This chapter introduces the aims, objectives, and methodology used in this study. The aims are described first and lead to three objectives. Next this chapter will discuss the study framework and the tracer used to study the effects of the disease management programme. This is followed by detailed methods for each objective. Finally, the study's limitations are discussed.

4.1   Aims and objectives

The aim of this study is to explore the introduction and functioning of a high-cost health benefit programme of the universal coverage scheme (UCS) in Thailand. Using the UCS's renal replacement therapy (RRT) programme as a tracer, the study will then assess how a disease management approach has facilitated the inclusion of RRT in the benefit package, now and in the longer term, and with what results.

The aims introduce three objectives, which are to:

1) Describe the rationale behind the initiation of a high-cost health benefit programme and the application of the disease management approach in the RRT programme;

2) Explore how the RRT disease management programme could have contributed to the changing patterns of i) entry of patients into the RRT programme and ii) mortality of adult UCS members who were diagnosed with end-stage renal disease;

3) Undertake long term projections of the number of patients and budget needs for the RRT programme to assess financial implications into the future.

The findings of this study are intended to build evidence to support a policy of including coverage for high-cost health benefits such as RRT in the context of a developing country.

4.2   Study framework

The study framework has been developed from the literature reviews on high-cost conditions, disease management, access to health services, and financial needs of the programme. This study explores two elements of the RRT programme: 1) disease management programmes as a result of the response to a high-cost condition and 2) the effects of disease management, in terms of access to services, mortality, and future implications. The framework of this study is shown in Figure 4-1. Study objectives are marked with corresponding numbers in the circle.

Figure 4-1 Framework of the study
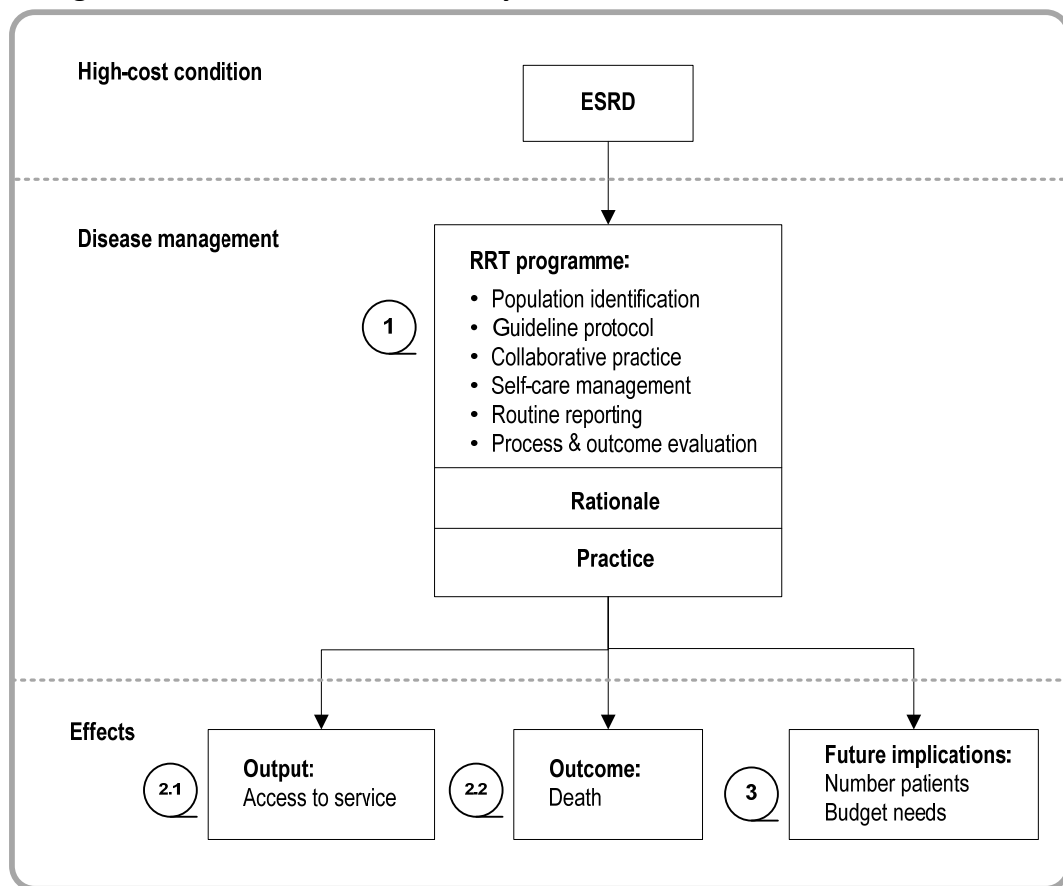
ESRD=end-stage renal disease

The disease management programme in this study is viewed as an intervention to facilitate access to a high-cost treatment. Objective 1 describes the development, rationale, design, and application of the RRT Thai disease management programme at both the national and regional levels. Also, it

defines the contextual environment and linkages within the programme and between other components in the health system.

Objective 2 explores outputs and outcomes of the RRT programme, which are i) patterns of access to services, in terms of new registrations for the programme, and ii) mortality of patients with an ESRD diagnosis both for overall patients and patients who were maintained on RRT in the programme and then identifies their changing patterns overtime.

Finally, Objective 3 carries out long term projections to support policy, planning, and decision-making regarding the burden on the health care budget. It quantifies the long term needs of the RRT programme in terms of number of future patients, estimates budget needs of the programme from the perspective of a health care payer, and draws conclusions on the financial implications for the next ten-year period.

4.3   Justification of tracer to study effects of disease management programme

Renal replacement therapy has been chosen as a tracer for assessing the disease management approach when including a high-cost treatment in the benefit package for three reasons;

1) High-cost condition

With only a small number of patients, end-stage renal disease accounts for a significant percentage of health care expenditure. Costs of renal replacement therapy, whether transplant or dialysis and essential medications, can drive a patient or a household without insurance coverage into impoverishment (Wyszewianski 1986).

2) Policy making process

Before the commencement of the RRT benefit, there were actions from several entities, both inside and outside government, to embrace the benefit in the UCS health care basket. They involved individual leadership and strong

relationships among the scholars, civil society, and politicians. These actions provided important practical evidence of the benefits of including a high-cost treatment in the benefit package in the context of a developing country.

3) Disease management approach of the UCS

The disease management approach was applied to the implementation and service provision of the RRT programme. In the UCS, RRT is one of the few disease management programmes that has all the basic elements of chronic disease management. They include for instance, design of the service delivery system, self-management support, use of a guideline protocol, and community support. Other so-called UCS disease management programmes have only a few components and are more likely to focus on central bargaining for purchases of medicines or medical devices, not the arrangements of service delivery.

4.4   Methodology

This study's methodology combines multiple approaches to answer the research questions. The methodology section is divided into three subsections according to each objective. Objective 1 incorporates a set of qualitative methods, which are document review, semi-structured interview, focus group discussion, and structured observation. These are then triangulated to draw conclusions. The method for objective 2 is an age-period-cohort analysis based on UCS databases. The method for objective 3 is a time-series projection of RRT patients and cost modeling of the RRT programme expenditure. Findings from all three methods are brought together and used to formulate policy implications and recommendations for future research.

In the data analysis, a range of computer software was employed. For quantitative analysis, this included MS Excel, Stata, and R-studio. For qualitative analysis, MS Word and Nvivo were used.

4.4.1 Objective 1: The rationale behind and the application of the disease management approach in the RRT programme

Method of objective 1: qualitative approaches of document review, semi-structured interview, focus group discussion, and structured observation

Objective 1 describes the RRT disease management system. Collected data were analysed thematically by using multiple data sources including reviews, interviews, a focus group discussion, and observations. Relevant findings were further used to explain RRT programme outputs and outcomes in greater detail, in addition to the quantitative analysis of objective 2. Also, interviews with policy makers provided possible future scenarios for budget predictions in objective 3.

4.4.1.1 Document review

The document review was conducted to understand the background and operation of the RRT programme and how the programme was organised within the NHSO. Document reviews also provided an inside picture of the RRT programme that might not be directly observable. In addition, it helped formulate questions for interviewing and developing an observation guide, as well as for developing data collection tools for the next study objectives.

The review of documents was a secondary data collection procedure. Many types of documents such as annual reports, clinical guidelines, newspaper clippings, newsletters, and the constitution were available online. Key words related to the policy change of the RRT programme were used as search terms, these included: "dialysis benefit", "kidney disease benefit", "chronic kidney disease patients", "renal replacement therapy", "universal coverage scheme", and names of people or entities involving in the policy change of the RRT. Some documents were later given by interviewees, which included meeting minutes and research studies and reports.

Retrieved documents were selected according to the study's framework and then read by the main investigator to input data for the analysis. Document review also helped generate new interview questions, and the development of

the observation checklist for assessing the quality of patient's self-care technique.

4.4.1.2   Semi-structured interview and focus group discussion

In order to understand the arrangements of the RRT programme in the central NHSO and implementation of the RRT programme itself, perceptions and practices of interviewees at various levels were assessed from semi-structured interviews and focus group discussion.

i.   Study sites

There were three sites of data collection: central NHSO, Bangkok; Phitsanulok province; and Kampangpet province, Figure 4-2. The central NHSO was where the RRT programme was formulated and administered. This site also included NHSO's supporting functions such as professional body of the nephrologists and patient representatives who act in NHSO's sub-committee boards or designing the monitoring process of the RRT programme.

In Phitsanulok province, the regional NHSO and a large-sized university hospital were selected to represent provisions of the RRT programme at the regional level. The selection criteria for the hospital were 1) had enough capacity to provide all three modes of renal replacement therapy, 2) the catchment area had a mixture of urban and rural characteristics, and 3) willingness of providers to participate.

A community hospital in Kampangpet province was selected to represent the context of conservative therapy (living without dialysis or kidney transplant) in chronic kidney disease. The hospital was selected to be one of the study sites because a number of informants noted that it offered patients with chronic kidney disease palliative care via a multidisciplinary team. The hospital is at district level, located approximately 115 kilometres southwest from the University Hospital in Phitsanulok. Although the hospital itself has no capacity to provide dialysis services, there are more than 150 ESRD patients living in its area who are undergoing conservative therapy. This study site provided wider insights into patients' decision making since patients who go to large size

hospitals tend to have already made the decision to undergo RRT. This community hospital was selected to probe views of patients who declined dialysis therapy.

Figure 4-2 Study sites: Bangkok, Phitsanulok, and Kampangpet
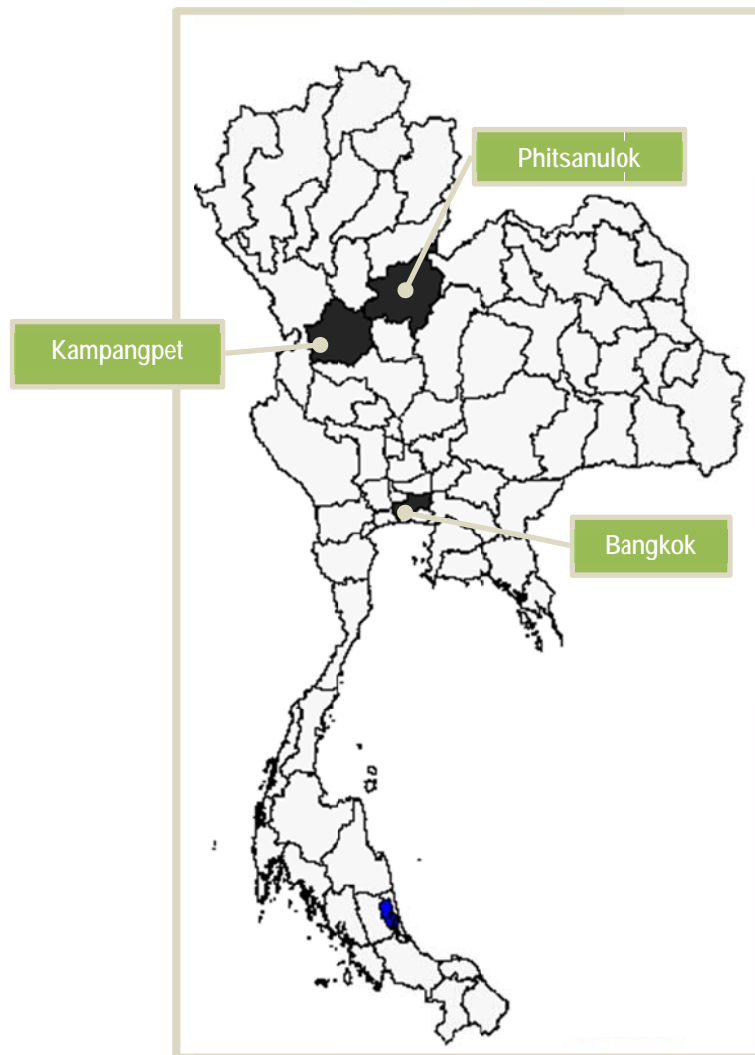
Bangkok is the capital city of Thailand. Phitsanulok and Kampangpet are provinces in the lower North of the country. Growing agricultural products, particularly rice and some other crops such as tapioca, sugar cane, and corn, is the main source of income for people in the two provinces. In comparison to Kampangpet, Phitsanulok has more characteristics of an urban area as it has smaller average household size, higher average income, and higher numbers of RRT facilities, Table 4-1.

Table 4-1 Selected characteristics of Phitsanulok and Kampangpet

Province	Population[1]	Average household size[2]	Monthly income (THB)*[3]	No. RRT unit[4]	
				HD	PD
Phitsanulok	858,988	3.0	27,490	7	2
Kampangpet	729,522	3.3	22,083	2	1
The whole kingdom	65,124,716	3.2	25,194	533	102

*Average monthly income per household in Thai Baht, based on the Household Socio - Economic Survey
Source: [1]National Statistic Office (2014) available from
     :http://service.nso.go.th/nso/nso_center/project/search_center/23project-th.htm
[2]National Statistic Office (2010) available from: http://popcensus.nso.go.th/upload/popcensus-08-08-55-E.pdf
[3]National Statistical Office (2010) available from:http://service.nso.go.th/nso/web/statseries/statseries11.html
[4]Thai RRT report (2012) available from: http://www.nephrothai.org/trt/trt.asp?type=TRT&news_id=418

ii.   Selection of interviewees

In order to collect a wide range of information, it was necessary to select a mix of interviewees from different roles in the RRT system. They included individuals who played key roles in developing RRT policy, working to support the RRT system, and ESRD patients. Policy makers and frontline staff were identified by their positions, while patients were chosen by the snowballing technique. Patients were divided into four types according to their treatment (the three RRT modalities and one non-RRT user who had ESRD and was eligible for the treatment but refused to have it), Figure 4-3.

Figure 4-3 Interviewees in different roles with methods of data collection
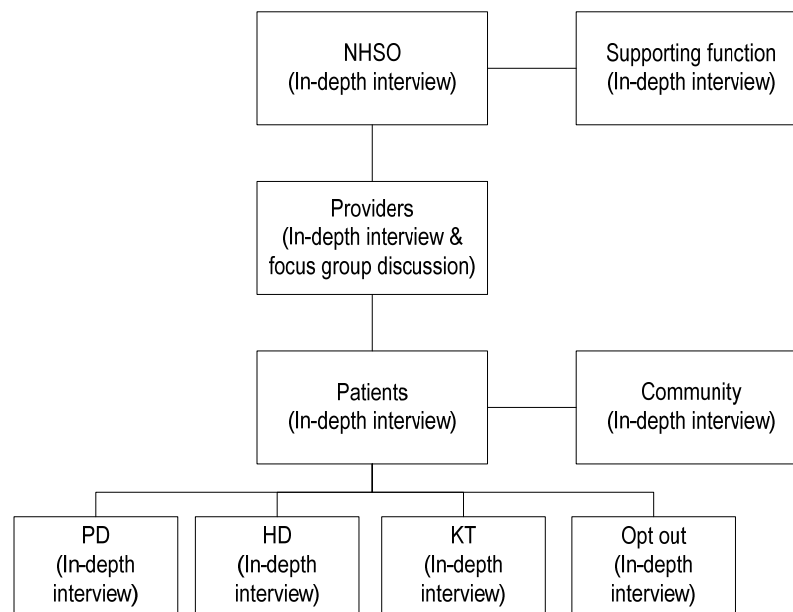
```
           ┌─────────────────┐         ┌──────────────────────┐
           │      NHSO       │─────────│  Supporting function │
           │(In-depth interview)│      │  (In-depth interview)│
           └─────────────────┘         └──────────────────────┘
                    │
           ┌─────────────────────┐
           │     Providers       │
           │ (In-depth interview &│
           │ focus group discussion)│
           └─────────────────────┘
                    │
           ┌─────────────────┐         ┌──────────────────────┐
           │    Patients     │─────────│      Community       │
           │(In-depth interview)│      │  (In-depth interview)│
           └─────────────────┘         └──────────────────────┘
         ┌──────┬──────┬──────┬──────┐
   ┌──────────┐┌──────────┐┌──────────┐┌──────────┐
   │    PD    ││    HD    ││    KT    ││  Opt out │
   │(In-depth ││(In-depth ││(In-depth ││(In-depth │
   │interview)││interview)││interview)││interview)│
   └──────────┘└──────────┘└──────────┘└──────────┘
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NHSO=National Health Security Office, PD=peritoneal dialysis, HD=hemodialysis, KT=kidney transplant

iii. Tools

A checklist of questions was used to collect information from interviews and the focus group, see Appendix 2. This included questions to elicit opinions on high-cost diseases and various areas of the RRT programme. These questions were developed from the literature review on high-cost conditions and caring for patients with chronic conditions, for example, the commentary article of Wyszewianski (1986) and the book edited by Nolte and McKee (2008). A summary of questions that were asked to each group of interviewees is shown in Table 4-2. Questions might be slightly adjusted in order to suit the context of different respondents. All conversations were recorded and were later transcribed in Thai for data analysis.

Table 4-2 Summary of areas of questions and groups of informants to be asked

Area of question	Issues of interest	NHSO	Professional body	Academician	Medical staff	Patient
1. Perception of high-cost diseases	What kind of diseases/conditions that can cause a burden on patients when paying for health care costs? Have you ever experienced this issue and what was your response?	✓	✓	✓	✓	✓
2. Purpose of the RRT programme	Why ESRD is selected to be managed separately?	✓	✓	✓	✓	
	How to select a disease/condition to be managed?	✓				
3. Design of the RRT programme	Why disease management and the PD-first are used?	✓	✓			
4. Process of the RRT programme	What is the patients' journey?	✓	✓		✓	✓
	How about	✓	✓		✓	✓
	• patient selection • patient self-care education • reporting system • practice guideline/protocol?					
5. (For patients only) decision making	Who made decision about getting in the programme? If chose not to get in, why?					✓
6. (For patients only) care costs and quality of life	Do you have to pay anything to receive dialysis?					✓
	How is quality of your life at the moment?					✓
7. Links between RRT programme and other components	What are linkages between levels of care and within the health system?	✓	✓	✓	✓	✓
	How do they work together?					
8. Programme implications	After the programme started, what has been changed in your perception/experience?	✓	✓	✓	✓	✓
	What are concerns of the programme in the future?	✓	✓	✓	✓	
	What is the perceived success of the programme?	✓	✓		✓	
	What are programme's barriers to success/access?	✓	✓		✓	

ESRD=end-stage renal disease, RRT=renal replacement therapy, PD=peritoneal dialysis

Where interviewees were patients, it was important to know whether they presented characteristics that correlate to the need for the high-cost treatment and whether health care costs pose a burden on them. In order to establish this, a range of questions relating to individual characteristics and other factors influencing health service use (as described by Aday and Andersen (1974) were asked. They included 1) demographic character: age and chronic illness, 2) social structure: education, occupation, income, and household size, 3) other factors: health belief and coverage of health insurance.

iv. Data collection

After the interviewees' permission was granted, the investigator made an appointment either by a phone call or a letter, or both if required by the interviewee. Interviews were conducted at interviewee's workplaces. If they were a patient, dialysis nurses helped investigators arrange appointments by phone calls or asking directly while patients were on dialysis care in the hospital. As each HD patient has to spend at least four hours on a hemodialysis unit, all HD patients asked the investigator to carry out the interview during this time. Since PD patients are on home-based dialysis, interviewing at their houses suited them better. Once a PD patient agreed, the investigator went to the patient's house for an interview along with an observation. For PD patients who lived far away or had never met the investigator in the RRT unit, interviews were accompanied by a PD nurse or an NHSO officer. Patients who had opted out were invited to be interviewed at the community hospital. Each interview lasted 30-45 minutes.

A focus group discussion was conducted with the multidisciplinary team in Klongklung hospital. The multidisciplinary team consisted of six healthcare professionals including a general practitioner, nurses, a pharmacist, a nutritionist, and a physiotherapist. The aim of the focus group discussion was to identify the link between patients and their healthcare providers.

The data collection team consisted of two main persons: the main investigator and a research assistant. The research assistant was a registered nurse with a doctoral degree in health policy. Her main roles in this study were arranging

appointments with informants and accompanying interviews. Before interviewing, the team was briefed on each interviewee's background and questions to be asked. After the interview was finished, the team shared their opinions about the interview's tone and key messages given by the interviewee.

There was no compensation for interviewees. Dialysis nurses and NHSO officers who helped with communications and arrangements for interviews with other interviewees were given compensations which were enough to cover communication costs (such as travel cost and phone calls) and their time spent. These amounts were in accordance with local practice.

4.4.1.3   Structured observational study

Being able to independently prepare and conduct PD with or without assistance from carers is an indicator of the success of the PD-first policy. Under the policy, NHSO hopes to see patients having good health outcomes and quality of life (NHSO 2013). A number of studies have demonstrated that a positive patient background was a major determinant of overall quality of life for dialysis patients. These factors may include for example gender, comorbidity, social deprivation, time on RRT, and lifestyle provided by the RRT modality (Hart and Evans 1987; Cameron, Whiteside et al. 2000). An observation study was conducted to investigate patients' characteristics and ability to perform self-care PD (so-called home dialysis). It allowed the researcher to develop a deeper understanding of how patients managed self-care and how it might affect a patient's everyday life.

i.   Patient

Patients were selected from the catchment area of the University Hospital. Criteria used to selected samples were: 1) having been registered with the NHSO's PD programme for at least 3 months[7], 2) aged between 20 and 89 years, and 3) willingness to participate in the study. The PD nurse was asked to identify 10 UCS patients who matched these criteria.

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[7]Within a three-month period, a new patient is expected to be keen enough to independently perform PD.

ii. Tool

Based on the guideline for peritoneal dialysis (Busapavanich 2009), a checklist containing key points to observe, main behaviours, and environmental domains relating to the procedure of PD were used. The full checklist is provided in Appendix 3. In summary, the things to observe were:

- Features of house, area to perform dialysis, and storage of dialysis solution.
- Practices of changing bag and aseptic technique.

iii. Data collection

Approaching a patient

After collating the list of potential participants, the PD nurse who acted as the patients' case manager made a phone call to each patient asking for the patient's agreement to be observed and interviewed. PD patients were then interviewed and at the same time, their PD practices were observed at their houses. There were some patients scheduled for a follow-up in the week of data collection. In this case, patients were interviewed in the RRT unit and asked if the observation team could go to observe their PD practices at their houses in the following day.

The main investigator's duties were interviewing the patient and taking field notes while the research assistant did the observation checklist and noted her personal impressions. After each observation and interviewing, the team discussed what each member thought.

Implementing data collection

In general, a PD patient has dialysis 7 days a week, 4 times a day (at 6AM, noon, 4PM, and 10PM approximately). One bag exchange procedure lasts 30-40 minutes. For these reasons, the team could observe up to 2-3 patients a day at noon and at 4PM appointments. The data collection period was 13-19 August 2014. Patients were asked consent to being observed, tape recorded, photographed, and to having the information used in the research. All agreed.

4.4.1.4   Data analysis

Thematic analysis was conducted to understand the system of RRT. Interviews and the focus group discussion were transcribed verbatim into a Microsoft Word document, in Thai, by an independent transcriber. Collected information including tape records, photos, and interview transcripts were later brought to Nvivo software (version10) for data management and analysis purposes. The documentary data were analysed together with data from interviews, the focus group discussion, and observations, so that themes would emerge across all sets of data.

Coding process

A primary set of codes was developed from the study framework. The set was then used to analyse data collected from the fieldwork. Initial coding or pre-set coding was defined before the interviews began and was accompanied by subcategory codes.

A subcategory code is a set of codes embedded in a main category. After going through the very first interviews (and observations), initial codes were reviewed and revised in order to allow a new set of codes to emerge from the real fieldwork. Codes were revised and compared to each other and to collected information in order to generate a coding framework for data analysis, Appendix 4.

4.4.1.5   Potential bias from investigators and the data collection process

There was scope for investigators and the data collection process to produce biased results, particularly in interviews and observations. Before each of these latter, investigators informed each participant about the study's aim (to describe the RRT programme's arrangements and further to assess the programme's outputs and outcomes). For this reason, policy makers who designed the RRT programme might want to present positive results to investigators and conceal the downside of the programme. Providers tended to report what they should do but less on what was actually done. Patient

informants might not report all negative feelings about providers, and because of Thai cultural norms they were unlikely to reveal their true feelings, especially about suffering. Archival documents might have some limitations in terms of the accuracy and completeness of the data. Further access to more documents could be unlikely. In observations, patients who were observed might change their self-care practices as a result of being studied.

4.4.1.6 Validity and reliability

The analysis process employed three methods to reduce bias and improve the validity of the qualitative research. These included 1) triangulation which compared results from document reviews, interviews, and observations; 2) respondent validation which involved telephoning or asking interviewees to give feedback on some part of the findings; and 3) attention to negative cases which seemed to contrast with the general pattern. This study sought to reexamine and explain these cases until there was no new theme emerged.

There was a pretesting for questions and points to be observed prior to the real interviews and observations. After the pre-test, investigators had a discussion to see if any adjustments were necessary.

4.4.1.7 Research ethics

i. Ethical approval

Ethical applications were submitted to the London School of Hygiene and Tropical Medicine (LSHTM) ethical committee, and to two ethical committees in Thailand, namely the Institute for the Development of Human Research Protections (IHRP) and the Khon Kaen University Ethics committee for Human Research, see Appendix 5.

ii. Consent

Permission request letters with information sheets and consent forms were sent to the NHSO and hospital administrators two weeks before interviews started. Before each interview started, the interviewee was asked to read and

sign the information sheet and consent form in order to give permission for the interview and photography. This action conformed to the guidelines of the British Medical Journal (1998, 316, 10091011). All forms were translated into Thai by the investigator. Participants were informed that they could withdraw from the study at any time without giving a reason.

Some patient participants felt uncomfortable about signing the forms. This might be because patients were worried about what would happen after signing. Instead, the investigator read the consent and asked whether the patient allowed the team to interview, voice record (and/or take pictures), and to quote their words in the report anonymously. All patients said that was fine. These conversations were recorded as a verbal agreement from patients.

iii. Confidentiality and anonymity

Confidentiality and anonymity were central to this study's practices. Participants were interviewed or observed in a private room or private location to ensure their privacy. Each participant was identified using a code which refers to their role. PM refers to a policy maker, PV refers to a provider, PD and HD refer to peritoneal dialysis and hemodialysis patients respectively, KT and OO stand for kidney transplant and opted-out respectively. Note that some participants have more than one role. For example, a health care provider also acted as a policy maker and a patient had another role as policy maker. All participants had the right to access information that related to them, and to be provided with a copy of the information on request.

Investigators made every effort to protect participants' confidentiality and anonymity. All forms of information given in this study, such as quotes and pictures, are anonymised or otherwise presented so that participants cannot be traced back. Access to such information will be restricted to the primary investigator and will be destroyed five years after the end of the study.

4.4.2 Objective 2: The changing patterns of access to service and mortality of ESRD patients overtime

Method of objective 2: Age-period-cohort analysis based on administrative data of the National Health Security Office

This method focuses on the longitudinal assessment of the renal replacement therapy programme (RRT) in terms of access to the programme and mortality. Access to the RRT programme was represented by registration for the programme. Mortality is one of the indicators used to measure population health outcomes. In this study, mortality referred to all-cause mortality, assessed in both groups of patients who were maintaining RRT and overall end-stage renal disease (ESRD) patients.

4.4.2.1 Justification of using the age-period-cohort analysis

Regarding changing patterns of birth, morbidity, and mortality, it is important to account for three factors: age, period, and cohort. Age effects are defined as variations associated with biological and social processes of aging. They represent development of changes across individuals' life times. Period effects are defined as variations over time periods that affect everyone equally, regardless of age or birth cohort. These variations can be an immediate change of any event such as economic crisis, endemic, and health care treatment or intervention. Cohort effects can be characterised by changes that individuals experienced in early life. Members of the same cohort group age together and share similar historical and social events at the same ages (Yang and Land 2008). For these reasons, cohort effects are sometimes referred as longitudinal effects and period effects are known as cross-sectional effects (Clayton and Schifflers 1987).

Conventional models are solely based on assessment of age, yet ignoring effects of cohort and period could result in misinterpretation of results. This is because such effects can be a mixed consequence of various time-related factors. To give an example, older age groups and older generations experience higher mortality, and consequently, dominate the overall death rate and mask real

events occurring in recent age groups and cohorts. Age period cohort analysis is one approach that allows us to separate the effects of age, period, and cohort through a statistical model and to understand why disease trends change over time by taking account of such three variables (Glenn 2005).

4.4.2.2   Data source

This method used four databases. Three databases were obtained from the NHSO and were collected from health care facilities all over the country. They were: inpatient, outpatient, and renal replacement therapy (hemodialysis and peritoneal dialysis). The NHSO has audit procedures to ensure quality as well as prevent duplicates of the claims data at both central and regional NHSO. The last database used in this study was mortality data which was obtained from the Ministry of Interior's civil registration system. All four databases keep information at the individual level and can be linked together by using the 13-digit citizen identification number. These numbers will be encoded before handing to any third party.

i.   Inpatient database

The inpatient database provides individuals' profiles (such as name, date of birth, address, occupation, and so on) and individuals' health information while they are hospitalised (such as diagnoses, care given, medications, laboratory tests, hospital code, and admission/discharge date). The inpatient database consisting of 18 sub-files was well designed; its structure has rarely been changed since the beginning of the UCS. A patient's diagnosis is the compulsory field since the NHSO has to calculate the relative weight for the diagnosis related group (DRG) payment.

ii.   Outpatient database

The outpatient database contains patient-level information including: individuals' profile and their ambulatory visits, such as outpatient, accident/emergency, prevention/promotion programmes, referral, and medications. Because of this diversity, the structure and details of the database

have been adjusted several times and became quite stable from 2012. Currently the outpatient database consists of 21 sub-files. It is noted here that outpatient data used in this study was from the period 2008 to 2013, while data from the inpatient database was taken from 2005 to 2013.

iii. RRT database

Renal replacement therapy databases can be divided into three categories according to the three modalities of RRT available under the NHSO's disease management. These are 1) peritoneal dialysis, 2) hemodialysis, and 3) renal transplant. These three databases are separately kept and administered. All RRT units are obliged to use these databases in activities regarding RRT service provision, such as patient registration, records of given services, medications, and laboratory tests.

iv. Mortality database

The mortality database was obtained from the Ministry of Interior's civil vital registry. Data from the civil vital registry have been computerised since 1980 and use ICD-10 as diagnosis code to identify causes of death. One drawback of the mortality database is the reliability of the reported causes of death. The majority of deaths (about 65%) in Thailand occur outside hospitals and in the absence of medical examiners. In most cases, causes of these deaths are recorded by nonmedical civil registrars based on lay reports from relatives, occasionally informed by medical opinion obtained during the illness leading to death (Tangcharoensathien, Faramnuayphol et al. 2006). Even in the case of deaths which occurred in hospitals, a study in Thailand reviewed cause-of-death certificates and compared to the patients' medical record found that 51% of deaths contained certification errors (Pattaraarchachai, Rao et al. 2010). Additionally, ESRD patients usually suffer from multiple illnesses, therefore ESRD may not be reported as their cause of death. For these reasons, this current study avoided bias by using all-cause of death instead of cause-specific death.

4.4.2.3   Cohort selection

Cohorts in this study were limited to adult UCS members aged 20 to 89 who were diagnosed with ESRD. ESRD patients were selected from patients who had ICD-10 code N180 or N185[8] in either primary diagnosis or secondary diagnosis in NHSO databases. The patient's first hospitalisation or first visit with end-stage renal disease diagnosis (ICD-10=N180 or N185) in the obtained databases were used to define the point at which a patient started having end-stage renal disease.

There are few ESRD patients younger than 20 or older than 90 years, patients outside these age groups give unstable rates and may affect the reliability of analyses, therefore they are not included in the analyses of this study.

To assess registration rates of the RRT programme, the study period was 1 January 2008 to 31 December 2013. The follow up period for assessing death rates was from 1 January 2005 to 31 December 2013, except the death rate among RRT patients, data were collected from 1 January 2008 to 31 December 2013. Censoring for deaths was at the end of the data collection period (31 December 2013).

4.4.2.4   Variables

Three main variables in this study (age, period, and cohort) were modelled in terms of the year unit. Age of the entry into the RRT programme model was determined by the time between the year of birth and the year of registration in the programme, and age in the mortality model referred to the time between the year of birth and the year of death. The period in all models denoted calendar years of studied period and cohort was the individuals' years of birth. In entry into the RRT programme models, the three modalities of RRT were separately used as covariates.

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[8] The ICD10 code for ESRD stage 5 was changed to N185 in April 2012.

4.4.2.5 Data analysis

Data were analysed in two ways; descriptive analysis and age-period-cohort analysis. Each analysis is presented in two sections according to the two models: entry into the RRT programme model and mortality model. Within the entry into the RRT programme model, the three modalities of renal replacement therapy are separately presented.

i. Descriptive analysis

According to Carstensen (2005), before conducting the age-period-cohort analysis, it is important to look at rates of observed events and explore whether rates are proportional between periods or cohorts.

In the descriptive analysis, age groups were first tabulated against the calendar year (or referred to as period) and the year of birth (or referred to as cohort) to display numbers of events (either numbers of registration of each modality or deaths). Next, numbers of events (registrations or deaths) were computed as rates and then graphically presented as rates for age at registration (or age at death), for calendar year, and for birth cohort.

Descriptive analyses of this study provide four classical plots:

a) Rate versus age and period: observations within each period are connected,

b) Rate versus age and period: observations within each birth cohort group are connected,

c) Rate versus period and age: observations within each age group are connected, and

d) Rate versus cohort and age: observations within each age group are connected.

The first (a) and the third (c) plots will exhibit fairly parallel lines if age-specific rates are proportional between periods in the graphs. The second (b) and the fourth (d) plots will also show fairly parallel lines if rates are proportional to

cohorts. These plots can be used as the first overview of the data but may not reflect the result of the entire analysis (Carstensen 2005).

In mortality models, age-standardised mortality rates (ASMR) for UCS patients aged 20-89 years who were on RRT and those of overall patients who had ESRD diagnosis are presented. All ASMRs were calculated using the World Health Organization's world population in the year 2000 as the standard.

ii. Age-period-cohort analysis

The general form of the age-period-cohort model for rates $\lambda(a, p)$ is:

$$\ln [\lambda(a, p)] \;=\; f(a) + g(p) + h(c)$$

where f, g and h are functions, and a, p and c are age, period and cohort respectively. This model can be used to predict the incidence or mortality rate for any combined effect of age, period, and cohort. However, due to the direct relationship between the terms where date of registration (or death) is the sum of the date of birth and the age at death (or death), p=c+a, there will be a constraint in any model that includes these three variables on a linear scale. Consequently, the components of this model cannot be directly determined by conventional linear regression (Clayton and Schifflers 1987; Carstensen 2007; Yang and Land 2008).

Age, period and cohort effects need to be modeled in order to separate their effects. Various approaches have been introduced to cope with the so-called identifiability problem (Clayton and Schifflers 1987; Carstensen 2007; Yang and Land 2008). Clayton and Schifflers (1987) described an approach to model mortality rates in terms of age, period, and cohort over time. Their proposed models were to overcome problems of the constraint in any model which included age, period, and cohort variables on a linear scale. This is in line with Heuer (1997), Holford (1983), and Carstensen (2007)'s parametisation technique.

This study used restricted cubic (natural) splines to model effects of age, period, and cohort within a Generalised Linear Model framework with a Poisson family

error structure, a log link function and an offset of log (person risk-time) which was suggested by Carstensen (2007). This was done by adding a drift term (a combined slope for period and cohort effects) with a selected number of parameters (or knots) to either period or cohort effect. Placement of the drift on period or cohort depended on the subject of interest.

In this study, the main focus was on the effect of period, therefore the drift was allocated to the period variable. In the analysis, a point of period was fixed, and cohort fitted values were constrained to have zero slope. Age effect was then interpreted as age specific rate regarding the reference period.

As a result, the age-period model was written as the first derivative functions of age, *f(a)* and period, *g(p)*as:

$$\ln[\lambda(a,p)] \quad = \quad f(a) + g(p)$$

When a non-linear regression model is estimated, the multiplicative age-period model can be fitted by choosing a reference period p_0 and a constraint $g(p_0)=0$. The model can be expressed as the function of rate as:

$$\ln[\lambda(a,p)] \quad = \quad fp_0(a) + \delta(p-p_0) + g(p);$$

where $f_{p0}(a)$ is the function for age, denoting age-specific rates in the reference period, p_0; δ is the slope of the log-linear trend in period (the drift); and $g(p)$ is the period function, which can be interpreted as a log relative risk of any period compared to the reference period, p_0.

All tabulations of cohorts and population, descriptive analysis, and age-period-cohort modelling were conducted using Stata version 12. Only goodness-of-fit in age-period-cohort analyses was assessed using R studio. All confidence intervals are 95% confidence intervals.

4.4.3 Objective 3 Long term projections of RRT population and payments of the RRT programme

Method of objective 3: cost modelling and time-series projection of RRT population

The method of this study involved three main steps. First, the study modelled yearly numbers of patients in the three RRT modalities into the future. Next, it estimated the annual costs of the RRT programme from the public payer's perspective using the NHSO claims data. Finally, an estimated figure of the future budget needs was forecast.

4.4.3.1 Forecasting numbers of RRT population

This section looks at the method to forecast future numbers of RRT patients. The auto-regressive integrated moving average (ARIMA) technique was taken to develop a set of models to predict numbers of patients enrolling in the RRT programme by each modality: PD, HD, and KT.

i. Data source

Information on patients who registered in the RRT programme (including peritoneal dialysis, hemodialysis, and functioning kidney transplant) in the period of fiscal year 2008 to 2013 (1 October 2007-30 September 2013) were obtained from the Disease Management System of the NHSO. The data contained claims data of individuals, for example encrypted identification number, modality (PD, HD, or KT), registration date, exit from the programme date with the reason, and dispensed medications.

ii. Study population

Patients of all ages who were registered and retained in the RRT programme between the fiscal years 2008 and 2013 were included. This study also identified anyone who had modality changes including kidney transplant during the study period. It excluded patients who had a history of temporary treatment with hemodialysis in a period shorter than 30 days and self-pay HD patients. KT patients who had transplantation before the RRT programme started in 2008, although they received free erythropoietin from the NHSO, were excluded. Since the RRT programme is designed to cover patients with chronic kidney disease, those who are diagnosed with acute renal failure are not included in the database.

iii. Data analysis

This study employed ARIMA modelling to forecast numbers of the RRT population by RRT modality consisting of 1) peritoneal dialysis, 2) hemodialysis, and 3) kidney transplant. In order to construct time series datasets, patient-level data were collapsed into a monthly basis for each RRT modality.

Time-series is a technique that can be used to predict future behaviour of a variable of interest by taking previous observations as the basis. The analysis of a time-series model does not count on various independent variables that may influence the variable of interest (Linden, Adams et al. 2003). In this study, forecasting models are used to predict numbers of renal replacement therapy users in the next ten-year period.

In healthcare, the time-series modelling technique has been widely used in many areas such as medicine, epidemiology, and health services. Generally, time-series analysis is used to discover the historical pattern in data series and forecast that pattern into the future (Makridakis, Wheelwright et al. 1998; Linden, Adams et al. 2003). There are many categories of time-series technique, of which the auto-regressive integrated moving average (ARIMA, so called Box-Jenkins) is shown to be useful when the series exhibit any trend or seasonal variation (Makridakis, Wheelwright et al. 1998; You, Hoy et al. 2002; Linden, Adams et al. 2003).

A stationary series is the key feature that needs to be accomplished before fitting an ARIMA model. This can be done by taking first differences, that is, making a new series of the present value less the past value (X_t - X_{t-1}). After a time series has been stationarised by differencing, the next step is to determine whether AR (autoregressive) or MA (moving average) terms are needed to correct any autocorrelation that remains in the differenced series (Nau 2014). Numbers of AR and MA terms can be identified by looking at the autocorrelation function (ACF) and partial autocorrelation (PACF) plots of the original and differenced series. An ARIMA model is always represented by ARIMA(p,d,q), where p is the number of autoregressive(AR) parameter, d is the

order of differencing (or integration, I) needed to remove the non-stationary from the series, and q is the number of moving average(MA) parameter (Linden, Adams et al. 2003).

Makridakis, Wheelwright et al. (1998) suggested an approach which was applied to Box-Jenkins' time series modelling. They propose three phases of ARIMA modelling; Phase 1: Identification, Phase 2: Estimation and testing, and Phase 3: Forecasting. First, the identification, the data are plotted against time and determined if a transformation of the data is needed to stabilise the variance. If the data seem non-stationary, the first differences of the data are taken until the data are stationary. Next, the estimation and testing, when the stationarity has been achieved, examine the autocorrelation function (ACF) and partial autocorrelation (PACF) plots to determine numbers of appropriate AR(p) or MA(q) terms for the appropriate model. After that, the chosen model(s) is fitted, and the Akaike Information Criterion (AIC) is used to determine a better model. Then the residuals from the chosen model are checked by plotting the ACF of the residuals, and a portmanteau test of residuals conducted. If they do not look like white noise (residuals are uncorrelated or independently distributed), a modified model is tried until the white noise is achieved. Finally, the selected model can be used to calculate forecasts.

4.4.3.2 Estimating annual costs of the RRT programme

The cost of the RRT programme was conducted from the NHSO's perspective. Cost objects are PD, HD, and KT for the one-year period. Only direct costs accounting for RRT services were included. Indirect costs such as travel costs and other costs impacting on patients' families were excluded. The RRT programme's claims and reimbursements in 2014 were acquired from the NHSO. Data were summarised into payments by each reimbursed item on a monthly basis by the NHSO. Material costs, labour costs, and investment costs, although were not separately identified in the NHSO's payments, were estimated here using proportions from selected past studies in order to provide

each element of the cost from the public payer's perspective. Costs were measured and reported in Thai Baht (50 Baht $\cong$ £1, year 2014 price).

Table 4-3 shows proportions of the material cost, labour cost, and capitation cost used in estimating their amounts in the total payment of each RRT modality.

Table 4-3 Proportions (%) of three types of costs by RRT modality

	PD[1/]	HD[2/]	KT[3/]
Material costs	74	43	79
Labour costs	25	40	18
Capital costs	1	13	3

PD=peritoneal dialysis, HD= hemodialysis, KT =kidney transplant

[1/] Laonapaporn, Punthunane et al. (2014)

[2/] Tisayaticom, Patcharanarumol et al. (2003)

[3/] Suksamran, Kongsin et al. (2012)

The researcher used these figures to calculate the unit cost per patient-year composed of the three main cost objects: material, labour, and capital.

4.4.3.3   Future budget needs

Results from the previous sections (costs and numbers of patients by each RRT modality) were drawn on to estimate future budget needs 2014-2023. The estimated future costs for the RRT modalities were further used to assess effects of four cost drivers: number of patients, labour costs, material costs, and capital costs. This is to explain effects of these drivers: how they influence the unit cost of each RRT modality, and how to control programme costs during the ten-year period. In this study, forecast budget needs are presented and discussed in terms of 2014-constant Baht.

After obtaining the predicted numbers of renal replacement therapy users, the total cost of each modality over the next 10 years (to the end of 2023) was estimated by multiplying the number of users by unit costs. Since there might be policy changes in the future, total costs of the programme were calculated under different scenarios.

Selected scenarios

Three scenarios that were most likely to occur were obtained from interviews with policy makers in objective 1. They were selected to explain effects of the three cost drivers on future costs of the RRT programme. All scenarios assumed that numbers of RRT patients would increase as projected. Capital costs would remain unchanged, not vary as the patient number increases. Labour costs and material costs would increase by the increasing number of patients. Material costs would vary in the three scenarios.

- Scenario 1 assumed material costs would remain unchanged.
- Scenario 2 assumed material costs would increase.
- Scenario 3 assumed material costs would decrease.

4.5 Summary of objectives and methodology used in the study

The study's objectives and their corresponding methods are summarised in Table 4-4.

Table 4-4 Summary of objectives and the methodology of the study

Objective	Method	Measures	Source of data
1. Describe the rationale behind and the application of the disease management approach in the RRT programme	Qualitative approaches: 1) document review, 2) semi-structured interview, 3) focus group discussion, and 4) observation	Responses of payers, providers, and patients to the RRT programme and effects of the programme on them	Various archival documents, 41 interviews, 1 focus group discussion, and 10 observations
2. Explore the changing patterns of access to service and mortality of ESRD patients overtime	Age-period-cohort analysis	Access to RRT services and mortality of ESRD and RRT patients	NHSO's administrative data and vital registry
3. Undertake long term projections of the number of patients and budget needs for the RRT programme	Cost modelling and time-series projection of the RRT population	Long term costs, number of patients, and RRT programme cost drivers	NHSO's administrative data

NHSO=National Health Security Office, ESRD=end-stage renal disease, RRT=renal replacement therapy

4.6 Limitations

4.6.1 Data sources

Data obtained in this study came from both primary and secondary sources. Primary data were collected from interviews, a focus group discussion, and

observations, where there were opportunities for the interviewer and observer to bias and mediate the discussion. Other sources of bias came from interviewees, who tend not to reveal their true feelings and beliefs to the interviewer (Bowling 2009).

Secondary data used in this study were mainly intended for administrative purposes, consequently, there were some limitations. For example, data for many fields which were not used for budget claims, were not routinely recorded. Claims data given for any given year may not be completely up to date, since the NHSO allows its health facilities to claim reimbursements for treatment up to a year later. Additionally, linking various databases resulted in losing a number of records that could not be merged and might threaten follow up of the cohort population and patient projections.

4.6.2 Lack of a counterfactual to assess cause-effect relationships

The age-period-cohort analysis in this study is a tool to describe the changing patterns in registrations and deaths among ESRD patients. This method of analysis does not establish a cause-effect relationship. In other words, it does not have a control or comparison group to assess whether the RRT disease management programme really causes an effect on the outcomes of interest (registration and death). In general, age-period-cohort studies cope with this limitation by providing and interpreting the study results with environmental circumstances to explain the likely causes of the changes occurred in the studied period.

4.6.3 Assumptions used in projections

Predictions in this study are vulnerable to inaccuracies due to a number of factors. First, they used results of past studies to estimate costs of material, labour, and investments for each RRT modality. Next, assumptions used to build scenarios have an effect on the estimated budget needs. If what happens in reality deviates from what was assumed, it threatens the accuracy of the forecasts.

CHAPTER 5   Disease management of the RRT Programme

5.1   Introduction

High-cost conditions can be a challenge to policy makers when designing benefit packages. It can be even more challenging when making a decision to include their treatments in the health basket when they were not available before.

Disease management programmes involve a multidisciplinary approach and comprehensive care along the patient's journey through the health care delivery system. With slightly different aims, disease management is a key approach used in the Universal Coverage Scheme (UCS) to care for patients with high-cost conditions which entail treatments with accessibility problems. In the UCS, the renal replacement therapy (RRT) programme is a result of advocacy from various stakeholders responding to the implications of high-cost conditions.

The objective of this chapter is first, to describe the development and rationale behind the inclusion in a health benefit programme of a high-cost treatment. Second, it will describe the application of the Thai disease management approach in the RRT programme, in terms of the relation between people at different levels of the health system: policy makers, providers, and patients. This is to obtain a better understanding of their views on high-cost conditions: how patients have coped with financial constraints, how policy makers and providers responded to patients with end-stage renal disease, and what was done to initiate the RRT benefit. In addition, this chapter will explore how the disease management approach was applied and practised in the RRT programme by such people. Finally, the chapter will discuss why some patients agreed to use RRT and why some patients did not.

This chapter first provides a background and features of the UCS RRT programme. Next, it introduces a brief methodology summary on data collection and the data analysis procedure. This is followed by results of data analysis, discussion, and conclusion.

5.2   Renal replacement therapy of the UCS

5.2.1   Background of the RRT programme

RRT was initially excluded from the benefit package when the UCS was launched in 2001 due to fiscal constraints and an unprepared system. Gradually, the National Health Security Office (NHSO) responsible for UCS was pressured to expand benefits to include RRT by civil society organisations and patient groups (Tangcharoensathien, Kasemsap et al. 2005). Their justifications for inclusion were that it would save lives and prevent indebtedness and health impoverishment among UCS members.

Before launching the RRT programme, the NHSO commissioned a group of researchers to conduct a set of comprehensive studies relating to RRT situations and the possibilities of an RRT programme for UCS beneficiaries. The intention was to present viable policy options to the NHSO board. Their final decision, supported by the government and the cabinet, was that the RRT would be provided universally regardless of age and socio-economic status (Dhanakijcharoen, Sirivongs et al. 2011).

Despite being cost-ineffective, in 2008 RRT was adopted into the benefit package of UCS. The new health benefit covered RRT services for every UCS member. The justification was to help patients have access to the essential treatment and protect them from catastrophic spending due to health care costs (Kasemsap, Teerawatananon et al. 2006).

5.2.2   Features of the RRT programme

5.2.2.1   The PD-first policy

The UCS-funded RRT has the 'PD first' characteristic. That means all new end-stage renal disease (ESRD) patients without contraindication to peritoneal dialysis (PD) must use continuous ambulatory peritoneal dialysis (CAPD) as the first-line therapy, otherwise they need to shoulder the costs of the other

modality of dialysis (hemodialysis) themselves[9]. HD patients who were on HD before the 'PD first' policy[10,] and patients with contraindications to CAPD, are eligible for full reimbursement of the cost of HD. Under the PD-first policy, renal transplant and all essential high-cost medications are also included in the benefits (Kasemsap, Chungsaman et al. 2009).

Before launching the RRT benefits, HD use was almost everywhere (352 HD centres across the country in comparison with 59 PD centres), but the underlying reasons for the PD first policy were 1) CAPD requires fewer health professionals, and there were not enough nephrologists and trained nurses to provide universal access to HD; 2) CAPD is based on self-management which means patients in rural areas do not need to come frequently for dialysis in town; and 3) CAPD showed evidence of cost-effectiveness over HD in some countries, plus CAPD costs might be lower under the condition that the cost of the dialysis solution is cheaper (Kasemsap, Chungsaman et al. 2009). In contrast to PD's advantages, patients who are on PD face a risk of infection, called peritonitis, due to unclean environment or contaminated devices.

5.2.2.2 Separate payment mechanism and administrative function

In the Thai UCS, costs of RRT are reimbursed according to the three modalities: PD, HD, and KT. While staff salary is a part of the capitation payment of out-patient services, the RRT budget is administered separately and costs are reimbursed on a fee schedule basis.

The NHSO introduced bundled payments that combined multiple services into a single payment for each modality. Recently, it stopped paying for individual activities such as launching a PD centre, PD catheter (Tenckhoff catheter) insertion, home visit, and volunteer programmes that were originally meant to persuade providers to expand the service provision of PD. Reimbursements of PD and HD cover most activities associated with dialysis including counselling, catheter implantation in PD or vascular access in HD, consumables such as

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[9] In this case, the NHSO supports the cost for EPO to prevent anemia in patients receiving HD.

[10] These patients had to pay copayment approximately £11 per session, but this rule was abolished in 2012.

medical supplies and PD solution, and follow-up. Erythropoietin and PD solutions are centrally purchased and allocated when they are requested from dialysis units. Reimbursements for kidney transplants cover all costs related to kidney operations of the patient and the donor, follow-up process, and immunosuppressant drugs (NHSO 2013).

In addition to the separate payment system, supply constraints, including limited numbers of CAPD nurses, nephrologists, CAPD centres, and limited fiscal capacity, challenged the implementation of the RRT programme. Policy makers of the UCS decided to manage the programme separately from the mainstream by splitting the RRT budget and setting up an ESRD administrative unit within the central NHSO. The intention of this split was to provide a managerial function for the RRT system (Tantivess, Werayingyong et al. 2013).

5.2.2.3 Co-ordinated system of RRT programme

The UCS's RRT programme is a system of coordination between various sectors: the NHSO, the Government Pharmaceutical Organization, the Central Office for Healthcare Information, the Renal Registry under the Thai Red Cross, the professional body of the Thai Nephrology Society, public and private RRT providers, primary care units, and patients and their communities.

The local RRT centres are mandated to register patients diagnosed with renal failure or patients who need RRT. A patient needs to be approved by the regional NHSO before starting RRT at an RRT centre. Once an RRT service is given to a patient, the RRT centre sends information about activities and PD solutions or erythropoietin (EPO) use to the central NHSO in order to be reimbursed the dialysis and staff fees according to the agreed guideline protocol. The Central Office for Healthcare Information is responsible for claims from HD patients. Medications, namely EPO and PD solutions, are reimbursed in the Vendor Managed Inventory System by the Government Pharmaceutical Organisation. The Government Pharmaceutical Organization is in charge of delivering EPO/dialysate to RRT centres, as well as delivering dialysate to CAPD

patients' houses. The renal registry acts as a middleman to collect ESRD prevalence and incidence data (NHSO 2013), Figure 5-1.

Figure 5-1 Coordinated system of RRT management
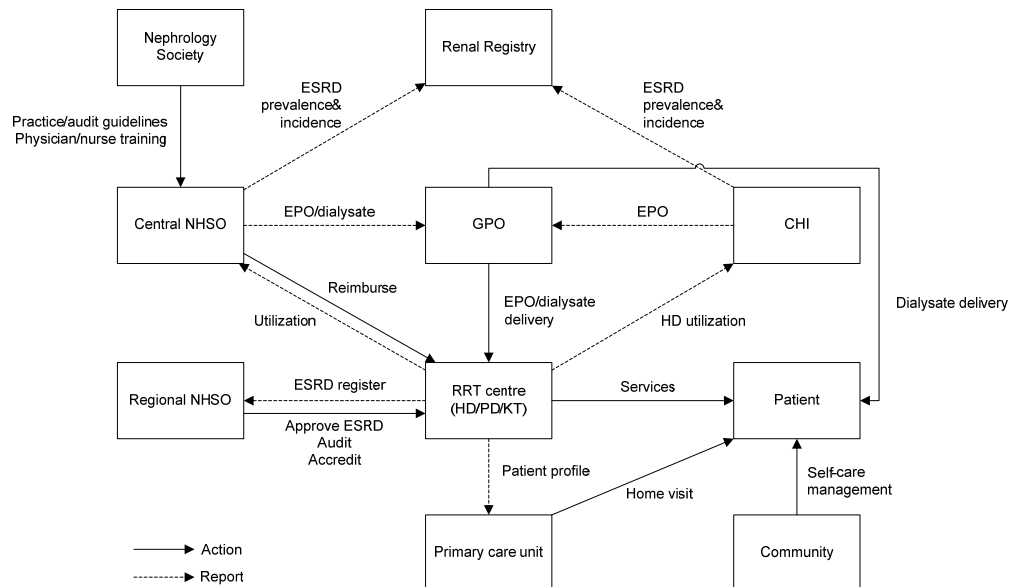
RRT=renal replacement therapy, CAPD=continuous ambulatory peritoneal dialysis, HD=hemodialysis, GPO=Government Pharmaceutical Organization, CHI=Central office for Health care Information
Source: NHSO (2013), ESRD administrative unit (2011)

Figure 5-2 shows a patient journey along the NHSO's RRT protocol. In the usual care system, if the patient has diabetes or hypertension, chronic kidney disease may be detected by the screening programme when the patient meets a GP in a primary care unit or an internist in the outpatient department of a larger health facility. When the patient presents with decreased kidney function, they will be referred and looked after by professionals in the RRT unit to. A nephrologist confirms the ESRD diagnosis when the patient's GFR level reaches 15 mL/min/1.73 m^2. If the patient presents no signs or symptoms of kidney failure, they will be provided with information on the treatment options when their GFR level drops to 6 mL/min/1.73 m^2. If the patient agrees to start dialysis, they will be registered with the RRT programme, or alternatively they will be living with conservative therapy (without dialysis).

The RRT programme uses PD as the first treatment modality. A patient without contraindications to PD will be trained for self-care management. During the training process (approximately 3 months), nephrologists and PD nurses

provide dialysis care, a pre-PD programme, to the patient. This includes laboratory tests, educational sessions for the patient and carer, and catheter insertion. Once the patient has completed the assessment for commencing PD, the regional NHSO committee has the next role to approve the patient for entering the RRT programme. The committee also has a role in approving initiating dialysis on HD or switching to HD if the patient is contraindicated to PD or fails using PD. The patient can register for a kidney transplant and have an operation once they are accepted as a transplant candidate (NHSO 2013).

Once the patient has established PD, they will be followed up by the nephrologist and other PD staff for evidence of complications and peritonitis, and routine medication every 1-2 months. The patient is also referred to their local primary care unit and is offered occasional home visits. A family member is encouraged to come along with the patient during the training period in order to be able to support the patient with PD exchanges at home.

Figure 5-2 A patient journey in the RRT programme
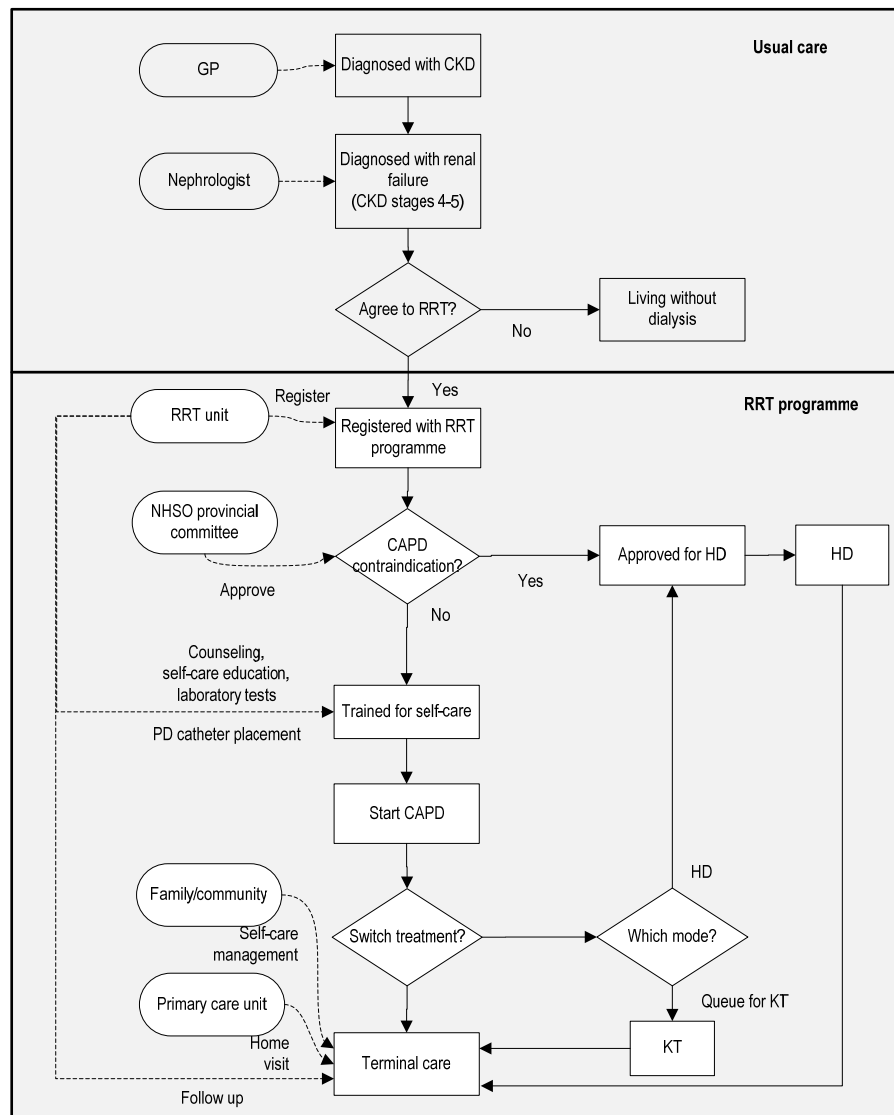
CKD=chronic kidney disease, CAPD or PD=continuous ambulatory peritoneal dialysis, HD=hemodialysis, KT=kidney transplant, RRT=renal replacement therapy

5.3 Summary of methodology

Three qualitative methods were used, consisting of 1) document review, 2) semi-structured interview and focus group discussion, and 3) structured observational study. Bringing the three methods together ensures the completeness of findings.

Data was first collected by reviewing available documents regarding the RRT programme, procedures, and reports. Then in-depth, open-ended interviews were conducted to know views and behaviours of interviewees. Finally,

observations of PD patients provided information on their self-care management. Data collection periods for in-depth interviews and observations were from 1st July to 31st August 2014 and from 16th to 20th March 2015.

5.3.1 Documents selected to review

Document reviews were conducted at the beginning of the study in order to have a comprehensive understanding of the RRT programme. Table 5-1 shows types of retrieved documents and information that were selected to review.

Table 5-1 Collected quantitative information

Type of document	Information selected
NHSO board meeting minutes	• RRT benefit
NHSO's RRT manual for providers	• UCS's RRT protocol • Payment system and reimbursements
NHSO's M&E reports	• Indicators on the RRT programme • Numbers of registered patients
National Health Security Act B.E. 2545 (2002)	• Budget allocation of the NHSO
Clinical guidelines	• Guidelines on caring patients with CKD • PD's self-care management
Newspaper clippings	• Kidney patient protests • RRT benefit • Interviews of key persons
Research reports	• Incidence and prevalence of ESRD in Thailand • Numbers of RRT human resources and facilities
Research articles	• Access to RRT • RRT benefits

5.3.2 Numbers and characteristics of interviewees

A mix of respondents from different roles in the RRT system were invited to take part in interviews. A multidisciplinary team who looked after patients with conservative therapy was invited to participate in a focus group discussion. Altogether there were 35 interviews, 10 observations, and one focus group discussion. They were divided into three levels; policy level, provider level, and patient level. The patient level consisted of patients who were maintaining peritoneal dialysis, hemodialysis, kidney transplant, and those who declined and chose to opt out from the RRT benefit, Figure 5-3.

Figure 5-3 Sampling framework with number of interviewees in brackets
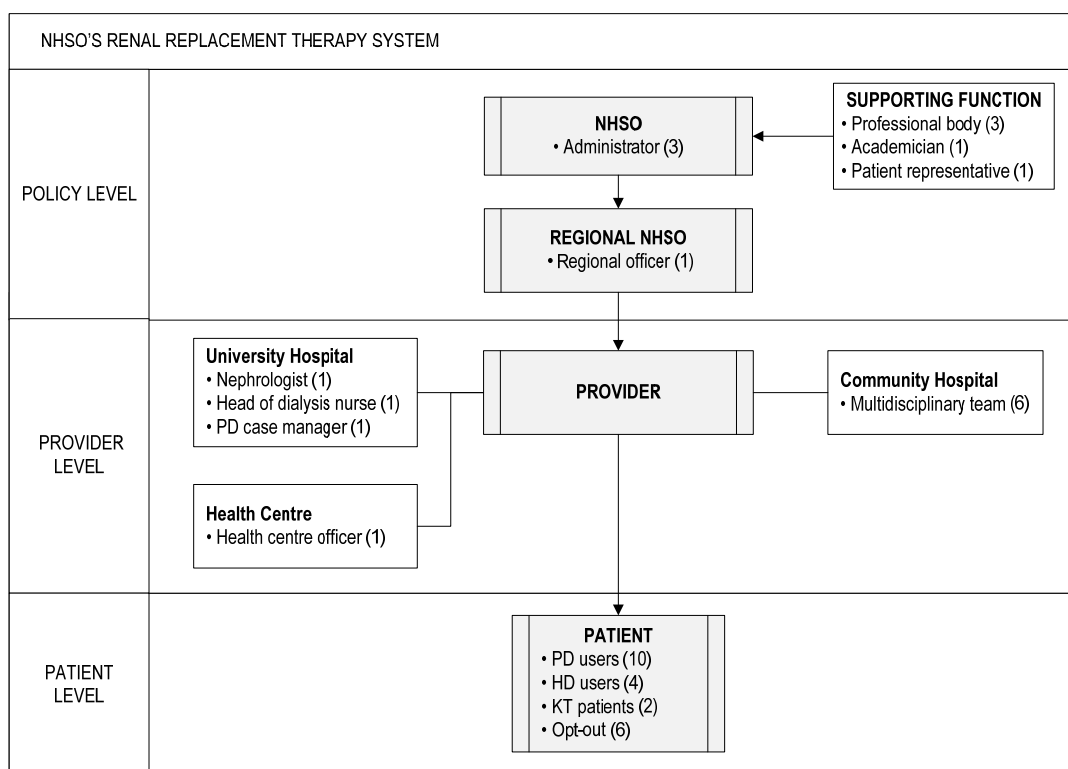
NHSO=National Health Security Office, PD=peritoneal dialysis, HD=hemodialysis, KT=kidney transplant

In terms of policy makers and providers, the majority of policy makers were male with a background as physicians. Three out of five policy makers also worked as providers in hospitals. A policy maker, the patient representative, had another role as a patient. In terms of providers, more than half of them were female with a background in nursing (see Table 5-2).

Table 5-2 General characteristics of policy maker and provider informants

Characteristics	Policy maker	Provider
Gender		
• Male	7 people	3 people
• Female	2 people	7 people
Years of experience*	5-30 years	3-15 years
Background or occupation		
• Physician	6 people	2 people
• Nurse	2 people	5 people
• Other	1 person	3 people
Total number	9 people	10 people

* in the current position

Patient interviewees were categorised by their economic status -
poorer/middle/richer- as judged by investigators. Criteria used to determine
the rough classification were the income level, source of income, job, and
characteristic of place of residence in comparison to their peers in this study.

The patient group of 22 persons can be subcategorised into 4 types according to
RRT modalities they were maintaining; peritoneal dialysis (PD), hemodialysis
(HD), kidney transplant (KT), and patients who chose to opt-out (OO). Their
ages ranged from 23 to 75 years. Just over half of the patients, especially those
who aged 60 years or higher, were educated up to primary school level. Sizes of
households varied, ranging from just one member to ten members. Due to their
illness, patients could not work full-time except that those who were
maintaining a functional transplant could go back to work. Two opt-out patients
had to continue working after the illness as they were the head of household
and the other members in the household could not work and earn money. Only
5 out of 22 patients were judged richer, while the majority of patients were
poorer or middle (see Table 5-3).

Table 5-3 General characteristics of patients with numbers in brackets

Mode	Gender	Age	Education	Started RRT	Household size	Job at present	Economic status[1]
PD	Female (6)	32-70	P (3) S (2) B (1)	2009-2013	1-5 people	None (5) Occasional job (1)	Poorer (2) Middle (2) Richer (2)
	Male (4)	36-70	P (1) S (3)	2006-2014	1-8 people	None (3) Occasional job (1)	Poorer (1) Middle (3)
HD	Female (2)	49,50	P (1) S (1)	2008,2012	3,10 people	None (2)	Poorer (1) Middle (1)
	Male (2)	57,70	P (2)	2006,2012	2,6 people	None (1) Occasional job (1)	Poorer (2)
KT	Male (1) Female (1)	40,52	S,B	2003,2007[2]	N/A	Full time job (2)	Richer (2)
OO	Female (2)	64,75	P (2)	2010,2012[3]	2 people	None, farmer	Poorer (2)
	Male (4)	59-74	P (4)	2007-2012[3]	2-4 people	None (3) Tailor (1)	Middle (3) Richer (1)

PD=peritoneal dialysis, HD=hemodialysis, KT=kidney transplant, OO=opt-out;
P=none or primary school, S= secondary school, B=bachelor's degree or higher;
[1] as judged by investigators, [2] year having kidney transplant, [3] year diagnosed with ESRD

5.3.3   Data analysis procedure

The findings of the study were brought together from information collected by the three data collection methods. To describe the system of the RRT programme in the context of disease management, results are described from the perspectives of the NHSO, providers, and patients.

Figure 5-4 shows the conceptual framework for describing the rationale and practices of the RRT programme. After the implementation of the UCS in 2002, the scheme expanded to cover 48.6 million people, 74.7% of the Thai population (NHSO 2013). UCS members are required to receive health care at the registered primary care units, which can be a community hospital or a health centre. Almost all of them are public facilities.

Different groups in the health system responded to patients with end-stage renal disease in various ways, according to their roles. The funder or the NHSO's main role is to provide access to essential treatments and protect its beneficiaries from catastrophic health spending. With its supporting agencies, the NHSO took the concept of disease management as an intervention to design the delivery system of RRT for providers. Responding to the RRT programme, providers have taken action to care for patients with end-stage renal disease. Consequently, the RRT programme affects providers' attitudes and practices. In this study, disease management and the chronic care model provide a detailed framework to describe the elements used in the system for caring for people with chronic diseases. They were adjusted to the UCS's RRT programme by focusing on 1) the system's resources, policies, and delivery system design and 2) actions and perceptions of disease management interventions given by policy makers and providers. The components included i) evidence-based guideline protocols, ii) population identification, iii) collaborative practice, and iv) self-care management support.

Patients' performance is viewed as one of the key components in a disease management programme's success. Patients are supported to make day-to-day decisions about their illnesses and to hold responsibility to manage their own condition (Bodenheimer, Lorig et al. 2002). In the RRT programme, patients can

choose if they need RRT. Some patients may agree to receive the high-cost treatment of the RRT programme but some patients may not and instead choose conservative therapy or self-pay dialysis. Some of this can be explained by individuals' characteristics, beliefs, and other factors such as their social structures. Other factors may also play an important role in individuals' decisions such as health benefit coverage (Aday and Andersen 1974), as well as the number of RRT facilities and their location.

On the patients' side, community groups such as community health care providers and health volunteers are supported to integrate into the RRT programme as part of the government's strategy to mobilise community resources in supporting patients with end-stage renal disease. Moreover, communities can support patients by bridging the gap between the arranged service provision and the real world of patients and their families (Epping-Jordan, Pruitt et al. 2004).

Figure 5-4 Conceptual framework for describing rationale and practices of the RRT programme
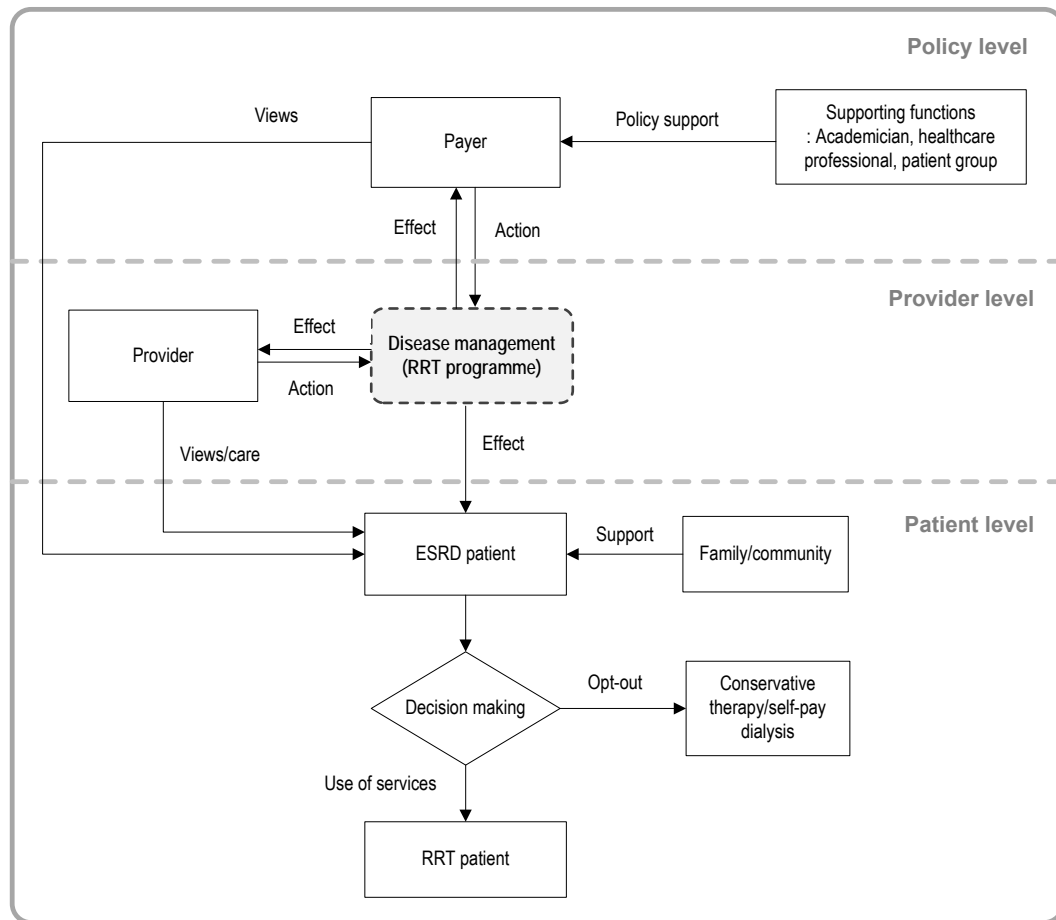
ESRD= end-stage renal disease, RRT= renal replacement therapy

5.4   Results

Results are reported according to the framework for qualitative analysis. The text starts with views on end-stage renal disease, responses, and actions from interviewees at different levels, and considers past attempts to initiate the RRT programme. This is followed by all interviewees' rationale for use and application of disease management as an intervention to manage the high-cost condition. Next, networking between components in the RRT system is highlighted. Finally, the chapter reports patients' perspectives on what determines the use of dialysis. This chapter aims to see how well the system of RRT is functioning, how people respond to the system's design, and how they respond to the disease management approach.

5.4.1 Views on high-cost, catastrophic diseases perceived by interviewees and their responses

Interviewees in this study had different views on high-cost, catastrophic diseases. Patients took account of both direct and indirect costs that they had to pay when they fell ill. Providers viewed high-cost treatments as a barrier for patients to receive health services, while policy makers considered this issue as part of their mission to provide access to care. The key factor responsible for the significant development of the RRT benefit was how policy makers and providers responded to patients with end-stage renal disease.

5.4.1.1 Patients

Direct costs for treatments, combined with indirect costs, could cause patients trouble when they needed health care. For an expensive treatment like RRT, patients who started having ESRD before the RRT benefit or who have recently discovered the existence of the benefit have already experienced a form of financial catastrophe. This includes taking out loans, making distressed sales of assets, stopping sending children to school, or thoughts about suicide. Patients shared their experiences and said that:

> *"I spent all I had for hemodialysis. We are not rich. When I started having kidney failure, my son was studying at university. He had to stop and find a job to make money for our family. His life was then finished. […] I once had an infection, and a doctor rescued me because the shock to my body would have killed me because it would have been better if he'd let me die."(HD2)*

> *"When I first knew that I had it (ESRD), I felt so depressed. Just think about it, I used to have everything like a great job and there used to be many customers. But when I got sick I lost everything too. I have tried committing suicide a couple of times. That was why my family asked me to enter a monkhood."(PD8)*

A patient mentioned the loss of opportunity cost of herself and a family member:

"While I was studying at university, I went back and forth between school and hospital to change my bag. [...] Before I could do this by myself, my mum had to quit her job to take care of everything for me." (PD4)

Since the RRT benefit became available to everyone, situations have become better. Patients were eligible for free health services, however, some of them mentioned difficulties such as travel cost and opportunity cost to themselves as well as family members. Altogether, these costs could bring a patient to incur financial catastrophe. As one patient pointed out:

"Now the dialysis cost is free but the travel cost is not, I pay 500 Baht[11] each week. It's really tough since I don't earn much. Having dialysis is just like waiting to die." (HD2)

5.4.1.2 Providers

In the providers' view, high-cost diseases were conditions that needed expensive treatments. Without coverage from a third-party, they could lead patients to catastrophic health spending. For chronic conditions or treatment for accidental injuries, although costs for multiple treatments were expensive, most conditions were covered by universal health coverage for a long period. They could not bring patients into bankruptcy.

The barrier of access to care was a consequence of high-cost conditions making them the main concern among providers. Before there was universal health coverage of the UCS, a physician recalled:

"There were ESRD patients who came to the hospital for hemodialysis, asking help from the subsidy fund for the poor. Most of them were turned down. Some were offered peritoneal dialysis and had it temporarily for 3-5 days. For around 2-4 weeks they came back. After a couple of times they no longer came again which was really sad." (PM5)

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[11] Approximately 10 pounds

5.4.1.3   Policy makers

The policy makers' attention was focused on access to care and equity. Providing access to essential healthcare and preventing beneficiaries from financial catastrophe due to high cost health care are NHSO's goals. As an interviewee stated:

> *"Suffering from diseases with are costly to treat, such as stroke, cancer, and cardiovascular disease may not be a big burden for the rich, but what about the poor? This is why we need a health insurance scheme to cover these costly treatments." (PM7)*

In terms of high-cost conditions, the NHSO used criteria to distinguish these conditions from others. First they looked for treatments that were not available in the benefit package. Next, the focus was put on health problems with new, expensive treatments, which meant they were most likely to be inaccessible. For high-cost treatments, policy makers believed that it was essential to set up a special arrangement in order to increase access to care. This was because the closed-end payments of the NHSO discouraged providers from providing high-cost treatments. As an interviewee from the NHSO explained:

> *"We think patients can't use these services because there are gaps between the policy and providing health services. […] This is why these costly treatments need some kind of special arrangement. For example, HIV/AIDS and RRT, we were pressured every year to put their treatments in the health benefit basket. We then made arrangements for HIV drugs and the RRT system." (PM2)*

5.4.1.4   Responses to ESRD patients

In Thailand, treatments for kidney disease, such as transplantation, hemodialysis and peritoneal dialysis had been developed during the 1990s (Supaporn, Krairittichai et al. 2005). Technologies in kidney disease were successful enough that patients could spend their everyday lives almost

normally, whether at work or socialising. But only the well-off or civil servant patients could access these new treatments.

Before RRT benefit was included in the core benefit of the UCS, there were very limited numbers of dialysis units and dialysis nursing staff. Only rich patients could undergo dialyses (Tangcharoensathien, Kasemsap et al. 2005). It was therefore in the public interest to provide funded treatment for end-stage kidney disease which could otherwise cause a patient financial catastrophe. However, concerns about the high-cost and poor cost-effectiveness were the main reasons that NHSO's administrators decided not to include the benefit in the UCS since its beginning in 2002 (Tantivess, Werayingyong et al. 2013).

A nephrologist once said that it felt like giving the death sentence to the patient; the effective inaccessibility of treatment for the majority of the population had put huge pressure on nephrologists. They started the idea to put the RRT into the health benefit even before the initiation of the UCS (in 2002). At first, nephrologists believed that they should work without contact with politicians otherwise people would think of them as dishonest and corrupt. An interviewee as a nephrologist/academician shared his opinion that:

> *"[…] from another point of view, we cannot change anything because the power lies within the politicians. So we changed our minds and asked to have a meeting with the Minister of Public Health." (PM4)*

Therefore, they thought about approaching the government, the Ministry of Public Health, and academicians whose work related to financing. It was an effortful and time-consuming process, as an interviewee recalled:

> *"We had several meetings, first we went to see the minister (of the Ministry of Public Health), and told him what we had experienced. He understood us well and invited his working team and ones who had important positions in the Ministry to listen. It went well, everyone agreed that there should be some action. Unfortunately, the government was changed shortly after*

that. When the new minister came, we started a new talk. Then, after just a while, the minister was moved again." (PM5)

On the patients' side, there were efforts to make connections with policy makers and politicians in order to strengthen the patient group and push for the RRT benefit. They had several meetings to accomplish the RRT benefit, despite the reshuffle and change of the government. The following is a newspaper archive of an interview with Subin Noksakun (see Box 1), former chair of the Friends of Kidney Patients Society:

Last mission with the remaining breath

ASTV online, 26 December 2006

"Once I had a discussion with the Public Health Minister, Pinij Jarusombat[12] of the Thai Rak Thai party. He agreed upon a tripartite copayment. The proposal was ready but the government was then abolished by the coup. [...] After the new government was in place (from the military coup), we proposed that the government give free treatment to chronic kidney patients via the UCS in fiscal year 2007. The proposal was then taken to present to Dr Mongkol Na Songkla[13,] the new Public Health Ministry. He understood and told us that the NHSO and some public hospitals) was launching a pilot programme to see how this benefit could go."

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[12] Pinij Jarusombat was in the position between October 2005 and September 2006

[13] Dr Mongkol Na Songkla was appointed to be the minister between October 2006 and February 2008

Box 1 Friends of Kidney Patients Society

From a small society of kidney patients formally established in 2006, the Society has now expanded to more than 40,000 members. This figure covers just beneficiaries of the UCS, many more members are in the other two public health insurance schemes: Social Security Scheme and Civil Servant Medical Benefit Scheme. Its members are the patients who suffer from the last stage of kidney disease, carers, and people who are at risk of kidney disease.

Going back ten years, the Friends of Kidney Patient Society was set up by Subin Noksakun, known as Uncle Subin, the first chairman of the society and the champion of kidney patients' rights. Subin once belonged to a rich family. He had a family business, properties, and savings of more than 10 million Baht: but most of it is gone due to 20 years of treatment for his kidney disease. At the time he gave the interview, just a house and a few hundred Baht savings were left. Chronic kidney disease ran in Subin's family, as his elder brother and son also suffered from the condition. One day Subin went to receive his treatment as usual, he listened to old, repeated conversations on how to control body weight and salt intake and felt that there was no improvement in benefits for kidney patients. He had once acted as a member in the Employee Labour Congress, and this inspired Subin to do something so that kidney patients would not face financial catastrophe like him.

With support from several networks such as the NHSO and other patient groups for cancer, heart disease, and HIV/AIDS sufferers, the Friends of Kidney Patient Society was set up. After several visits and talks with politicians, and together with the movement of academicians/policy makers, the RRT was included in the health benefit of the UCS, starting in January 2008. From this success, the group moved to call for expanding the RRT benefit to those who had developed ESRD before they became members of the Social Security Scheme. The success took two years to achieve, and is indebted to Subin's significant effort. He once mentioned, "When I do the visit, I go alone. Other members are not allowed to come along, otherwise they can't earn money for their dialyses. I don't have much too but I have no choice. My daughter asked 'Is it better to just stay home?' But I can't. I haven't got much time left so I have to do something worthwhile. Can Thailand have decent health benefits like those developed countries? The answer is 'Yes, we can' but there needs to be someone to start it."

According to the Director of AIDS Access Foundation, "Before the establishment of the Friends of Kidney Patients Society, kidney patients did not gather into groups and there was no existing relationship between kidney patients and other patient groups. Because of the movement since Subin coming in and Dr Sanguan's (NHSO's first secretary general) intention to help kidney patients, the establishment of the RRT benefit succeeded in a short amount of time, less than a year. Compare that to the HIV/AIDS benefit, where we spent almost ten years."

Subin passed away at the age of 62 on 6[th] May 2012, six months after the death of his son. Now the Friends of Kidney Patients Society has a new chairman and has been contributing to many activities; building up knowledge of self-care management to patients and carers, and also movements for public participation. The society has its branches in every province across the country, where the core members run monthly visits and set up forums in order to expand the network and develop collective approaches, such as building up knowledge and friendship support groups, and how to fundraise for spending on various activities. Besides the effort to put RRT in the health benefit basket and improve the benefit thereafter, the group, with its networks, also plays important roles in a number of actions to assure equal opportunities in society. For example, they called for the abolition of the rule prohibiting patients with chronic kidney disease and tuberculosis from positions in the civil service in 2009. Recently, in 2015, they gathered to request that the minister of the Ministry of Public Health reconsider the changes in the NHSO's budget allocation and the introduction of patient charges/ co-payment under the UCS.

- Based on interviews and archival sources (*Manager Online*, 26 December 2006; *Consumerthai*, 12 February 2009; *Bangkokbiznews*,19 May 2012; *NHSO newsletter*, July 2013; *Matichon*, 3 February 2015

On the political side, the 1997 Thai constitution and the subsequent 2007 constitution (Constitution of the Kingdom of Thailand B.E.2550 (2007)) emphasise human rights and equality, stating that everyone will receive equal benefits and protection from the government. Equality, therefore, became a mindset of political promises. Despite the political transition due to the military coup in 2006, the new governments led by the appointed General Surayuth Chulanont[14], and the Public Health Minister, Dr Mongkol Na Songkla, still relied on the principle of equality.

Another advantage of the UCS was that the scheme is supported by the National Health Security Act B.E. 2545(2002), in which Section 39 clearly states that the cabinet are obligated to consider and approve the budget for the NHSO. This is advantageous to the NHSO because the spending plan is sent directly to the cabinet to make decisions. In contrast, other government department budgets have to be set up by the Bureau of Budget (which estimates the budget based on the final year spending) and sent to the cabinet to approve. Each year the NHSO has a large budget demand, approximately 5% of the total government expenditure. Also, new health benefits are always being introduced, causing additional budget allocations to the NHSO which are not based on the previous year's spending. Given this legitimacy, the NHSO can request its expected budgets with extra amounts and pass them directly to the cabinet. If the cabinet decides to initiate the new health benefit, they can support extra funding at this stage. However, other public sectors have to negotiate via the Bureau of Budget, who may not be motivated to push a new policy.

5.4.2   Initiation of the RRT programme

There were combined efforts to introduce the RRT programme to the UCS beneficiaries. The three factors that facilitated the remarkable achievement of the new benefit were creation of knowledge, social movements, and political actions.

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[14] acting as the Prime Minister during 2006-2008

5.4.2.1   Creation of knowledge

The NHSO sought support from various supporters when generating policy recommendations regarding the RRT benefit. By the end of 2004, the NHSO had commissioned a working group consisting of representatives from various stakeholders to identify overall conditions of the available RRT system in Thailand; this working group included the Thai Red Cross, the Thai Renal Replacement Therapy Registry, the Nephrology Society of Thailand, the Kidney Foundation of Thailand, and a number of researchers. The working group was to investigate six aspects relating to renal replacement therapy (RRT Benefit Research Committee 2004): 1) what had been done in other countries, 2) available infrastructures of the RRT system, 3) estimated numbers of patients who needed RRT, 4) cost-effectiveness of peritoneal dialysis and hemodialysis, 5) budget needs for the RRT benefit, and 6) public opinion of the new RRT benefit.

Results of the research studies showed that, in countries with well-developed health insurance systems, RRT is included in health care benefits. In countries with tight government budgets and insufficient numbers of hemodialysis units, peritoneal dialysis is the option the government usually prefers for the health benefit (Tangcharoensathien, Kasemsap et al. 2005). In Thailand, access to RRT was limited only to those who were well-off, at around 23% of overall ESRD patients (Kasemsap, Tangcharoensathien et al. 2001). There were 14,000 RRT patients in 2005, and this amount was expected to increase to 50,000 in 2009 (Kasemsap, Teerawatananon et al. 2006). In the case that every ESRD patient would use RRT, the first year of the programme would require 4,000-6,500 million Baht to treat patients. This amount would increase to more than 50,000 million Baht per year in the fourteenth year (Kasemsap, Prakongsai et al. 2006). A survey of public opinion showed that most Thais supported including the RRT benefit into the UCS. Just half of respondents agreed with paying a small contribution of less than 800 Baht (approximately £17per month) (Tangcharoensathien, Vasavid et al. 2006). A full list of research studies is shown in Appendix 6.

Given concerns over the financial constraints on the government health care budget, a set of policy options was proposed. The options comprised four alternatives to select patients into the RRT programme ranging from high-intensity to low-intensity RRT benefits. In addition, policy recommendations were developed and proposed. They suggested a marked improvement for several issues including primary and secondary prevention of ESRD, adequate and sustainable health care financing for the extension of RRT, an efficient RRT service provision system, the establishment of central purchasing and bargaining systems on PD solutions and erythropoietin injections, a reporting system of the renal registry, incentives for promoting the PD first policy, and an effective kidney transplantation system (Tangcharoensathien, Kasemsap et al. 2005).

The results and policy options were first brought to the executive board of NHSO in March 2005.The board adopted resolutions (NHSO Executive Board 2005) to:

1) launch a pilot project of 'PD first policy' to develop the RRT benefit in three sites; Banpaew Hospital, Samutsakhon province; Srinagarind Hospital, Khonkaen province; and Sonklanagarind Hospital, Songkla province. The pilot project would be extended to more areas in 2006. The final decision on the new RRT policy was expected to be announced in 2007.

2) coordinate with all relevant parties such as RRT units, local administration in each province, patients and carers, and their societies all over the country in terms of the budget need, staffing, and service provision.

A policy maker shared his opinions that:

> *"I really used the recommendations to make a plan for the system and get it ready for the new policy. [...] We (the NHSO) had specific objectives in the pilot project. First, to respond to social pressure about the RRT benefit: by starting in 3 pilot centres we could buy time, and promise a real start in the next 3 years. Second, to answer some questions, which were: 'Will providers and patients accept PD first (because in that time,*

PD use was limited in terms of numbers of facilities, healthcare staff, and patients)?', 'Can patients and communities pay contributions?' Also, we wanted to make managing guidelines for service provision and staffing. And finally, we wanted to pilot service provision for 3 years." (PM1)

5.4.2.2   Societal movement

Not long after the action of the academician group, there were movements led by patients. A small group of kidney patients who had been given funding support for dialyses by the Kidney Foundation of Thailand[15] formed a formal patient group called Friends of Kidney Patients Society in 2006 (see previous Box 1). The Society, reinforced by the NHSO, sought to extend the UCS benefit package to cover RRT services.

When patients gathered into a large group, their voices were powerful and got the public's attention. They asked for the RRT benefit via the Kidney Foundation of Thailand, government, and mass media, as well as directly to the NHSO, as newspapers reported:

> ***Kidney patient plea for free treatment***
> *(Kom Chud Leuk, 16 May 2006)*
> *Over 200 members of the Friends of Kidney Patients Society gathered, requesting that the government put renal replacement therapy in the Universal Coverage Scheme's benefit package.*
> ***Kidney patient plea to the government***
> *(Delinews, 30 August 2007)*
> *[…] more than 300 kidney patients gathered in front of the Ministry of Public Health, asking to meet Mongkol Na Songkla, the Minister of Public Health as they cannot shoulder costs of the expensive treatments at several thousand Baht per month.*
> ***Friends of Kidney Patients marching to government house***
> *(Kom ChudLeuk, 10 October 2007)*

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[15] A humanitarian organisation for kidney patients, patronised by Her Royal Highness Princess Galyani Vadhana

> *[…] around 50 members of the kidney patient supporters gathered at the government house to deliver a letter to the Prime Minister, General Surayuth Chulanont, asking for support for the kidney patients by putting the benefit in the UCS.*

5.4.2.3   Political action

The RRT issue was considered by the meeting of the NHSO executive board in September 2007, where research studies commissioned by the NHSO were presented. The board then resolved to fully fund kidney transplant and peritoneal dialysis. Hemodialysis was fully funded only if a patient was contraindicated to peritoneal dialysis. Old hemodialysis patients who wanted to retain on hemodialysis would be subsidised just two-thirds of the price, and the rest would be patients' responsibility. Because of the large amount of need for RRT (the expected spend was 17,000 million Baht, almost 10% of the UCS budget for outpatients), a member of the executive board suggested separating the budget for the RRT programme from outpatient's capitation (NHSO Executive Board 2007). UCS beneficiaries could go to receive services from any RRT units that had enough capacity and were ready for the new policy.

It was near the end of the Surayuth government, and there was a concern that what had been done so far would be wasted. On 30th October 2007, the Public Health Minister, Dr Mongkol Na Songkla ,who had continuing concerns over this matter, presented the policy recommendations to the cabinet and allowed the academicians to give reasons to support his judgement by the end of cabinet meeting. An interviewee who worked closely with NHSO gave details:

> *"[…] At first, the research group gave the cabinet alternatives to the free RRT benefit, such as copayment and age limitations, but the cabinet and audiences still doubted whether the recommendations could be met. Finally, the Prime Minister took his role and asked to make the final decision. He said 'our people have been suffering and waiting painfully. Could we just start by doing what we can then gradually develop it?"* (PM5)

Another interviewee shared his opinion:

"In my opinion it was a perfect mixture. We had General Surayuth who supported equality and Dr Mongkol who understood the health system as a physician, accompanied by research knowledge and societal movement." (PM2)

Finally, the resolution was passed by the cabinet to include the RRT service to the UCS benefit package (Cabinet Resolution 2007). Since the cabinet resolution was announced in October and would become effective the following January, there was a concern that the large budget for RRT programme had not been set up in advance. In order to have enough funds for the first year, the NHSO's coordination committee proposed to use the remaining budget of HIV/AIDS programme at the amount of 836 million Baht for initiation of the new RRT programme (NHSO Executive Board 2007).

5.4.3   Disease management approach to the RRT programme

This section is divided into two sub-sections. The first sub-section is about the surrounding context relating to the implementation of the RRT programme. The other sub-section describes effects of the RRT programme as perceived by policy makers, providers, and patients as well as their actions on the programme. The content of this sub-section is arranged according to four components of disease management: use of evidence-based guidelines, patient identification, collaborative practice, and patients' self-care management.

5.4.3.1   System's resources, policies, and delivery system design

i.   RRT staff and facilities

Before the RRT programme started, numbers of RRT centres were limited and mostly concentrated in the vicinity of Bangkok. In 21 out of 76 provinces there was only one RRT centre. Around 70% of nephrologists[16] and 65% of dialysis nursing staff were working in the vicinity of Bangkok (Supaporn, Krairittichai et

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[16] including trained kidney doctors from other subspecialties including internists and pediatricians

al. 2005). Therefore, it was important to rapidly increase the number of RRT facilities, particularly PD centres and nursing staff to ensure patients' access to the PD first programme. Table 5-4 shows numbers of PD and HD centres in 2006 to 2012.

Table 5-4 Numbers of peritoneal dialysis and hemodialysis centres 2006-2012

	2006	2007	2008	2009	2010	2011	2012
PD centres	57	61	105	120	139	144	178
HD centres	399	395	428	440	447	497	533

Source: Thailand Renal Replacement Therapy Registry Report 2012

Before the initiation of the RRT benefit, the NHSO spent three years to make universal access to RRT possible under the UCS system. PD first and disease management were key strategies used to arrange for provision of the service and to overcome system inadequacies.

ii. PD first policy

As it was anticipated that there would be huge demand for dialysis after the announcement of the new benefit, PD was the best choice given the short staffing of the health workforce. In comparison to HD, PD requires fewer amounts of nurses to look after patients. Given PD as home dialysis, patients residing in rural areas can be trained to rely on self-care management. This is in contrast to HD, which requires patients to receive care at a hemodialysis unit, and therefore suits patients who live in the city and have no problem with frequent travel.

In addition, from the NHSO's point of view, the costs of PD to the NHSO are expected to be lower, or at least controllable in the future. One example is the expected scenario that PD solutions can be locally made.

iii. Disease management initiatives

Disease management interventions were used to administer the RRT system, including setting up guideline protocols and reporting systems. An interviewee from the NHSO explained how the disease management approach was adopted:

"A member of our staff reviewed experiences from other countries and suggested we use the disease management approach, which the NHSO applied to tertiary care and treatments for many specific conditions such as cancer, stroke, heart disease, RRT, and so on. We also tried to cover all aspects of the care process from prevention programmes, patient identification, service provision, payment reform to quality control." (PM1)

5.4.3.2 Actions and perceptions on disease management components

Most components of disease management are included in the UCS's RRT programme. The processes of population identification, guideline protocols, reporting systems, collaborative practice, and patients' self-care management are explicitly stated in the NHSO's manual for providers. All RRT providers are obliged to follow these processes as they are bound with the programme's registration system and the payment system. Process and outcome measurements for providers are optional and may vary depending on which indicators RRT units adopt. The case manager, dialysis nurse, and the nephrologist act as main care providers. Collaborative practice is applied but the degree of coordination with professionals in other sections is based upon the level of integration within the facility and between its networks (see Table 5-5).

Table 5-5 RRT programme features linking to disease management components

Components	Features
Evidence-based guideline protocol	Protocols for providers are developed from evidence-based-guidelines and linked to the payment system
Population identification	Secondary prevention programme to identify patients with CKD risk factors. Patients are referred to a nephrologist if they reach advanced stages of CKD
Reporting system	Electronic reporting system to manage the care process: registration, service delivery, medications that link to the payment system
Process & outcome measurement	National level: indicators such as number of patients in the programme, survival rate, and PD-related infection rate Facility level: may vary
Collaborative practice	Dialysis nurses act as a case manager or central person to

Components	Features
	communicate with patients and nephrologists. Patients may be referred to other professionals upon nephrologists' requests.
Self-care management support	All patients are taught to perform self-care PD, as well as monitoring their clinical conditions, medicines and dietary intakes

CKD= chronic kidney disease, PD= peritoneal dialysis

i.   Evidence-based guideline

Evidence-based guidelines in the RRT programme were mainly used for payment purposes. This is because the NHSO facilitates the RRT delivery system by separating the programme from conventional payment mechanisms (capitation and DRG with global budget), so services in the RRT programme are reimbursed by a fee schedule with global budget. As a result, protocols were crucial for providers as a standard for reimbursements and reporting system, as a policy maker stated:

> "The protocol benefits health care providers, particularly case managers, they know what else needs to be done." (PM9)

A policy maker explained why a fixed price per session or per procedure is used as a strategy to manage the common system failure to motivate providers to provide the costly services:

> "Providers can estimate the amount of profit they will earn for a case. Although, the financial risk for unexpected events is transferred to providers, they seem to like this kind of payment. This is how the NHSO stimulates service behaviour of providers." (PM2)

As guideline protocols were linked to the provider payment, some providers had concerns about the blurred boundaries of guidelines (particularly between health care sectors) and how these might affect their hospitals' income.

> "In my opinion, this programme is good but the procedure (for payment) is confusing. The money went to the hospital where the patient registered. But if that patient has a complication due to PD and goes to another hospital, the cost of this treatment can't be claimed because it's already

paid to the first hospital. […] and there is no guideline about who the money goes to." (PM4)

Providers also felt it was unclear exactly which items could be claimed, and that the list was complex and subject to change.

"The protocol always changes. My hospital director never knows in details of what can or cannot be done (for the claim/reimbursement). So the burden is put on us, the frontline staff." (PV3)

It is true that some issues of the NHSO manual for providers do not contain proper information about reimbursable items, which might therefore make providers unsure how they should proceed. For example, the manual for providers in 2015 did not provide reimbursement rates on PD and did not indicate which items were included in the PD bundle. Furthermore, sometimes reimbursable items in the manual are just general instructions/guidelines but not the exact items which the NHSO reimburses.

ii.   Patient identification process

Policy maker and provider interviewees agreed that the separation of the RRT programme from the normal healthcare mainstream was to ensure patients' access to service, as an interviewee described:

"In this first period, separating the administration of RRT from normal system is good. Patients are targeted and selected to enroll for the programme according to the guideline protocol." (PM9)

Beyond the ease of access to treatment, providers also thought that patients fully benefited from the programme as they were supported along their journey in the care process and could live longer without catastrophic payment. At the same time, providers did not feel they were burdened by this process, as an interviewee explained:

"It is our normal routine to screen and select patients into the dialysis system." (PV2)

However, the programme's mission to find patients who developed early stages of kidney disease in communities had not been fully achieved. Most patient interviewees in this study found out they were suffering from chronic kidney disease when they were already in the last stage and needed urgent treatment.

> *"I had hypertension for two years, then one day I became very ill and vomited a lot and when I went to a doctor, he told me I had end-stage kidney disease." (PD2)*

A nephrologist also confirmed that:

> *"Around half of the ESRD patients weren't aware they had chronic kidney disease. They found out that they had reached the last stage when they got very sick and were taken to the hospital." (PM4)*

iii. Collaborative practice

The inclusion of various groups in the health system into the RRT programme was to strengthen linkages between system components and consequently improve quality of care. The network covers policy makers, health care providers, patients, and patients' communities.

a. NHSO-provider

The NHSO developed partnerships with providers in other governmental sectors, private sectors, and health care professional groups. One key purpose was to increase the number of RRT facilities. Working as a network made covering and building more RRT centres possible even in remote areas. Firstly, the central NHSO asked the regional NHSO to deal with health facilities in their area of responsibility, particularly provincial hospitals. They were supported and encouraged to join the programme until all of them had enough capacity to provide dialysis care. Next, large-size community hospitals and hospitals in remote areas with availability of nephrologists or trained internists were targeted.

In the first phase of the RRT programme, the NHSO once thought about inviting the private sector to take part in expanding RRT services, as there were a large number of private RRT facilities. However, there were concerns about quality control, and the private sector has just begun recently to enter the field via a pilot model which is expected to expand in the near future.

Another purpose was to increase the production of PD nurses, regarding which one interviewee provided further detail:

> *"Before the introduction of the RRT programme, PD nurses were barely trained. So we talked with professors of nursing schools about the amount of new PD nurses needed for the new programme. For any school that could produce such an amount, we would support funding to set up training courses and scholarships for student nurses. (PM3)*

Unlike nurses, physicians were supported by sponsoring conferences and meetings using connections between NHSO and the Nephrology Society of Thailand in order to increase their interest in PD.

b. NHSO-patient

Coordination between NHSO and patient groups played an important role in convincing patients of the value of RRT and of the PD first policy. Also, working as a group can increase bargaining power of patients in negotiating the health benefit package. Since the RRT policy was formulated, representatives from the patient society have been allowed to sit in the meeting of NHSO's sub-committee and are able to express opinions regarding the benefit. An interviewee pointed out about how the RRT programme empowers patients to take an active role in their health care benefit:

> *"It's good that kidney patients have chance to voice their concerns and needs: some others (patient groups for) long term conditions have not been as lucky as we are. The thing is if you (the NHSO) want to know what is going on here, you need us to tell you. I always convince the board about this. So far, I act as a member of the NHSO subcommittee, at which I have equal rights to those of physicians to express my opinions on what kidney*

patients should have. Once there are developments on this issue, I put them on our Facebook to tell everyone in the network. We also have our own newsletters which are issued quarterly. These are how we introduce new health benefits and updates to patients. […] We have working groups of kidney patients in every province. Each working group has similar activities and has its committee which links to their regional hospital. Every year, members are selected from each region to make policy recommendations." (PM8)

c. Patients and community groups

Communities could provide services that complemented the RRT service provision. For example, local health centres, although they had no RRT professionals or equipment, took part in screening patients with chronic kidney disease and cared for them with what they could. If the patient needed to use the injection (erythropoietin), the patient could keep prefilled syringes at a health centre and come back when it was time to use them. This practice helped strengthen their relationships as an interviewee from a health centre stated:

"By doing so, we meet the patient 2-3 times a week. When he comes, we measure the patient's blood pressure, examine his feet, and ask if he needs anything else. Before this, patients had to buy dressing sets themselves which are a bit pricey. So I asked the hospitals to provide a stock of dressing sets at the health centre and patients can get them for free." (PV5)

Health volunteers were another community group who helped bridge the gap between the RRT provision and patients. However, the long-term future of the collaboration was uncertain due to the lack of concrete guidelines and funding. A provider gave details:

"At first, we promoted health volunteers to do home visits to PD patients and assess if their house was qualified for home dialysis, we got good response rates. Sometimes we came along with them to the remote area and sometimes to other provinces. To be frank, it was successful because

there was budget for this activity. At the moment, we don't do home visits

very frequently because the NHSO no longer supports this activity." (PV2)

Patients also built up connections among themselves, which could be via informal talking or the Friends of Kidney Patients Society. The society developed networks working in communities by educating students and young people about kidney disease and other chronic conditions.

"Before these people grow up and become chronically ill, they need to know

how to have a healthy lifestyle and how to prevent themselves from chronic

conditions." (PM8)

However, the degrees of patient-community network varied and depended on the area. An interviewee from a local health centre said:

"As far as I know, there's no kidney patient group in this area. What I saw

is that patients talk about their experiences while they're waiting for

treatments in the hospital." (PV5)

iv. Self-care management

This section focuses on the bag exchanging technique of ten PD patients. The patient who had the longest dialysis period started the treatment in 2009. Most patients had diabetes with or without hypertension. Six patients had never experienced peritonitis (infection of the peritoneum). The majority of patients were living with their family and received support, such as expenses, a place to live in, instruments for PD, or care, from their family members.

a. Places to perform exchange and dialysis bag storage

There were three patients who had a separate room in their house to perform exchanges. The rest did the exchange in their bedrooms in which an extra wash basin for hand washing was fixed in order to perform the exchange. Patients used a corner inside or outside their house to place the stock of dialysis bags. Five out of ten patients had proper storage. This means dialysis bags were kept in a clean place where there was good airflow and no direct sunlight.

b.   Equipment and exchange technique

Seven patients always changed the dialysis bag by themselves while the others needed help from carers. From observations, 5 out of 10 patients had all the essential equipment in line with the CAPD self-care guidelines.

Patients' exchange techniques were generally good. Effective hand washing was the behaviour that 30% of patients failed to perform correctly. All patients knew well how to combine individual pieces and could follow each step correctly. After patients finished loading the dialysis fluid, the majority of them correctly weighed the used solution, recording the result in their diary, and then discarded the waste (see Table 5-6).

Table 5-6 Observed behaviours and percentage of compliance

Behaviour	% compliance
1) Arranging equipment	80
2) Hand washing	70
3) Surface cleaning	80
4) Checking the unused bag	90
5) Combining and connecting exchange devices	100
6) Weighing of used dialysis solution	90
7) Updating health records	90
8) Waste disposal	100

5.4.4   Patients' decision making

Patients' treatment decision is critical when making up their mind on the use of care. Once diagnosed with ESRD and the need for dialysis, patients and their families are informed about the condition and treatment alternatives. If there is no contraindication, patients are obligated to use PD. Because PD is a self-care management and relies heavily on support from the patient's family, the characteristics of the patient and their family, as well as their relationships, are crucial to the decision to accept or refuse PD.

i. Reasons to accept PD

In the PD first policy, in addition to being a normal PD patient, a number of patients had turned to PD after they were no longer able to afford self-pay HD. PD patient interviewees gave advantages of PD that PD relied on them taking responsibility, meaning they could manage their daily life almost as usual:

> *"I like taking responsibility of my own care." (PD1)*

> *"It fits my lifestyle well, I can manage it. When I need to travel, I just take the dialysis kit along." (PD8)*

> *"I live 30 kilometers from the hospital, I can't make frequent journeys (like HD patients), it makes me too tired." (PD5)*

The advantage about travelling, a provider interviewee added:

> *"After starting the RRT programme, patients can easily access dialysis care, even ones who reside far away. It's true that my patients who live on a mountain can have the treatment." (PV1)*

ii. Reasons to refuse PD

One out of the six patient interviewees was wealthy enough to opt out and was having self-pay hemodialysis, in spite of age. Others were on conservative treatment, living without dialysis. The main reason they reported was 'dialysis is too burdensome'. Common characteristics found in these five opt-out patients were advanced age with multiple comorbidities, low literacy levels, being in an underprivileged family, residing in rural areas, and lacking strong family support. These conditions together made patients worry about putting a burden on their family.

However, patients would not say this directly, instead they mentioned 'I'm not afraid of dying'. They also mentioned they were 'scared of being hurt' or 'can't do it' which could be a response or an excuse for unwillingness to have PD. A patient on conservative therapy stated:

"I was afraid, didn't want to be hurt, and didn't want more burdens. Doctors taught and told me everything. They even had a dummy to show me how to do it. My daughter wanted me to try but I just didn't want to. She worked so hard and had too many burdens so I didn't want to burden her any more. [...] I'll finally die someday, and I'm not afraid of it." (OO2)

Some patients with conservative therapy had sole responsibility for taking care of a family member. Therefore, dialysis was too burdensome:

"I told the doctor I'd like to wait (for starting treatment). I didn't have much money and have no one to help me take care of my son who is mentally ill. He can just sit without saying a word. There're just two of us, no money, no car. Treatment is free but not the travel costs, and some medicines, there are so many things to pay for. [...] I took out a loan to rent some land for growing rice and hired someone to help me, so I don't have time to do (dialysis). (OO4)

The GP added his opinions on how people in rural communities are concerned about their families, particularly when they fall ill. Also, an issue about the social norm of rural communities was raised:

"Family is a very important factor. They (patients) worry that doing dialysis will take money from the household, or that their children will have to leave their job to take care of them, and that they will become a burden on the family. [...] Several patients here aren't happy having some medical equipment sticking on their body. They feel like a severely ill person. 'I'd rather die than have that thing in me', they say." (PV6)

iii. Conservative management of end-stage renal disease

Along with renal replacement therapy, conservative therapy is an alternative approach for patients who prefer not to have dialysis. Palliative care, therefore, can support conservative management of ESRD by the practice multidisciplinary team. It involves multiple dimensions of care which have close links to patients' families.

In health facilities where there was a multidisciplinary team, palliative care for patients with chronic kidney disease appeared to facilitate better quality of life and patient self-care. Because the family was encouraged to be involved in care management, another effect on patients was that family members were more bound together.

> *"We found that families who have no choice but to take care of their sick members mostly wanted to get on with their daily lives and ignore the ill. This left the ill alone and lacking in emotional support. This condition makes the ill feel as if they were a burden but after their family came to look after them properly, it relieved the feeling of being a burden." (PV10)*

5.5 Discussion

This section is divided into four parts according to findings from this study. It begins with a discussion on perceptions of high-cost disease by different components in the health system. Next, the policy change and the disease management of the RRT programme are discussed. Finally, this section ends with discussions on patients' decision making and self-care management.

5.5.1 High-cost diseases

Policy makers and providers' views on high-cost diseases focused more on the financially catastrophic definition than the high-cost definition which proposed by Wyszewianski (1986). This may be because the UCS already covers treatments for chronic conditions (such as heart disease and diabetes) that are inexpensive to treat once but require multiple visits, meaning costs soon add up. Patients' views on high-cost diseases were slightly different in that they not only looked at cost of treatments but also indirect costs when they fell ill. For example in this study, although eligible for free treatment, a number of patients commented that paying for travel costs, no carers, and being the sole working member in the family were barriers to receive services. Altogether, these situations can cause a patient to incur catastrophic payment or decline health care.

5.5.2   Creating an environment conducive to policy change

The UCS policy change to include the high-cost benefit, RRT, is best explained by the 'Triangle that moves a mountain' framework proposed by Wasi (2000). The triangle model of Wasi has been widely used in explaining policy process in Thailand (Wibulpolprasert, Chokevivat et al. 2011). This could be the reason that interviewees who were working in the health policy area had this model in their mind, so they always mentioned keywords relating to this model while giving interviews.

Wasi's triangular model highlights the essential interaction between three components. The first component is knowledge generation, which studies the issue until it can explain the possibility of the policy implementation. This may be accompanied by lessons learnt from pilot studies. The next component is the public, who raise the issue to the attention of politicians. The last component is the politicians, who ensure that the issue is ranked as top priority (Wasi 2000).

Figure 5-5 Triangle that moves a mountain model

Creation of knowledge

Societal movement   Political involvement
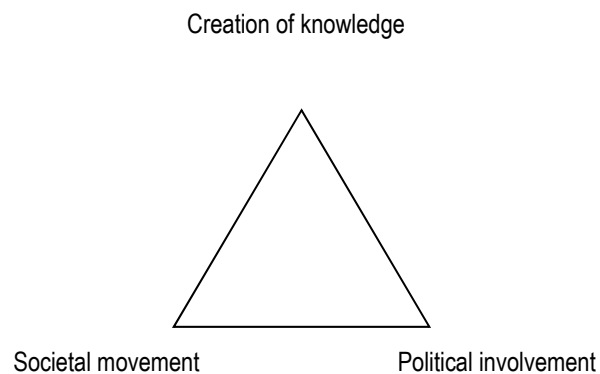
Adapted from: Wasi (2000)

The process of including the RRT benefit is one example of Wasi's model. The creation of knowledge presented various aspects that needed to be considered. These included numbers of available health care staff and facilities, budget needs, public opinion, and policy options and recommendations on this issue. Meanwhile, the public were aware that renal failure could bring patients into catastrophic health spending. This corresponded to the desire of UCS policy makers who aimed to protect its beneficiaries from financial catastrophe. The

government, which at the time had the full power of the military coup and government leaders' intention to support equality, meant that the move to introduce the RRT benefit was successful.

5.5.3 Disease management of RRT in Thailand

Generally, applications of disease management programmes vary in terms of common definitions of concepts, levels of integration among sectors in the health system, and each programme's focus (Krumholz, Currie et al. 2006; Nolte and McKee 2008; Hisashige 2012). The UCS adopts the disease management approach to address the issue in its normal mainstream where the capitation and DRG payments are not persuasive to treatment providers, particularly in terms of providing treatment for patients who are suffering from high-cost conditions.

In arranging the RRT programme, its administrative functions and financing system were separated from mainstream UCS services. By doing this, the disease management approach was more focused, and providers were motivated by fee schedule payment to provide this high-cost care as they could earn more by providing more services.

The key disease management interventions used were evidence-based guidelines and reporting systems. The evidence-based guidelines lay down the procedure based on medical evidence for providers. The guidelines were bound with the payment mechanism and led to other components of disease management which were patient identification, collaborative practice, reporting systems, and self-management by patients and families. In the RRT programme, patients are targeted and selected to enroll for the programme according to the guideline protocol. Payments are paid to RRT units by the reporting system. The collaborative practice is an integral part of the RRT programme between and within the groups: policy maker, provider, and patient. It is used as a means of improving the quality and efficiency of caring for patients with end-stage renal disease.

Some providers mentioned difficulties they had about guideline protocols. This might reflect the fact that making a guideline protocol that suits everybody's preference is a challenge to policy makers, particularly linking a protocol with payment and frequent updating with new information. This is because guideline protocols are made at the central NHSO and are used by providers at different levels of care, protocols should be practical and new information should be clear for providers what they should do to fulfill their duty.

5.5.4   Patients' self-care management

Patient's self-care management is a crucial part in the RRT disease management programme. It was a result of limitations in UCS resources since numbers of RRT units and health care professionals were poorly distributed and were not numerous enough to meet the high need of patients with end-stage renal disease. Policy makers of the UCS agreed that peritoneal dialysis was best suited to the UCS context as it had enough capacity to expand the RRT health benefit to reach patients quickly once the policy was launched. Given the developing country setting of the UCS, the benefits of peritoneal dialysis outweigh those of hemodialysis as the former requires fewer nurses to look after patients and fewer visits to hospitals.

Patients who first enroll in the RRT programme rely upon PD. PD is a home-based dialysis and the patient characteristics can influence their practices and performance. All patients and/or their carers in this study know how to perform the exchange procedure, but due to being poor or unaware of the infection, there was some lack of essential equipment for bag exchange, violating sterile technique, and having unclean environment for PD bag exchange. Consequently, these situations may lead to the infection of the peritoneum.

Family plays an important role in patients' decision making before they enroll in the RRT programme and in supporting patients once they have joined in. Encouragement and help from family were mentioned by all interviewees who chose to undergo dialysis and those who were functioning post-renal transplant

in this study. Conversely, family support was lacking among those who declined to start dialysis.

Although the RRT programme is carefully designed, a number of patients who are eligible for the programme decided not to enroll because dialysis is viewed as too burdensome. Common characteristics of these patients include advanced age, belonging to an underprivileged family, low levels of education, and no carer to help. Social norms can also determine the use of care. In particular, having dialysis instruments on them makes some patients feel they cannot maintain their ordinary life like others. These patients refuse dialysis so as to avoid social exclusion. An alternative to dialysis, conservative therapy, is efficiently applied in some health facilities where a multidisciplinary team exists. A constraint to this approach may include the limited number of health facilities in Thailand offering multidisciplinary team management, as well as variation in practices and the level of collaboration.

5.6   Conclusions

This study has highlighted how the combination of three components: the academicians, public actions, and politicians, in long effort to launch the UCS RRT programme, has achieved. Despite Thailand, in the first place, is a developing country lacking nationwide RRT staff and facilities. A disease management approach was used to arrange RRT service provision aiming to increase ESRD patients' access to care.

From the UCS experience with the RRT programme, building the system resources and designing policies are the basic elements which support the reform of delivery system design. This includes the application of disease management: evidence-based guidelines, patient identification process, self-care management, and reporting systems by means of collaboration between people at different levels in the health system.

After launching the RRT programme, the majority of patient interviewees reported that they had good quality of life, however some patients felt indirect

costs of travelling to the RRT unit were too large for them. This study found a number of patients in a community hospital refused to start dialysis but were looked after by a multidisciplinary team. This multidisciplinary approach was found to be able to fill a gap between primary care providers and ESRD patients.

CHAPTER 6   The changing patterns of access to service and mortality of the RRT programme overtime

6.1   Introduction

This chapter aims to assess the changing patterns of 1) entry into the RRT programme of adult UCS patients diagnosed with end-stage renal disease (ESRD) and 2) mortality of adult UCS members who had an ESRD diagnosis, using descriptive analysis and an age-period-cohort analysis. The main point to establish is whether launching the RRT programme promoted entry into the programme and reduced the mortality rate over time.

Next section, 6.2 provides the framework for data analysis, a summary of variables used in all models, and explains how the datasets were constructed and analysed. A number of indicators to measure access to RRT services and mortality are described here. Section 6.3 presents the results of an analysis of these indicators. Sections 6.4 and 6.5 discuss findings and limitations of this chapter.

6.2   Data analysis and modelling approach

The conceptual framework for the analysis of this objective is presented in Figure 6-1. From the general UCS population, a number of patients develop chronic kidney disease. After that, a number of them develop the final stage and need RRT. Access to RRT is measured by new registrations into each RRT modality as a proportion of the number of new patients diagnosed with ESRD. Death while on RRT is measured as the proportion of all-cause mortality among patients who were maintaining RRT. Because there are many untreated patients, all-cause mortality of all patients with an ESRD diagnosis would be assessed as an indicator to show patients' overall health status.

Figure 6-1 Conceptual framework for analysing access and mortality
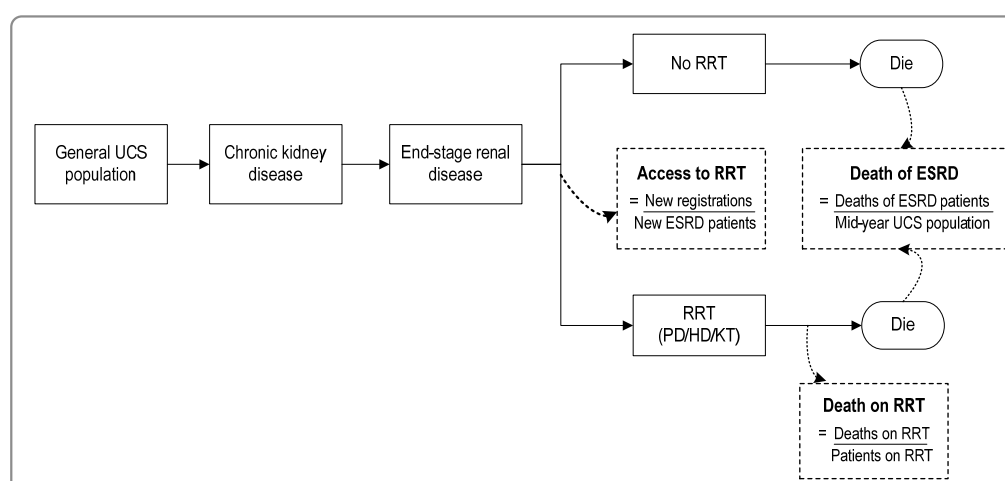
UCS=Universal Coverage Scheme, RRT=renal replacement therapy, PD=peritoneal dialysis, HD=hemodialysis,
KT=kidney transplant, death=all-cause of death

6.2.1 Summary of models and variables

Table 6-1 provides a summary of models and variables used in both descriptive analysis and age-period-cohort analysis. In terms of entry into the RRT programme, the study period is between 2008 and 2013. In this study, mortality refers to death by any cause, assessed between 2005 and 2013.

To assess the pattern of entry into the RRT programme, three models were separately analysed in line with the UCS's RRT modalities: peritoneal dialysis (PD), hemodialysis (HD), and kidney transplant (KT). To assess changes in death rates, all-cause mortality is assessed in two groups of patients: all patients with an ESRD diagnosis and patients who were maintaining any RRT modality.

Age of the entry into the RRT programme model was determined by the time between the year of birth and the year of the programme's registration where age in the mortality model referred to the time between the year of birth and the year of death. Cohort was the individuals' years of birth. The period in all models denoted calendar years of studied period. As a short duration was available for period (6-9 years in comparison to durations of age and cohort), period was used as a single year interval. In entry into the RRT programme models, three modalities of RRT were separately used as covariates.

Table 6-1 Summary of models and variables

Model	1. Entry into the RRT programme	2. Mortality
Follow-up period	Jan 2008 – Dec 2013	Overall ESRD mortality: Jan 2005 - Dec 2013
		CFR and RRT mortality: Jan 2008-Dec 2013
Measure	ESRD patients who have experienced dialysis registration or kidney transplant	ESRD patients who died due to any cause or patients who died on RRT
Numerator	Number of new registrations or transplantation	Number of deaths
Denominator	New ESRD diagnoses of UCS	Mortality of ESRD patients: mid-year UCS population
		Case fatality: UCS patients with ESRD diagnosis
		RRT mortality: UCS patients who used RRT
Variable: Age	Number of years between the year of birth and registration with the RRT programme (or transplantation)	Number of years between the year of birth and the year of death
	Range: 20-89 years (dialysis)	Range: 20-89 years
	: 20-60 years (KT)	
Variable: Period	Calendar year of registration or transplantation	Calendar year of death
	Range: 2008-2013	Range: 2005-2013 or 2008-2013
Variable: Cohort	Calendar year of birth	Calendar year of birth
	Range: 1908-1993	Range: 1905-1993
Covariates	HD, PD, and KT	None

UCS=universal coverage scheme, ESRD=end-stage renal disease, CFR=case facility rate, RRT=renal replacement therapy, HD=hemodialysis, PD=peritoneal dialysis, KT=kidney transplant

The data analysis involved three main steps; 1) constructing main dataset, 2) descriptive analysis, and 3) age-period-cohort analysis.

6.2.2   Constructing main datasets

To construct the main dataset for all types of analyses in this study, the first step was to select all patients who were diagnosed with end-stage renal disease from the inpatient and outpatient databases. Next, their encoded citizen numbers were matched with encoded citizen numbers in the RRT database and

vital registry. This stage yielded 189,059 UCS patients with an ESRD diagnosis. Table 6-2 gives an example of the dataset at this point.

Table 6-2 First ten observations of the main dataset

	Encoded citizen number	Date of Birth	Year of Diagnosis	Year of Registration	Year of Death	Modality
1	++GlXQAecEU+pRH01JSPEg==	.	2011	.	2013	None
2	++GlXQAecEU3g9P0Vpp5ow==	.	2009	.	.	None
3	++GlXQAecEUbnKTSWrSB+w==	.	2008	.	.	None
4	++GlXQAecEUvA3rv2+ZMyA==	02-Sep-64	2011	2011	2012	PD
5	++GlXQAecEV2J/Jw/D9uJw=	25-Sep-63	2013	2014	.	PD
6	++GlXQAecEV7qhDaldT8xg==	.	2012	.	2013	None
7	++GlXQAecEVDUCjKc6qO/Q==	.	2004	.	2005	None
8	++GlXQAecEVMHvANBIlfCA==	.	2011	.	2012	None
9	++GlXQAecEVN4i514t1G2g==	09-Mar-45	2008	2011	2011	HD
10	++GlXQAecEVUyXW6hqRF+A==	01-Jul-53	2008	2009	2012	HD

Next, individuals were grouped into 14 five-year age at registration (or at death) groups (aged 20-24 to 85-89), 15 five-year cohort groups and a two-year cohort group (5-year group from 1916-1990 and 1991-1993). Period is used as a 1-year interval (from 2005-2013). Table 6-3 provides an example of the dataset when individuals were grouped into ranges of age, cohort, and period.

Table 6-3 First ten observations of the aggregated dataset of the death model

	Age	Cohort	Period	Age Group	Cohort Group	Period Group	Death Counts	Population
1	20	1988	2008	35-39	1986-90	2008	13	51
2	21	1987	2008	20-24	1986-90	2008	12	73
3	22	1986	2008	20-24	1986-90	2008	8	71
4	23	1985	2008	20-24	1981-85	2008	8	70
5	24	1984	2008	20-24	1981-85	2008	11	94
6	25	1983	2008	25-30	1981-85	2008	14	71
7	26	1982	2008	25-30	1981-85	2008	11	112
8	27	1981	2008	25-30	1981-85	2008	17	107
9	28	1980	2008	25-30	1976-80	2008	16	126
10	29	1979	2008	25-30	1976-80	2008	16	128

Age=age at death, Cohort=calendar year of birth, Period=year of death, death counts=number of deaths in a particular group, population=number of patients in a particular group

6.2.3   Descriptive analysis

The descriptive analysis is presented in two sections for the two main models: entry into the RRT programme model, and a mortality model.

6.2.3.1   Entry into the RRT programme models

For peritoneal dialysis (PD) and hemodialysis (HD) entries into the RRT programme were identified by patient registrations. Patients who had a kidney transplant (KT) were identified as entering into the programme according to their date of transplantation.

For the dataset of entry into the RRT programme, only those who used such treatment were retained. Three variables in the three models, namely age, period, and date of birth were generated from the pooled data of all individuals. Age denotes number of years between the year of birth and the year of first registration in the RRT programme. Period is calendar years spent registered. Cohort refers to individuals' years of birth.

To calculate rates of registrations, numbers of new registrations with PD or HD or numbers of transplantation were used as numerators. The reference population, the denominator, was the annual number of new patients diagnosed with ESRD. The period for studying entry into the RRT programme was 2008 to 2013. This is because the RRT programme started in January 2008, and data was available from this point. Rates were expressed as rates per 100 new ESRD diagnoses (PD, HD) and 1,000 new ESRD diagnoses (KT).

6.2.3.2   Mortality models

There are three types of mortality models: 1) the death rate of ESRD patients, 2) the ESRD case fatality rate, and 3) the RRT mortality rate. These all differ in terms of numerators and denominators used.

To construct the dataset of the death cohort from the main dataset, only those who died were kept. Next, individual records were collapsed in order to create aggregate level data for age, period, and cohort. In these models, age denotes

the number of years between the year of birth and the year of death. Period is the calendar year of death. Cohort refers to an individual's year of birth.

i. Death rate of ESRD patients

Death rates of ESRD patients were calculated to estimate deaths of patients with an ESRD diagnosis among the UCS population. All-cause death counts of those with ESRD in each age group were used as the numerator. The denominator was the number of mid-year UCS members. Rates were expressed as rates per 100,000 UCS population. The follow up period to estimate all-cause mortality was 2005 to 2013.

$$\text{ESRD death rate} = \frac{\text{Number of deaths from all causes among patients with ESRD x 100,000}}{\text{Number of mid-year UCS members}}$$

Age-standardised mortality rates were estimated to compare all-cause mortality rates of patients with ESRD over time, in case there was a change in the age structure of the UCS population. Rates were calculated by the direct method using the WHO world population (2000) as the reference and expressed as rates per 100,000 UCS population.

ii. Case fatality rate (CFR)

The case fatality rate is a measure of the severity of a disease. It is the proportion of persons with the disease who die from it. In this study, it was calculated using the formula below:

$$\text{CFR} = \frac{\text{Number of deaths from all causes among patients with ESRD x 100}}{\text{Number of all patients with ESRD}}$$

Gordis (2008) suggested that the CFR is ideally suited for measuring the severity of short-term diseases or acute conditions. For example, Mason and Goldacre (2004) used the CFR of emergency admissions to compare hospital performance. The current study calculated the CFR to estimate the trend of deaths. This made it possible to compare deaths among ESRD patients (in this section) with deaths in the UCS population (in section *i*).

iii.   RRT mortality

RRT mortality was calculated in order to reveal mortality rates in patients who were maintaining RRT. The numerator was death counts from any cause of those UCS members using any RRT modality (peritoneal dialysis, hemodialysis, and kidney transplant). The denominator was the number of UCS members who were on RRT. Rates were expressed as rates per 1,000 patient years at risk. The age-standardised mortality rate was calculated by the direct method using the WHO world population (2000) as the reference. The formula is shown below.

$$\text{RRT mortality rate} \quad = \quad \frac{\text{Number of deaths from all causes among patients on RRT x 1,000}}{\text{Number of all patients on RRT}}$$

6.2.4   Age-period-cohort analysis

There were two steps of age-period-cohort analysis. The first step was to select the model which yielded the lowest deviance in comparison to the standard model (or the null model which contains only the age parameter). The second step was to model effects of age, period, and cohort. They are presented in the assessing goodness-of-fit section and modeling effects of age, period, and cohort section respectively.

6.2.4.1   Assessing goodness-of-fit

A set of nested models (likelihood-ratio test) was used to compare the goodness-of-fit within a set of models. This was done by first comparing the deviance of any model that deviates from linear effects (the null model). The deviance was then compared in this manner until the deviance of the last pair models was obtained. The preferred model was selected by the lowest deviance. There were five models to be compared with the null model: 1) Age-drift (linear effect), 2) Age-period, 3) Age-cohort, 4) Age-period-cohort, and 5) Age-drift (non-linear effect). The best fitting model would be further used to estimate effects of age, period, and cohort.

6.2.4.2   Modeling effects of age, period, and cohort

This study modeled effects of age, period, and cohort using the parametrisation method proposed by Carstensen (2007). After identifying the best model, the effects of the key variables (age, period, and cohort) were estimated by using a log-linear Poisson regression. For parametrisation, drift was extracted by the weight average method. Knots (parameters) were equally spaced. Equal numbers of knots were allocated to age, period and cohort. The study used five knots in all models. As this study sought to explain the effects of calendar time on death and registration, drift was put on the period variable. Then the cohort effect was constrained to have no overall slope and to be zero on average on the log scale. After adjustment of the cohort effect, the age effect was estimated for the selected reference period (year 2010).

Data analyses and graphical presentations in this study were conducted by using Stata version 12. Modelling was carried out using the *apcfit* command (Rutherford, Lambert et al. 2010). Only goodness of fit was assessed using R studio version 3.0.2. All confidence intervals are 95% confidence intervals. Selected Stata commands were shown in Appendix 7.

6.3   Results

In this section, descriptive analysis is presented first. It is followed by the age-period-cohort model fitting. The results of entry into the RRT programme (for hemodialysis, peritoneal dialysis, and kidney transplant) and mortality are separately reported.

6.3.1   Entry into the RRT programme

Entry into the RRT programme was represented by new registrations with the two dialysis modalities or undergoing transplantation. The selected time period to conduct data analysis was six years between 1 January 2008 and 31 December 2013.

6.3.1.1   Descriptive analysis

Table 6-4 and Table 6-5 show numbers of new patients with ESRD, aged 20-89, registered with PD and HD programmes respectively. From 2008 to 2013, annual figures of new PD patients increased over time and the total number of new PD registrations in this period was 27,386.

Table 6-4 Numbers of new peritoneal dialysis registrations 2008-2013

Age	2008	2009	2010	2011	2012	2013	%Total
20-24	63	94	80	104	132	113	2.17%
25-29	66	130	106	129	138	121	2.55%
30-34	94	144	179	155	167	201	3.37%
35-39	101	201	208	251	247	259	4.56%
40-44	150	315	330	346	412	460	7.15%
45-49	185	428	498	571	608	641	10.42%
50-54	196	518	639	729	813	838	13.36%
55-59	201	557	734	837	955	1,078	15.67%
60-64	118	506	699	839	992	1,101	15.58%
65-69	76	362	495	636	726	838	11.58%
70-74	42	196	362	399	476	555	7.61%
75-79	18	103	148	216	225	304	3.93%
80-84	7	33	48	80	91	90	1.50%
85-89	-	7	15	22	18	21	0.54%
Total	1,317	3,594	4,541	5,314	6,000	6,620	100.00%

In the same period and for the same age groups, the number of new HD registrations was lower than that of PD at a total of 19,055 registrations. In 2008, figures of HD registrations were high as a consequence of the policy that allowed current self-funded HD users to enter the RRT programme and access free HD. Total numbers of HD registration increased to a peak in 2011 and declined slightly after that, Table 6-5.

Table 6-5 Numbers of new hemodialysis registrations, 2008-2013

Age	2008	2009	2010	2011	2012	2013	%Total
20-24	141	141	141	141	141	141	4.44%
25-29	161	29	65	69	58	51	2.27%
30-34	206	45	88	86	87	75	3.08%
35-39	288	52	99	127	110	129	4.22%
40-44	403	81	163	177	148	142	5.85%
45-49	534	90	205	264	267	219	8.29%
50-54	788	110	280	336	316	308	11.22%
55-59	874	150	343	433	426	445	14.02%

Age	2008	2009	2010	2011	2012	2013	%Total
60-64	901	134	386	482	465	469	14.89%
65-69	893	97	287	364	374	313	12.22%
70-74	725	73	252	319	275	265	10.02%
75-79	434	37	132	199	182	146	5.93%
80-84	194	12	69	87	101	57	2.73%
85-89	58	4	22	27	33	14	0.83%
Total	6,600	1,055	2,532	3,111	2,983	2,774	100.00%

The total numbers of ESRD patients who had a kidney transplant increased slowly from 2008 until 2012. After that, a slight drop was observed in 2013. The age group 35-39 accounted for the highest proportion at around 15% of overall cases. From 2008, there was a total of 992 kidney transplants (see Table 6-6).

Table 6-6 Numbers of kidney transplants 2008-2013

Age	2008	2009	2010	2011	2012	2013	%Total
20-24	9	9	17	39	31	18	12.40%
25-29	6	17	16	19	33	21	11.29%
30-34	13	12	17	34	37	28	14.21%
35-39	15	20	16	37	37	22	14.82%
40-44	15	9	20	17	33	32	12.70%
45-49	12	24	11	19	35	26	12.80%
50-54	11	11	22	12	27	27	11.09%
55-59	12	12	14	25	11	20	9.48%
60-64	0	0	4	0	3	5	1.21%
Total	93	114	137	202	247	199	100.00%

Table 6-7 shows annual numbers of UCS patients who were newly diagnosed with end-stage renal disease in the corresponding age groups and periods. New ESRD diagnoses decreased from a maximum of 35,186 diagnoses in 2008 and then fluctuated between 15,000-34,000 diagnoses per year. Although there was a variation in the total numbers, percentages of patients within each age group did not much change after the initial year (2008).

Table 6-7 Numbers of new ESRD diagnoses with percentages in parentheses 2008-2013

Age	2008	2009	2010	2011	2012	2013
20-24	418 (1.2%)	168 (1.1%)	284 (0.8%)	360 (1.1%)	293 (0.9%)	174 (0.9%)
25-29	638 (1.8%)	285 (1.9%)	400 (1.2%)	474 (1.4%)	377 (1.2%)	218 (1.1%)
30-34	970 (2.8%)	411 (2.7%)	612 (1.8%)	689 (2.0%)	535 (1.7%)	329 (1.6%)
35-39	1257 (3.6%)	511 (3.4%)	771 (2.3%)	936 (2.7%)	795 (2.5%)	481 (2.4%)

Age	2008	2009	2010	2011	2012	2013
40-44	1825 (5.2%)	769 (5.1%)	1206 (3.5%)	1392 (4.1%)	1185 (3.7%)	802 (4.0%)
45-49	2549 (7.2%)	1084 (7.2%)	1804 (5.3%)	2210 (6.5%)	1828 (5.7%)	1208 (6.0%)
50-54	3677 (10.5%)	1410 (9.4%)	2663 (7.8%)	2995 (8.8%)	2688 (8.4%)	1719 (8.5%)
55-59	4392 (12.5%)	1811 (12.1%)	3339 (9.8%)	3841 (11.3%)	3680 (11.5%)	2425 (11.9%)
60-64	4407 (12.5%)	1904 (12.7%)	3830 (11.2%)	4509 (13.2%)	4326 (13.5%)	2849 (14.0%)
65-69	4613 (13.1%)	1943 (13.0%)	3741 (11.0%)	4394 (12.9%)	4274 (13.3%)	2758 (13.6%)
70-74	4555 (12.9%)	1872 (12.5%)	3919 (11.5%)	4632 (13.6%)	4460 (13.9%)	2577 (12.7%)
75-79	3448 (9.8%)	1553 (10.4%)	3320 (9.7%)	4054 (11.9%)	3782 (11.8%)	2388 (11.8%)
80-84	1776 (5.0%)	863 (5.8%)	2017 (5.9%)	2507 (7.4%)	2650 (8.3%)	1635 (8.1%)
85-89	661 (1.9%)	419 (2.8%)	872 (2.6%)	1113 (3.3%)	1207 (3.8%)	733 (3.6%)
Total	35,186 (100%)	15,003 (100%)	28,778 (100%)	34,106 (100%)	32,080 (100%)	20,296 (100%)

i. Peritoneal Dialysis

Results from the peritoneal dialysis database show a broad range of new registration rates across age groups, calendar years, and cohort groups (Figure 6-2 a-d).

Figure 6-2 a and c

Over the six-year period, it is clear that registration rates decreased with increasing age. Although the registration rate in 2008 was low due to the start of the programme, in 2009, the rates went up to a peak across most age groups and then gradually decreased in successive years. Between 2010 and 2012, PD registration rates went down and were approximately equal within same age groups. In 2013, most age groups showed significantly increasing registration rates.

Figure 6-2 b and d

An increase in the registration rates among the more recent cohort groups (birth cohorts 1956-60 to 1991-93) and younger patients (20-24 to 50-54 years old) was observed. In contrast, earlier cohort groups (birth cohorts 1916-20 to 1936-40) and older patients registration rates (65-69 to 85-89 years old) increased but at a slower rate.

Figure 6-2 Registration rates of new peritoneal dialysis cases 2008-2013
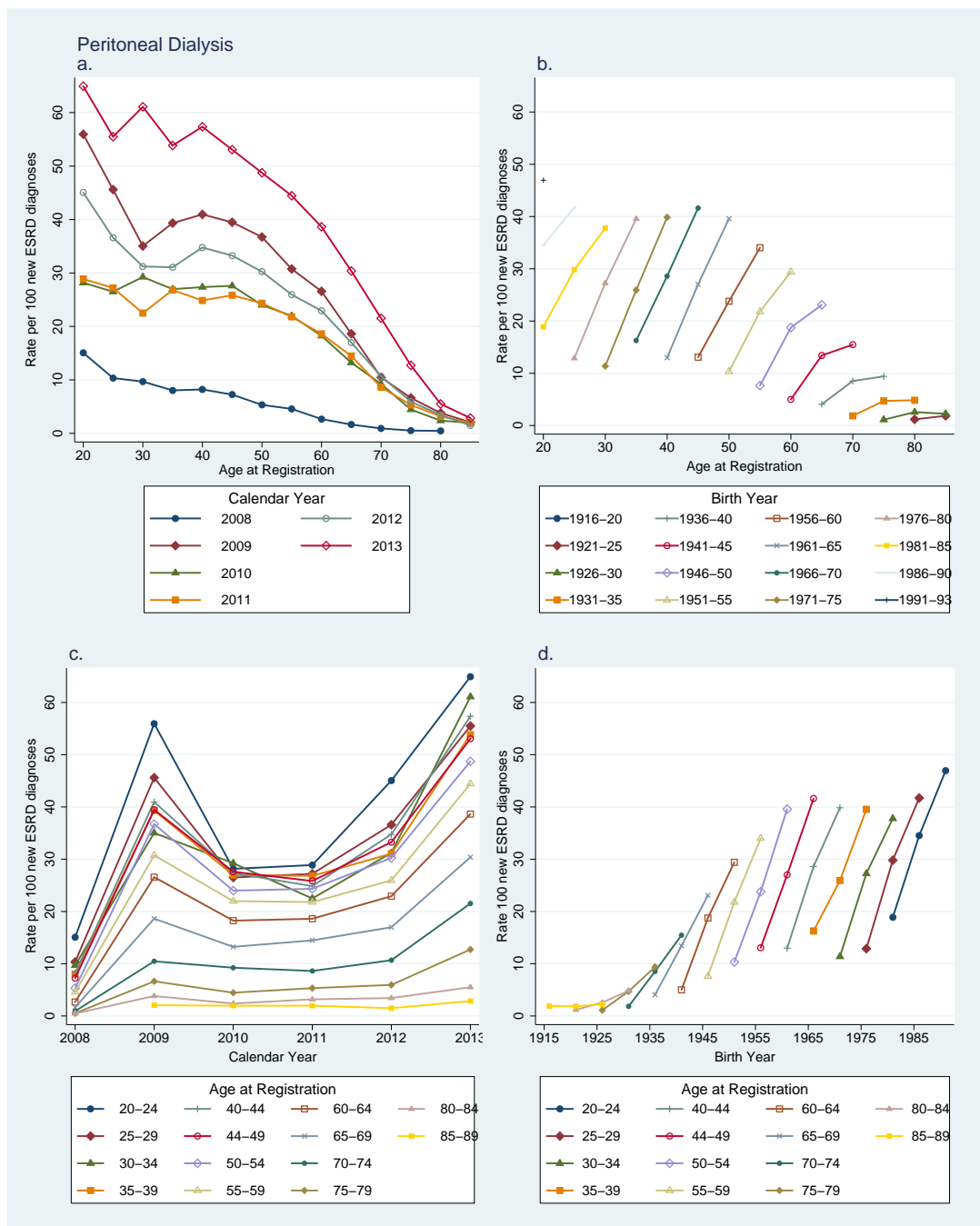
ii.   Hemodialysis

Figure 6-3 a-d give information about registration rates of ESRD patients into the UCS's hemodialysis programme between 2008 and 2013 by calendar year, age group, and cohort group.

Figure 6-3 a and c

In 2008 HD registration rates were high, at around 20 cases per 100 new ESRD diagnoses, and were more apparent in patients under 65. This however, was a consequence of the transfer of existing self-funded HD patients into the UCS programme. From 2009 to 2012, hemodialysis registration rates went down and were fairly homogeneous across patients aged 20-60 years, at around 10-15 cases per 100 ESRD diagnoses. In 2013, rates in these age groups rose to 15-25 cases per 100 new ESRD diagnoses.

Figure 6-3 b and d

The majority of cohorts showed a decreasing trend over the study period. There were some cohorts that showed a slight upward trend of registration into HD as they aged, which were 1966-1970 and 1976-1980 cohorts.

Figure 6-3 Registration rate of new hemodialysis cases, 2008-2013
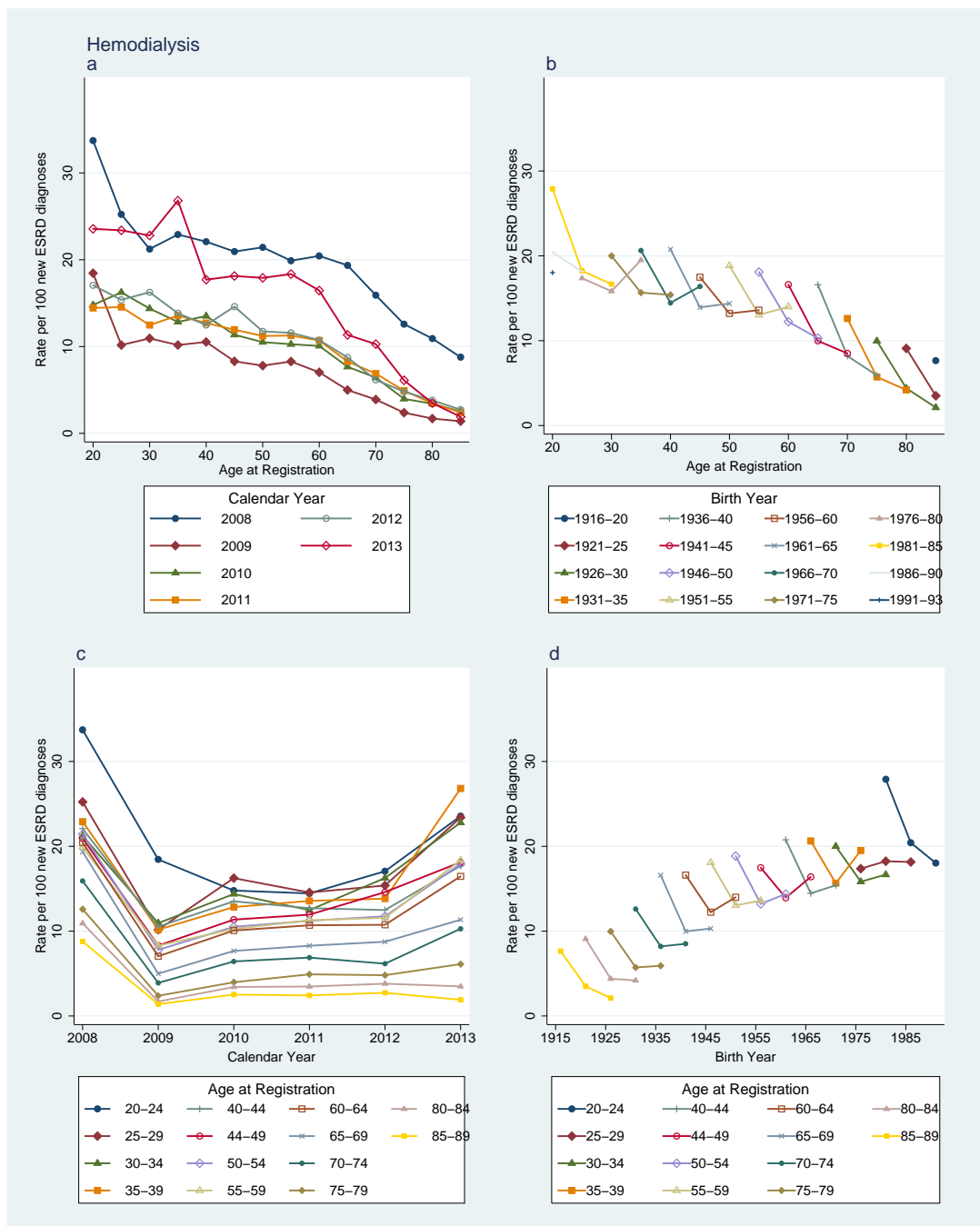
iii. Kidney transplant

Kidney transplant rates in patients aged 20-60 years were expressed as a rate of new transplantations per 1,000 new ESRD diagnoses, Figure 6-4 a-d.

Unlike registrations for PD and HD, it is clear that transplant rates increased over time from 2008. However, rates decreased rapidly with age. Patients aged

20-35 years had the highest transplantation rates, with 80-100 cases per 1,000 new ESRD diagnoses. Rates went down to 20 or less cases per 1,000 new ESRD diagnoses in patients aged over 44 (see Figure 6-4 a and c).

Transplant rates increased significantly in 1961 and subsequent cohorts while cohorts before 1961 had low and stable rates, see Figure 6-4 b and d.

Figure 6-4 Kidney transplant rates of new ESRD diagnoses 2008-2013
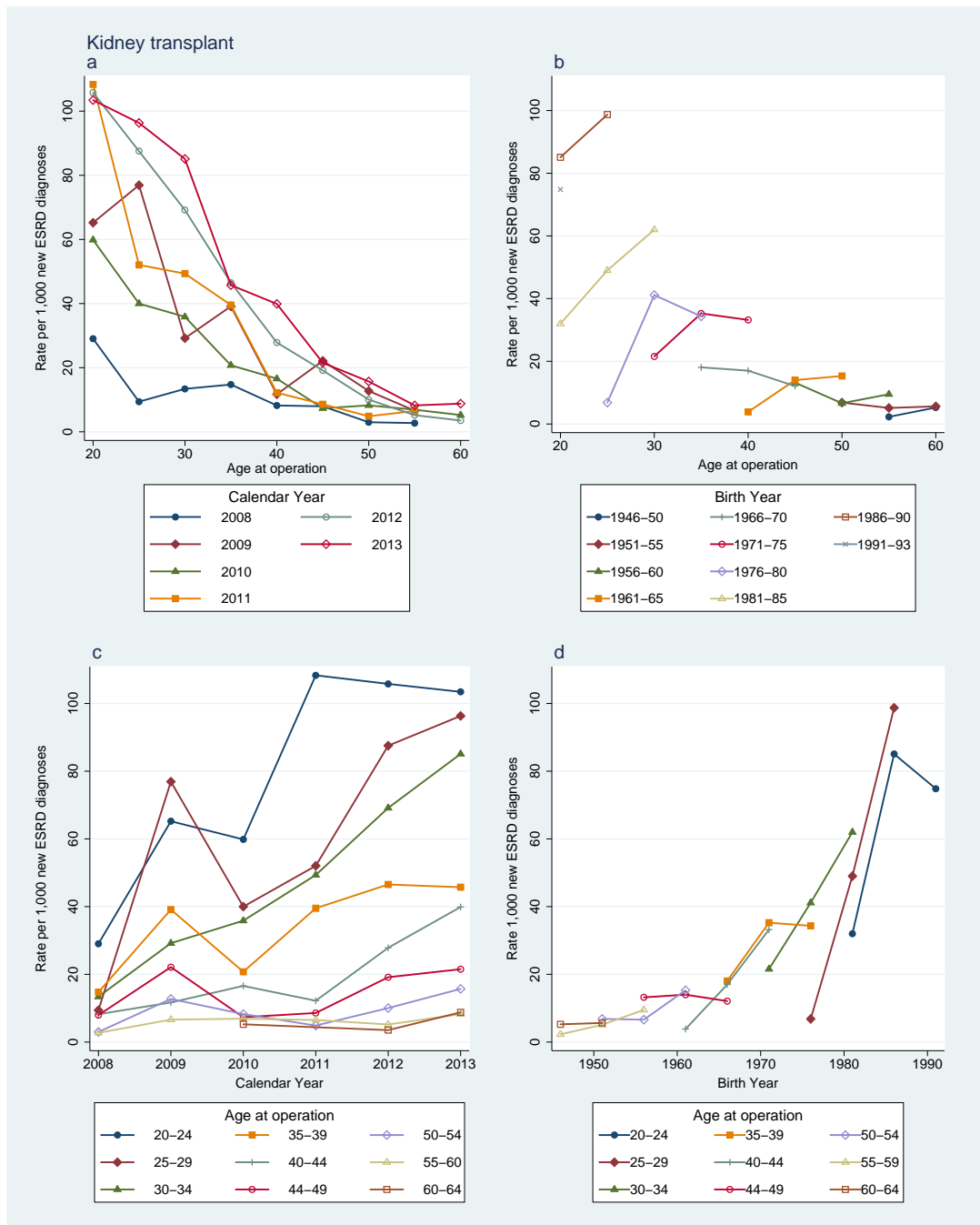
6.3.1.2 Model fitting

Table 6-8 shows the model selection procedure for the age-period-cohort analysis. For both peritoneal and hemodialysis dialysis, the age-cohort model and age-period model were comparable in terms of calculated deviance difference (48 and 52 in peritoneal dialysis and 12 and 16 in hemodialysis respectively) and far better than the full age-period-cohort model (ΔD 195 in

peritoneal dialysis and ΔD 14911 in hemodialysis). These results showed that either age-cohort or age-period was enough to explain registration rates over time. As this study was more focused on the period effect than the cohort effect, the age-period model was selected for age-period-cohort analysis.

Table 6-8 Comparison of age-period-cohort sub-models

	Model	Effect	D[a/]	Residual df	ΔD[b/]	*p*-value
PD	Age	Reference	2713.9	539	Reference	
	Age-drift	Δ|A[c/]	2659.7	538	54.127	<0.001
	Age-Cohort	C|A[d/]	2612.2	534	47.535	<0.001
	Age-Period-Cohort	P|A,C[e/]	2416.8	530	195.357	<0.001
	Age-Period	C|A,C[f/]	2469.2	534	-52.409	<0.001
	Age-drift	C|A[g/]	2659.7	538	-190.483	<0.001
HD	Age	Reference	25537	542	Reference	
	Age-drift	Δ|A[c/]	21934.1	541	3602.9	<0.001
	Age-Cohort	C|A[d/]	21922.3	537	11.9	0.018
	Age-Period-Cohort	P|A,C[e/]	7011.3	533	14911	<0.001
	Age-Period	C|A,C[f/]	7027.6	537	-16.3	0.002
	Age-drift	C|A[g/]	-14906.6	541	-14906.6	<0.001

[a/] Residual deviance
[b/] Increase in residual deviance from the next upper model
[c/] Linear effect of cohort or period adjusted for age
[d/] Non-linear cohort effect adjusted for age
[e/] Non-linear period effect adjusted for age and cohort
[f/] Non-linear cohort effect adjusted for age and period
[g/] Non-linear period effect adjusted for age

6.3.1.3   Effects of age and period

Estimated effects of age and period on entry into peritoneal dialysis, hemodialysis, and kidney transplant are presented in Figure 6-5. In the reference year 2010, effects of age on both types of dialysis were strongest for patients aged 20-60 years. Among patients aged 20 to 60 years in the chosen reference period (2010), peritoneal dialysis saw many more new registrations than hemodialysis at the rate of around 220 PD patients per 1,000 new ESRD diagnoses for the 20-60 age group. This meant PD could take up to 220 new patients in this age group for every 1,000 new ESRD diagnoses in 2010. Above

age 60, registration rates for both PD and HD fell rapidly. The hemodialysis registration rate stood at around 15 patients per 1,000 new ESRD diagnoses. These meant there were 15 new HD registrations for every 1,000 new ESRD diagnoses in 2010 (Figure 6-5 a and c). The kidney transplant rate decreased exponentially with age. It started with a rate of 60 cases per 1,000 new ESRD diagnoses at age 20, and fell to 2 cases per 1,000 new ESRD diagnoses at age 60 (Figure 6-5 e).

Period (calendar year of registration) showed fluctuating trends in both dialysis modalities and in kidney transplant. For peritoneal dialysis registration, there was a sharp increase between 2008 and 2010. Just after 2011, numbers of registrations dropped, followed by an increase by the end of 2013, Figure 6-5 b. Hemodialysis registration rates were at their highest between 2008 and 2009, as reflected by the rate ratio at 40. This means that in this period, HD registered 40 times more new patients than in 2010. After this period the ratio fell and was followed by a sharp increase at the beginning of 2011. Like the trend of peritoneal dialysis, hemodialysis registrations decreased in 2011-2012 then started to increase again in 2013, Figure 6-5 d. Kidney transplant in 2008-2012 was performed, at best, at around 1.5 times the rate in 2010. However, after the middle of 2012, the rate increased, Figure 6-5 f.

Figure 6-5 Effects of age (a, c, and e) and period (b, d, and f) on dialysis registrations and transplant
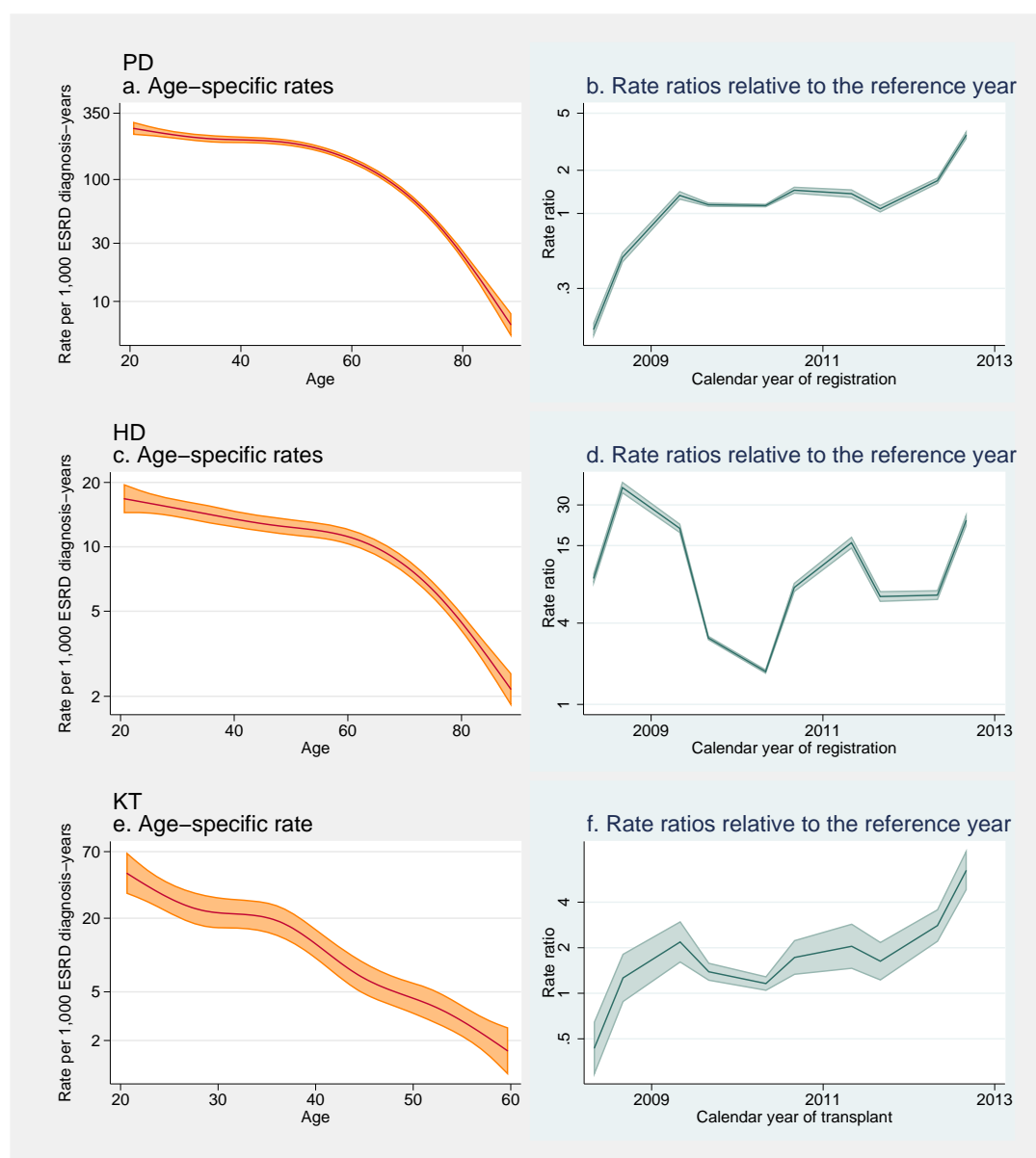
HD= hemodialysis, PD=peritoneal dialysis, KT=kidney transplant

Note: Figures a, c, and e show estimated rates by age of (a) peritoneal dialysis: PD, (c) hemodialysis: HD, and (e) transplantation: KT. Rate ratios in Figures b, d, and f compare new registration rates of PD (b), HD (d), and transplantation rates (f) in a particular year and the rate in the reference year (2010). Shaded areas are 95% confidence intervals

6.3.2   ESRD mortality

6.3.2.1   Descriptive analysis

Table 6-9 shows numbers of deaths of adult patients with end-stage renal disease from 2005 to 2012. Table 6-10 shows numbers of the UCS population in

corresponding periods. There were 75,131 deaths in total, increasing from 2,658 in 2005 to 12,811 in 2012, then reducing to 10,754 in 2013. Deaths were most concentrated in patients aged between 55 and 79 years, accounting for 11-13% of all deaths between 2005 and 2013. The population of UCS members aged 20-89 years increased from 30 million in 2005 to 32 million in 2013.

Table 6-9 Numbers of deaths in patients aged 20-89 who were diagnosed with ESRD, 2005-2013

Age	2005	2006	2007	2008	2009	2010	2011	2012	2013	%Total
20-24	49	42	46	52	48	57	60	41	48	0.59
25-29	44	60	70	74	86	69	78	84	65	0.84
30-34	73	81	107	93	100	123	114	119	101	1.21
35-39	103	125	157	149	167	179	185	181	154	1.86
40-44	152	208	261	292	301	313	345	358	242	3.29
45-49	189	297	387	419	487	512	556	593	449	5.18
50-54	272	378	577	725	745	838	937	964	776	8.27
55-59	286	451	644	830	1066	1187	1313	1365	1074	10.94
60-64	281	469	627	846	1171	1450	1707	1753	1368	12.87
65-69	351	512	681	908	1297	1598	1729	1921	1590	14.09
70-74	276	434	639	891	1347	1743	2032	2146	1642	14.84
75-79	171	288	468	663	1139	1545	2005	2094	1510	13.15
80-84	73	134	246	370	647	1058	1350	1532	1163	8.75
85-89	33	76	92	166	323	439	607	785	572	4.12
Total	2,658	3,588	5,045	6,419	8,587	10,716	12,478	12,811	10,754	100.00

Table 6-10 UCS population aged 20-89, 2005-2013

Age	2005	2006	2007	2008	2009	2010	2011	2012	2013	%Total
20-24	3,091,952	3,081,401	3,006,693	2,954,843	3,063,563	3,130,619	3,237,013	3,361,135	3,423,030	10.02
25-29	2,867,485	2,801,673	2,637,599	2,581,614	2,582,281	2,580,171	2,505,985	2,620,408	2,550,342	8.39
30-34	3,497,324	3,371,738	3,235,964	3,117,867	3,032,949	2,955,463	2,777,820	2,874,706	2,828,223	9.79
35-39	3,871,765	3,846,779	3,760,168	3,657,674	3,602,595	3,538,083	3,333,770	3,393,167	3,291,369	11.42
40-44	3,754,485	3,846,979	3,792,642	3,836,540	3,853,588	3,818,217	3,764,295	3,810,279	3,717,279	12.09
45-49	3,247,610	3,336,704	3,357,882	3,448,739	3,543,271	3,617,283	3,711,115	3,749,433	3,796,563	11.24
50-54	2,768,381	2,847,564	2,815,610	2,873,622	2,982,492	3,072,667	3,195,213	3,255,673	3,339,159	9.60
55-59	2,136,423	2,270,491	2,312,280	2,429,176	2,517,530	2,602,010	2,692,012	2,725,311	2,779,112	7.94
60-64	1,640,010	1,666,310	1,658,030	1,749,639	1,867,292	2,018,386	2,205,744	2,261,073	2,373,041	6.16
65-69	1,439,750	1,440,314	1,425,979	1,430,170	1,459,139	1,482,657	1,545,203	1,554,247	1,633,569	4.74
70-74	1,086,790	1,117,640	1,091,743	1,133,569	1,180,408	1,219,016	1,266,427	1,269,010	1,261,197	3.76
75-79	722,991	725,753	724,144	756,237	808,702	843,941	915,930	909,758	931,894	2.59
80-84	406,112	404,181	395,234	427,276	463,313	501,880	556,589	552,467	561,637	1.51
85-89	221,151	208,110	201,662	211,995	227,994	239,342	273,002	263,901	273,429	0.75
Total	30,752,229	30,965,637	30,415,630	30,608,961	31,185,117	31,619,735	31,980,118	32,600,568	32,759,844	100.00

The age-standardised mortality rate (ASMR) of UCS patients who had end-stage renal disease increased from 5 per 100,000 UCS population in 2005 to 24 per 100,000 UCS population in 2012, then dropped to 18 per 100,000 UCS population in 2013, Figure 6-6.

Figure 6-6 Age-standardised mortality rates (ASMR) per 100,000 UCS population for UCS patients with end stage renal disease 2005-2013
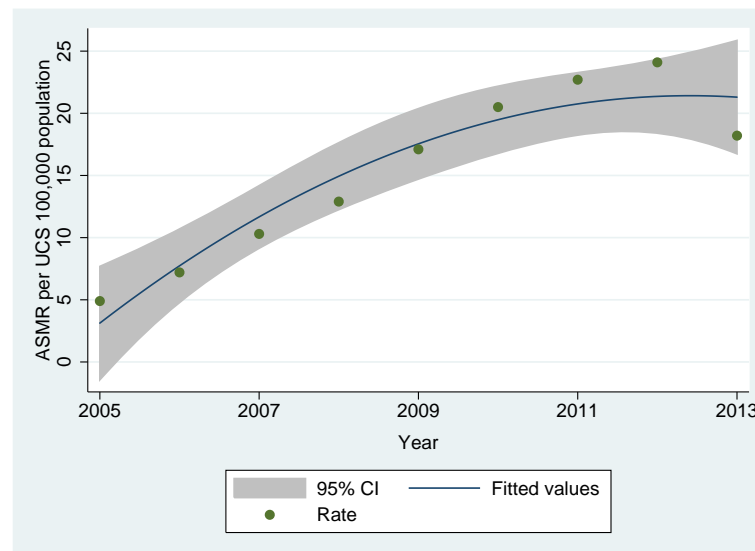
Figure 6-7 a and c show crude death rates for UCS patients who had ESRD per 100,000 UCS population. Rates are shown against age at death and calendar year, while Figure 7b and d compare crude death rates of the same patient group by age at death and year of birth.

Figure 6-7a and c

Figure 7a and c show that the crude death rate for ESRD patients increased between 2005 and 2013. Death rates tended to increase from age 45. Between 2005 and 2008, rates were low and there was not much difference across all age groups. They stood below 50 deaths per 100,000 UCS population. After that in 2009 to 2013, death rates among the elderly ESRD patients, especially patients aged 70 years and higher, rose significantly, ranging from 100 to 250 deaths per 100,000 UCS population.

Figure 6-7b and d

Examination of birth cohorts indicates a continuing increase in mortality rates among older ESRD cohorts with high variation. The mortality rates of older cohorts ranged from 50 to 250 deaths per 100,000 UCS population. For those born in 1945 and before, there were increasing rates with declining slopes afterward, meaning the death rate tended to decrease with increasing birth year. In more recent cohorts, those born after 1951, death rates were low and less varied, at less than 50 deaths per 100,000 UCS population.

Figure 6-7 Mortality rates per 100,000 UCS population for UCS patients with ESRD aged 20-89 years by age at death, calendar year, and birth year
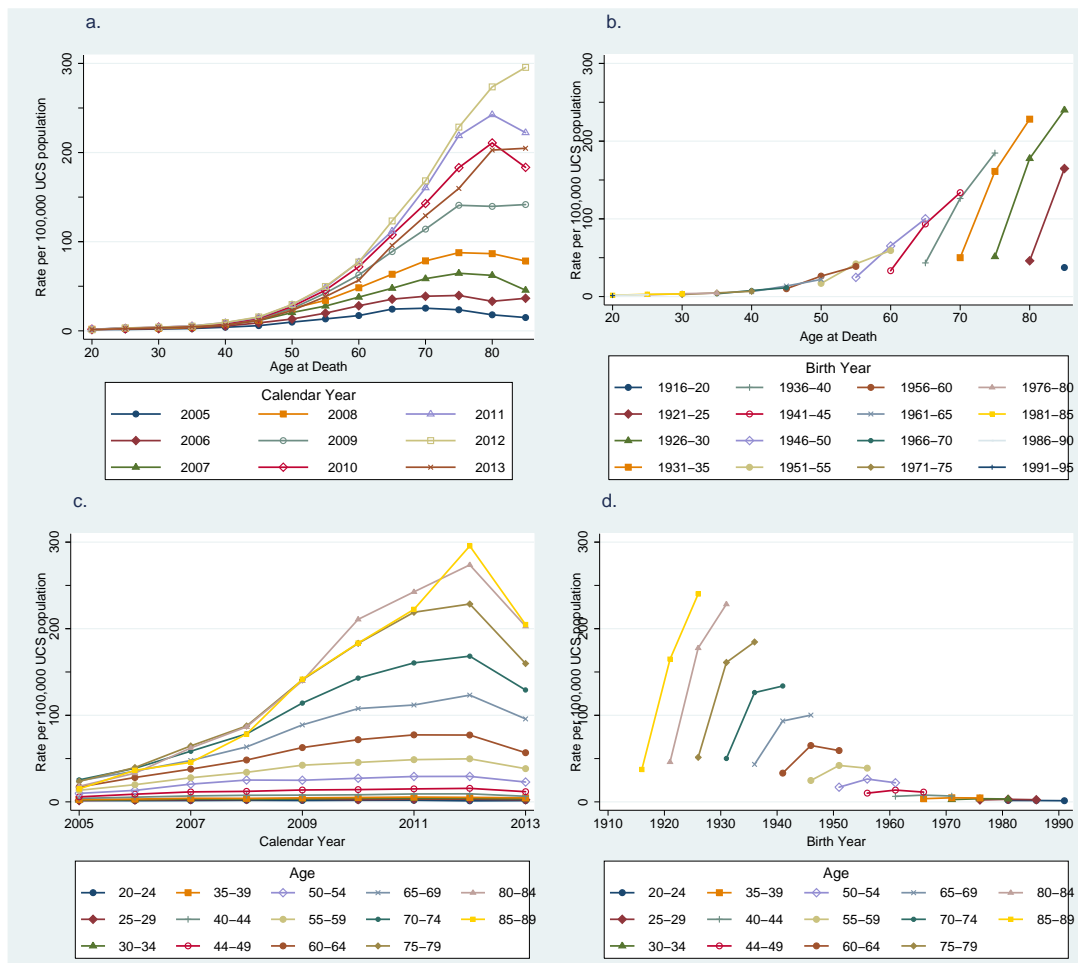
6.3.2.2 Age-period-cohort analysis

i. Model fitting

Analysis of deviance indicated that change in the mortality of end-stage renal disease is complex and is not well explained by a linear trend over time (see Table 6-11). The age-drift model, referring to the change that occurred from linear effects of cohort and/or period, showed a significant deviance from the age model at 8696. The age-period model improved the model fit over the age-drift model and gave the lowest deviance difference at 180 when compared to other models. Consequently, the age-period model was selected as the best fitting model and will be used in the age-period-cohort analysis.

Table 6-11 Comparison of age-period-cohort sub-models

Model	Effect	Dª⁄	ΔDᵇ⁄	p value
1. Age	-	10765.1 (828)	Reference	Reference
2. Age-drift	Δ |A ᶜ⁄	2069.5 (827)	8695.6	<0.001
3. Age-Period	P|A ᵈ⁄	1889.8 (816)	179.7	<0.001
4. Age-Period-Cohort	C|A,P ᵉ⁄	374.0 (670)	1515.8	<0.001
5. Age-Cohort	P|A,C ᶠ⁄	597.7 (680)	-223.7	<0.001
6. Age-drift	C|A ᵍ⁄	2069.5 (827)	-1489.8	<0.001

ª⁄ Residual deviance
ᵇ⁄ Increase in residual deviance from the next upper model
ᶜ⁄ Linear effect of cohort or period adjusted for age
ᵈ⁄ Non-linear cohort effect adjusted for age
ᵉ⁄ Non-linear period effect adjusted for age and cohort
ᶠ⁄ Non-linear cohort effect adjusted for age and period
ᵍ⁄ Non-linear period effect adjusted for age

ii. Effects of age and period

The effect of age on mortality shows an S-curve and the mortality rate increased significantly when patients were in their forties or above (Figure 6-8a). In the reference year (2010), mortality rates of ESRD patients reached a peak at 140 deaths per 100,000 UCS population in their late seventies, meaning in 2010 there were 140 deaths (from all causes) of patients with an ESRD diagnosis per 100,000 UCS population. The rate then gradually levelled off.

Period (calendar year of death) showed a strong effect on mortality, as reflected by the upward trend of the period graph (Figure 6-8b). The mortality ratio[17] rose rapidly from 2005 to 2007, and after that continued increasing at a slower rate. In the short period of mid 2009 to 2011, the death rate became stable, followed by a slow increase thereafter. In 2012, patients with an ESRD diagnosis had a risk of death 1.5 times greater than those in the reference year 2010.

[17] Risk ratio for the death outcome is also known as relative risk. It is the risk of an event (eg. death and registration) in a particular year in comparison to the reference year, and can be calculated by the rate in that particular year divided by the rate in the reference year.

Figure 6-8 Effects of age (a) and period (b) on ESRD mortality
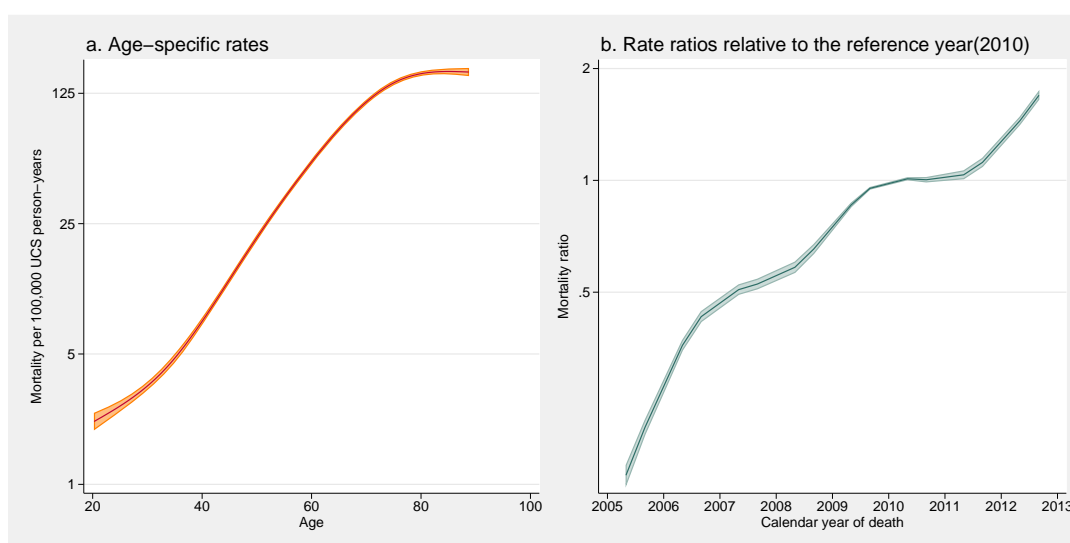
Note: Figure a shows estimated ESRD mortality rates by age in 2010 and Figure b shows mortality rate ratios (relative difference measure of mortality rate in any particular year divided by rate in the reference year-2010) for calendar years of death. Shaded areas are 95% confidence intervals.

6.3.3   Case fatality rate (CFR)

6.3.3.1   Descriptive analysis

The numbers of UCS patients diagnosed with end-stage renal disease are used as denominators to calculate the CFR and are shown in Table 6-12. Numbers of adults with ESRD increased over time. In 2010 there was a significant increase by 43%. Patients in the 55-59 to 70-74 age groups accounted for the highest proportions of total ESRD patients.

Table 6-12 End-stage renal disease patients of the UCS, 2008-2012

Age	2008	2009	2010	2011	2012	2013	%Total
20-24	433	537	741	1,033	1,207	1,333	1.63
25-29	630	803	1,098	1,480	1,708	1,785	2.35
30-34	968	1,219	1,664	2,193	2,496	2,673	3.52
35-39	1,241	1,511	2,076	2,767	3,201	3,433	4.44
40-44	1,707	2,019	2,806	3,711	4,230	4,756	5.96
45-49	2,317	2,705	3,749	5,162	5,858	6,620	8.15
50-54	3,264	3,536	5,079	6,812	7,700	8,696	10.86
55-59	3,831	4,076	5,821	7,946	8,994	10,467	12.62
60-64	3,789	3,998	5,866	8,047	9,073	10,755	12.67

Age	2008	2009	2010	2011	2012	2013	%Total
65-69	3,863	3,938	5,571	7,507	8,231	9,675	11.98
70-74	3,758	3,804	5,429	7,291	7,882	9,084	11.59
75-79	2,736	2,704	3,961	5,383	5,745	6,727	8.45
80-84	1,345	1,353	1,966	2,718	2,873	3,478	4.22
85-89	477	468	758	1,046	1,043	1,242	1.56
Total	30,359	32,671	46,585	63,096	70,241	80,724	100

Figure 6-9 shows case fatality rates for UCS patients who had an ESRD diagnosis.

Figure 6-9 a and c

It is clear that the case fatality rate increases with age, Figure 6-9a. There were declining trends over time, from 2008 to 2013 (see Figure 6-9c). Between 2012 and 2013, rates of all age groups went down approximately 5%-20%. Patients aged 55-75 tended to have greatest decreasing case fatality rates.

Figure 6-9 b and d

The case fatality rate showed a decreasing trend across all age groups born after 1935. Conversely, for those born in 1936 and before, there was a significant increasing trend (see three rightmost lines on Figure 6-9b).

Figure 6-9 Case fatality rates for patients with ESRD aged 20-89 years
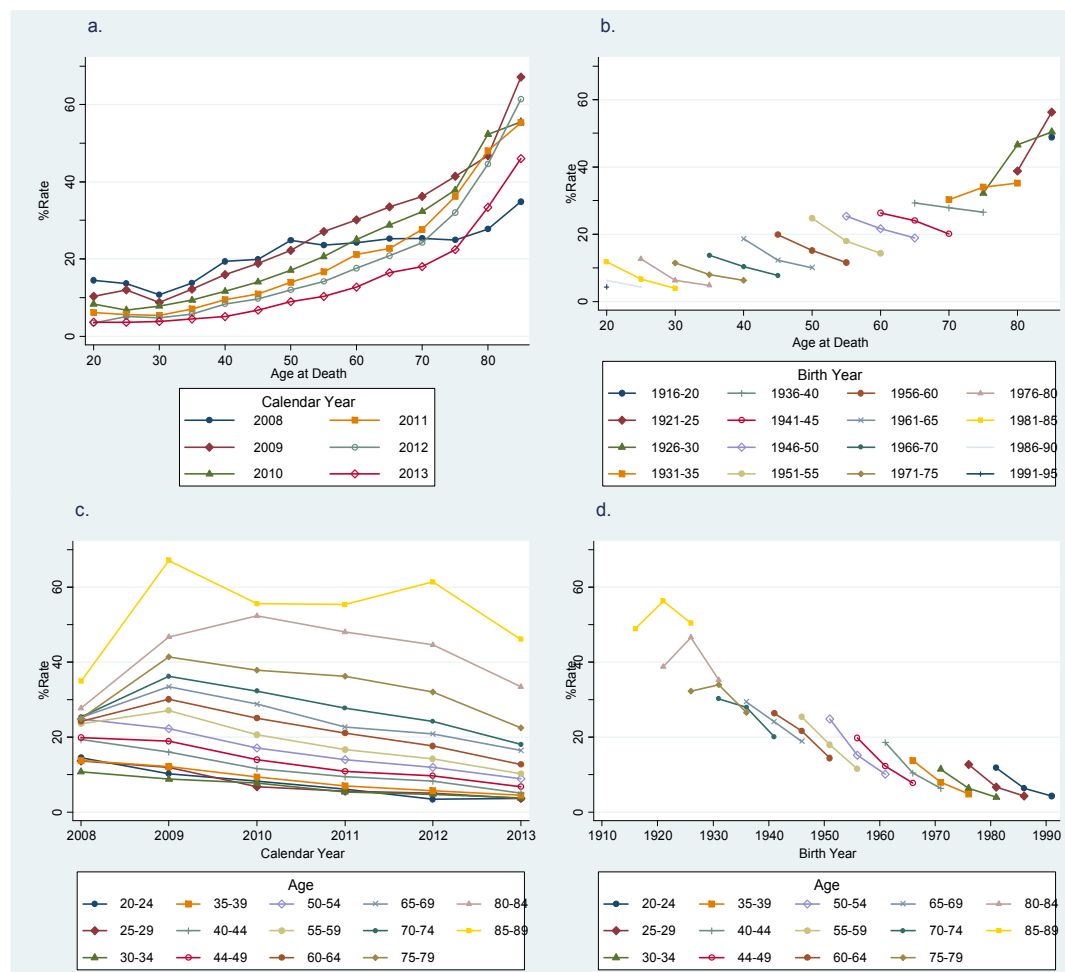
Note: Rates were percentages of all-cause death counts of UCS patients diagnosed with ESRD divided by numbers of all UCS patients diagnosed with ESRD. Rates are presented by age at death, calendar year, and year of birth.

6.3.3.2 Effects of age and period

Figure 6-10a shows the age effect on the case fatality rate and fatality rate ratio. After age 30, the fatality rate increased exponentially. In the reference year 2010, the case fatality rate at age 40 years was 10% and increased to 25% at age 60 years. This meant in 2010, there were 10 deaths for every 100 ESRD-diagnosed patients aged 40, and 25 deaths for every 100 ESRD-diagnosed patients aged 60.

The period effect had the highest peak in 2009 when patients with an ESRD diagnosis had a 1.2 times greater risk of death than those in the reference year 2010. A downward trend was observed just after the peak, which reached the lowest point in mid-2012. At this point, risk of death among patients having

ESRD was 0.4 times lower than that in 2010. After this period the rate started increasing again (see Figure 6-10b).

Figure 6-10 Effects of age (a) and period (b) on case facility
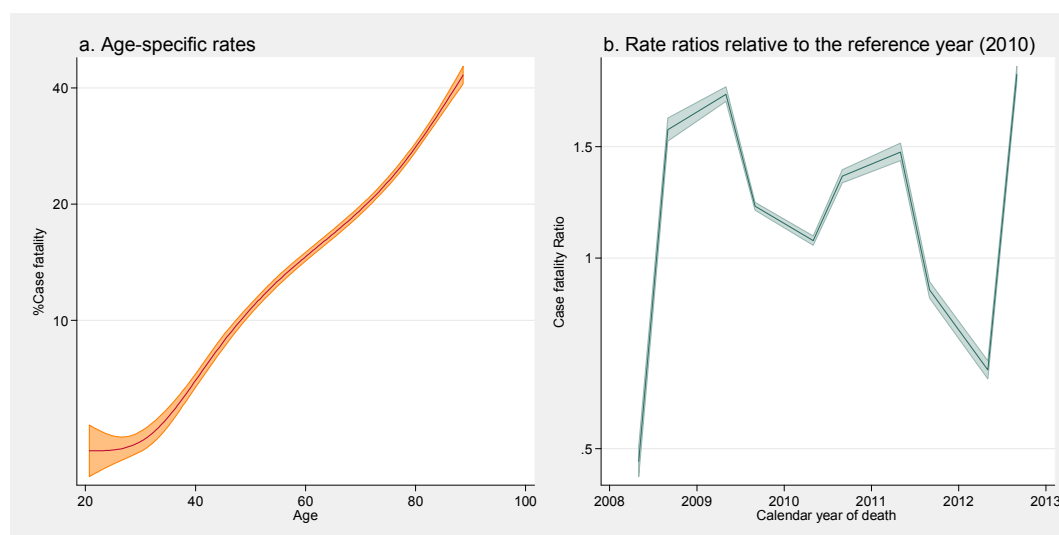
Note: Figures show estimated case fatality rate by age in 2010 (a) and case fatality rate ratio (relative difference measure of fatality rate in any particular year divided by rate in the reference year-2010) in 2008-2013 (b).

6.3.4   RRT mortality

Numbers of total deaths among ESRD patients who were on RRT increased between 2008 and 2012, then began to drop significantly in 2013, Table 6-13.

Table 6-13 Numbers of deaths among patients on RRT by age group and modality, 2008-2013

Age	RRT	2008	2009	2010	2011	2012	2013	Total	%Total
20-24	HD	2	4	6	5	6	6	159	1.1%
	PD	7	17	17	25	31	25		
	KT	-	-	1	3	2	2		
25-29	HD	3	13	5	9	12	5	235	1.6%
	PD	9	24	39	33	43	36		
	KT	-	-	-	3	1	-		
30-34	HD	5	9	14	16	21	11	292	2.0%
	PD	6	23	45	35	62	44		
	KT	-	-	-	-	-	1		
35-39	HD	3	12	23	25	32	12	350	2.3%
	PD	9	34	42	48	59	50		
	KT	-	-	-	-	1	-		
40-44	HD	11	29	27	31	46	24	616	4.1%
	PD	14	53	74	98	118	86		
	KT	-	-	1	1	2	1		
45-49	HD	8	43	45	65	70	41	1,048	7.0%

Age	RRT	2008	2009	2010	2011	2012	2013	Total	%Total
	PD	29	83	138	160	205	156		
	KT	-	-	3	1	-	1		
50-54	HD	26	95	77	88	96	74	1,590	10.6%
	PD	28	111	189	249	294	252		
	KT	-	-	-	1	6	4		
55-59	HD	25	106	105	151	170	97	2,121	14.2%
	PD	26	144	222	350	413	299		
	KT	-	1	3	2	3	4		
60-64	HD	23	125	137	191	222	147	2,394	16.0%
	PD	19	96	278	347	448	345		
	KT	-	-	3	4	4	5		
65-69	HD	33	147	161	193	243	136	2,198	14.7%
	PD	4	90	189	275	404	314		
	KT	-	1	2	2	2	2		
70-74	HD	23	137	148	206	226	136	1,903	12.7%
	PD	5	57	169	243	315	233		
	KT	-	-	2	1	2	-		
75-79	HD	25	129	106	138	190	111	1,266	8.5%
	PD	2	36	80	135	198	116		
	KT	N/A	N/A	N/A	N/A	N/A	N/A		
80-84	HD	11	35	69	86	105	46	575	3.8%
	PD	1	16	27	63	72	44		
	KT	N/A	N/A	N/A	N/A	N/A	N/A		
85-89	HD	6	18	26	37	50	28	226	1.5%
	PD	-	5	5	22	18	11		
	KT	N/A	N/A	N/A	N/A	N/A	N/A		
Total		363	1,693	2,478	3,342	4,192	2,905	14,973	100.0%

HD= hemodialysis, PD=peritoneal dialysis, KT=kidney transplant

Over the six-year period, numbers of live ESRD patients aged 20-89 who were maintaining RRT increased from 7,310 to 23,566 (Table 6-14). Patients aged 55-59 accounted for the highest proportion, at 15% of overall patients.

Table 6-14 Numbers of annual UCS patients aged 20-89 years who were receiving RRT, 2008-2013

Age	2008	2009	2010	2011	2012	2013	%Total
20-24	174	290	388	501	603	657	2.7
25-29	187	339	458	583	683	753	3.2
30-34	217	424	617	783	886	1,000	4.1
35-39	358	579	800	1,069	1,241	1,421	5.8
40-44	513	825	1,176	1,513	1,759	2,025	8.2
45-49	661	1,082	1,553	2,090	2,420	2,735	11.1

Age	2008	2009	2010	2011	2012	2013	%Total
50-54	909	1,326	1,906	2,529	2,931	3,286	13.6
55-59	1,002	1,481	2,156	2,785	3,200	3,694	15.1
60-64	968	1,387	1,992	2,647	3,034	3,476	14.2
65-69	926	1,145	1,538	1,998	2,148	2,361	10.6
70-74	739	807	1,066	1,280	1,292	1,396	6.9
75-79	424	392	477	589	525	573	3.1
80-84	188	182	199	209	182	180	1.2
85-89	44	43	46	33	19	9	0.2
Total	7,310	10,302	14,372	18,609	20,923	23,566	100

Figure 6-11 presents the age-standardised mortality rates (ASMR) for UCS patients aged 20-89 years who were on RRT. After adjustment, mortality rates decreased from around 80 deaths per 1,000 patient years at risk in 2009-2012 to 60 deaths per 1,000 RRT patient years at risk in 2013.

Figure 6-11 Adjusted mortality rates per 1,000 patient years at risk for UCS patients who had RRT aged 20-89, 2008-2013
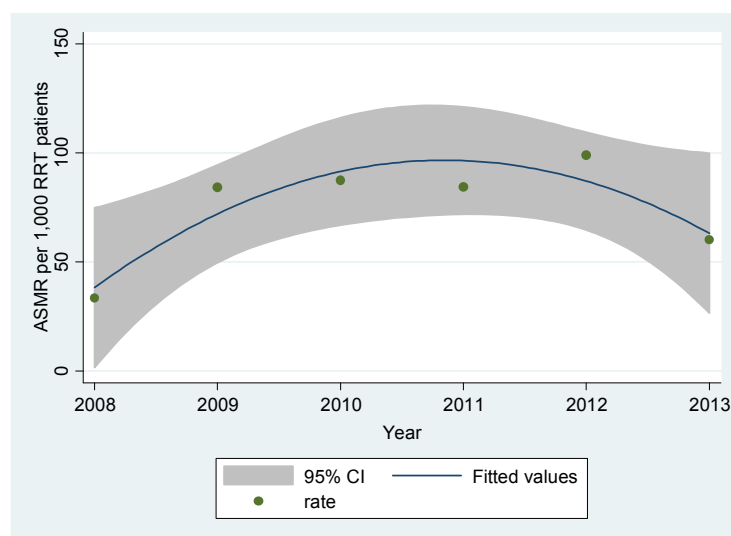
Unadjusted mortality rates for ESRD patients who used RRT are shown in Figure 6-12. Due to large differences in mortality rates between patients on RRT aged 20-64 years and the elderly aged 65-89 years, results were presented in two graphs. In 2008, rates were low across all age groups, which might be a consequence of the fact that the new RRT programme could not enroll many patients. From 2009, as expected, mortality rates increased by age and were

considerably higher after age 65. Between 2009 and 2012, rates were quite consistent within each age group in patients aged 35-65 years. Mortality rates were 75 deaths per 1,000 patient-years for those aged 35 years at death and 200 deaths per 1,000 patient-years for those aged 60 years. In 2013, rates for patients aged 35-65 years fell by 50 deaths per 1,000 patient-years. For the elderly, mortality rates seemed to increase over time until 2012, then dropped slightly in 2013 (Figure 6-12).

Figure 6-12 Mortality rates for UCS patients who had RRT aged 20-64 years (a) and 65-89 years (b)
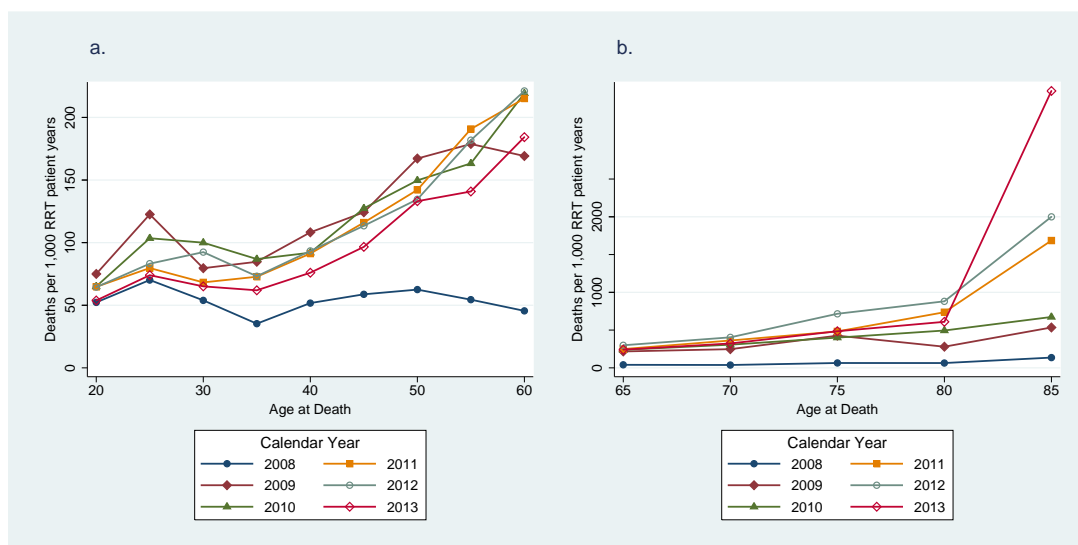
Age effects on the mortality rate for UCS patients who used RRT is shown in Figure 6-13a. The mortality rate increased dramatically after the age of 40. In the reference year 2010, the rate for those aged 40 was 75 deaths per 1,000 patient-years and 250 deaths per 1,000 patient-years for those aged 70.

The period (calendar year of death) effect increased rapidly and reached a peak in 2010. After that, the rate showed a slight downward trend. By 2012 the mortality rate began to increase again, reaching twice that of the reference period in 2013 (see Figure 6-13b).

Figure 6-13 Effects of age (a) and period (b) on RRT death
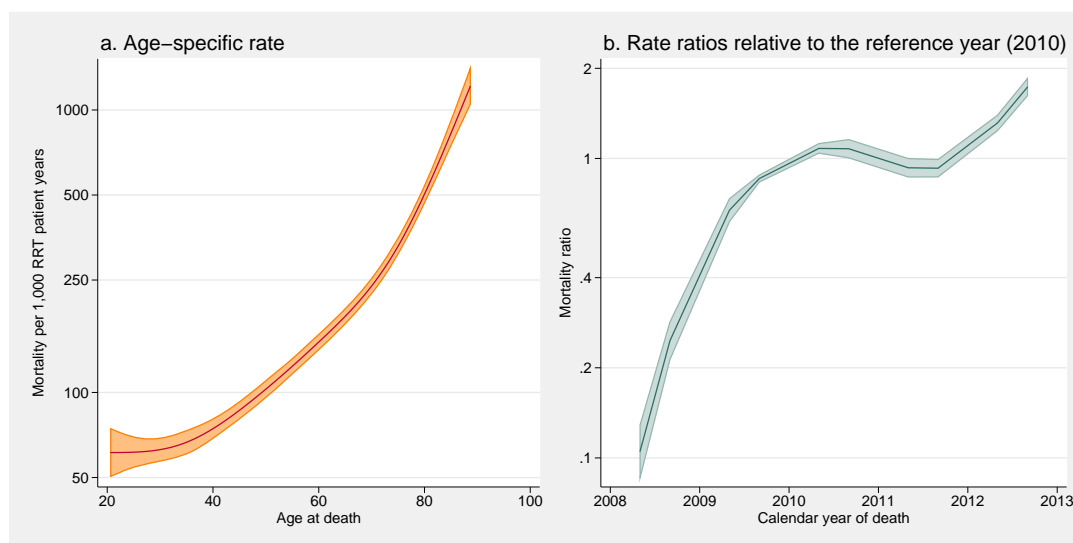
Note: Estimated mortality rate for RRT patients by age in 2010 (a) and mortality rate ratio (relative difference measure of mortality rate in any particular year divided by rate in the reference year-2010) in 2008-2013 (b).

6.3.5   The patients in 2013

Key points for 2013 are summarised here to provide recent information about the incidence (the occurrence) of adult ESRD patients in the UCS, access of these patients to RRT, and mortality of those who were maintaining RRT in comparison to death rates of overall UCS members.

The incidence for access to RRT is represented by a count (number of cases) or by a rate. The rate was expressed per million population (pmp) per year. For all-cause mortality rates, they were expressed as deaths per 1,000 patient-years.

Incidence

- There were a total of 20,296 adults in the UCS newly diagnosed with ESRD, a decrease of 37% from new diagnoses in 2012. The modal age group was 60-65 years (14% of all new ESRD patients).
- The number of adult ESRD patients newly starting RRT was 9,593 registrations (47% of all new ESRD patients). The modal age groups were 55-59 years and 60-65 years (16% of all new RRT patients each).

- The total new RRT patients above represented an incidence rate of 197 pmp[18].

Access to RRT modalities

- Of the above newly diagnosed ESRD patients; 6,620 patients (33% of newly diagnosed ESRD patients) went on to receive PD.

- 2,774 patients (14% of newly diagnosed ESRD patients) went on to receive HD, possibly because they were contraindicated to PD or because they failed PD then had modality changes to HD.

- Just a small number of ESRD patients (199 or 1% of newly diagnosed ESRD patients) were able to exit to transplantation.

- There were 10,703 patients (53% of newly diagnosed ESRD patients) who did not agree to start RRT.

All-cause mortality rate:

- The age-standardised mortality rates (ASMR) for adults in the UCS who were on RRT reduced from around 80 deaths per 1,000 patient-years at risk in 2009-2012, to 60 deaths per 1,000 RRT patient-years at risk in 2013.

- Figure 6-14 compares age-adjusted, all-cause mortality rates in RRT patients and the overall UCS population[19]. Relative risk is shown on the right hand axis, which compares adjusted death rates of RRT patients over the UCS population. Adjusted rates of death for RRT patients were 7 to 20 times greater than for individuals in the general age-matched UCS population, and the relative risk of death on RRT decreased with age. This means that the more RRT patients age, the closer their death rate becomes to the overall UCS population.

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[18] The denominator used for this rate was the entire UCS population including patients under 20 years old. When population aged less than 20 years were excluded from the denominator, the incidence rate was 293 pmp.

[19] Using the UCS population in 2013 as the reference population

Figure 6-14 Age-adjusted mortality rates in RRT and UCS population
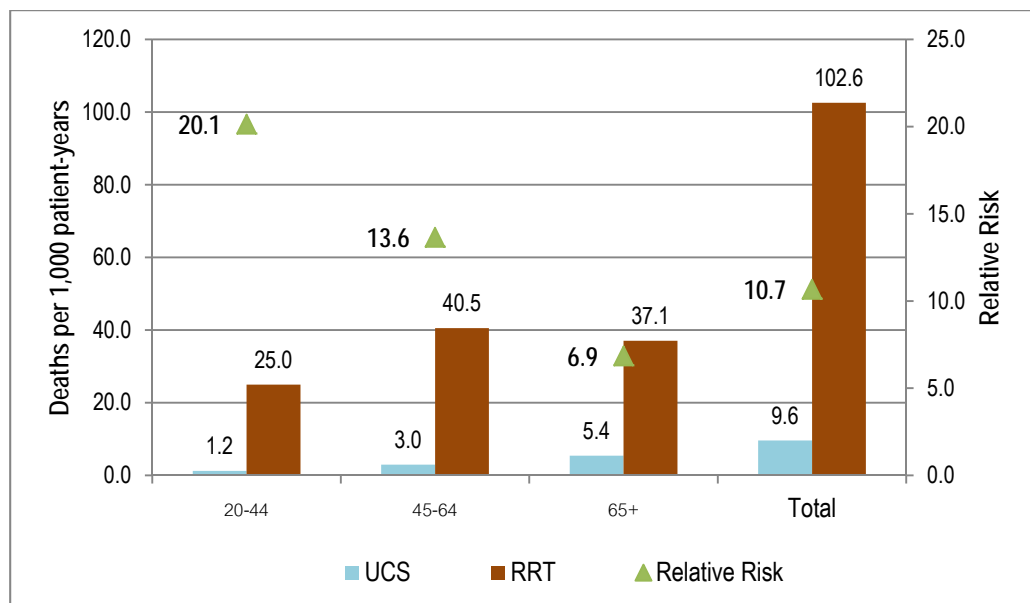
RRT= renal replacement therapy

6.4   Discussion

6.4.1   Concerns of age-period-cohort model fitting

Using the age-period-cohort approach can eliminate the identifiability problem that occurs from the relation: age = period-cohort. The age-period-cohort models may separate the effects of age from the effects of cohort and period by the parametrisation technique proposed by Carstensen (2007). There are, however, questions raised from the parametrisation technique about the number of knots, placement of knots, and reference point used. These parameters are user defined, meaning any selection can alter results (Carstensen 2007). An example from this study is the dips in most period graphs. When using a lower number of knots (such as 3 instead of 5), graph lines became smoother, there was no dip presented. Nonetheless, the fact was that a smooth graph cannot detect the small effect from events occurring in that period. Interpreting results from age-period-cohort models and other information, such as descriptive analysis and key events in various time periods is, therefore, necessary.

6.4.2   Summary of findings

i.   *Registration rates*

Assessing the rate of registration into the RRT programme by the age-period-cohort method revealed fairly stable patterns with upward trends of registration rates in all three RRT modalities. There were notable drops in dialysis registration rates and transplant rates between 2011 and 2012. In 2013, the incidence of RRT patients began to increase again. PD accounted for more registered patients in comparison to HD, in 2010 at roughly 220 and 15 patients per 1,000 new ESRD patients respectively. These rates, however, fell sharply in patients aged 65 years and older.

A descriptive analysis of registration into the PD programme showed decreasing registration rates among older patients, aged 65 years and over, despite the increasing rates among younger patients, aged 20-54 years.

ii.   *Mortality rates*

All-cause mortality rates of patients with ESRD diagnoses among the UCS population increased with age as presented by an S-shaped age effect in the analysis. At age 40 the death rate was approximately 8 patients per 100,000 UCS population-years, and increased exponentially with age. When age increased to 60 years, the death rate rose to 50 cases per 100,000 UCS population-years, and became fairly stable at age 70 years and above, at 140 cases per 100,000 UCS population-years. Patients on RRT might benefit from their treatments as their mortality rates increased rapidly later than those of overall ESRD patients, when the former are aged 70 years and more as observed in Figure 6-13 and Figure 6-8.

From 2005 to 2008, the age-period-cohort analysis showed that overall, the mortality rate among patients with ESRD increased over time. It started with a sharp increase until 2007. After that, the death rate started to level off and was followed by a stable period between 2009 and 2011. However, after 2011, the death rate increased rapidly to what it had been before the 2007 period. This

was in contrast to the result from the descriptive analysis, where the death rate appeared to decrease after it reached a peak in 2012.

The age effect and period effect of ESRD deaths among UCS members were in accordance with those of RRT patients, since their trend lines in rate ratio graphs showed similar shapes. Rates started with sharp increases until 2009, followed by relatively stable trends until 2012. Both rates showed increasing trends from 2012.

The case fatality rate analysis suggested different findings, in particular during the period 2008-2012. While calculated rates of the other two types were increasing in this period, case fatality rates were decreasing. However, in 2013 all types of rates increased.

6.4.3   Discussion of findings

The variation in trends in access to RRT services, and overall mortality of ESRD patients and patients who use RRT, may be explained by the introduction of the RRT programme, changes in the RRT policy, and environmental events.

Linking the timeline of the RRT programme with dialysis registration and mortality provided more explanations for their trends, Figure 6-15. The opening of pilot PD centres may be a possible explanation for the declining death trend in 2007. After the RRT programme was fully implemented in 2008, both dialysis modalities could have high registration rates, resulting in an immediate effect of the new programme on patients who had never previously had RRT coverage. Consequently, the programme brought a large number of patients into all three RRT modalities and reduced the increasing death rate between 2008 and 2011.

After commencement of the RRT programme, the registration rate might have responded to the new policy since registration trends increased after each new reimbursement started. This was evident in 2009, when the NHSO started to reimburse erythropoietin[20] for PD users, effectively making the medication

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[20] for the treatment of anemia of ESRD patients

cost-free. This benefit is likely to have boosted the PD registration rate until 2010.

Deep drops in dialysis registration and transplantation in 2011 could be a consequence of flooding that affected major cities in 63 out of 77 provinces in Thailand. More than 600 public health facilities could not open as usual and many private clinics were temporarily closed down (The World Bank 2013). The Nephrology Society of Thailand estimated that 30% or 12,000 dialysis patients[21] resided in flooded areas. Hemodialysis patients were affected the most since they could not go to receive care at dialysis units. Peritoneal dialysis patients could perform home dialysis as the NHSO guaranteed home-delivery of dialysis solution (The Nephrology Society of Thailand 2011). Although there was collaboration between various agencies to mitigate the situation, registration rates of PD and HD went down in this period.

Increases in PD and HD registrations in late 2012- 2013 might be explained in a number of ways. The first explanation is the harmonisation of RRT benefits across the three public health insurance schemes, namely the Social Security Scheme, the UCS and the Civil Servant Medical Benefit scheme. The harmonisation made for easier access to RRT services, since the three schemes agreed to use the same standard guidelines in taking on and caring for ESRD patients. Patients who changed their insurance schemes to another scheme had no barrier to continue RRT care in their transition phase. The RRT programme also benefited from the harmonised data management system, coherent and standard procedures, and standard validation processes. Consequently, data quality improved and timely information was available.

HD patients gained great advantages from the harmonisation. This is because within the other two schemes, the majority of dialysis users were HD. After the harmonisation, all three schemes had to allow new beneficiaries to retain their previous dialysis mode. Therefore, these HD patients could enter the UCS RRT programme without using the PD-first policy. Additionally, in 2012 more benefits were added to HD, for example free erythropoietin and exemption from

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[21] of all 3 public schemes and all over the country

copayment. In addition to the harmonisation, UCS patients who were self-funding for hemodialysis might register to use free dialysis as they had more confidence in the quality of RRT services provided by the UCS.

Figure 6-15 Comparison of registration rates and all-cause mortality with RRT programme's key events

2005-2006 Launched 3 pilot PD centres
2007   Cabinet resolution approved the RRT benefits of the UCS
          Preparation for the new policy (setting up)
2008   Started "PD-first policy"
          Current HD users (who started HD before 2008) could enter the
             programme by paying contribution
          Numbers of PD centres increased to 105 centres
2009   Reimbursement of erythropoietin for PD users
2011   Flood in July-December in 63 out of 77 provinces in Thailand
2012   Reimbursement of erythropoietin for all dialysis users including HD patients
          Old HD patients (started HD before 2008) were eligible for free HD service
          Harmonisation of the three public health insurance schemes

Note: adjusted from the rate ratio graphs of registration into the RRT programme and mortality.
Y-axis is not the actual scale, UCS=universal coverage scheme, PD=peritoneal dialysis, HD=hemodialysis

The increase of the mortality rate during 2011-2013 could be a combined effect of epidemiology of chronic renal disease, a disproportionate number of new registrations given increasing patients with ESRD, and loss of follow up while flooding. Given the fact that 90% of ESRD patients who do not receive proper dialysis will die within 3-6 months (Tantivess, Werayingyong et al. 2013), these patients were sensitive to the change in the availability of the RRT benefit in 2008. As a result, patients who had ESRD before the programme started could prolong their life when they used dialysis. However, this effect was transient since dialysis could only slow the progress of kidney disease, not cure it. This is

a likely explanation for the increase in death rates after 2012. To support this account, we can look at an analysis of kidney function (eGFR: estimated Glomerular Filtration Rate level) of patients first entering into the programme, Figure 6-16 found that most patients in the RRT programme had a late start[22]. This means 70-75% of these patients were likely to die within 3 years (Wright, Klausner et al. 2010).

Figure 6-16 eGFR levels at registration into the RRT programme of PD patients between 2007 and 2014
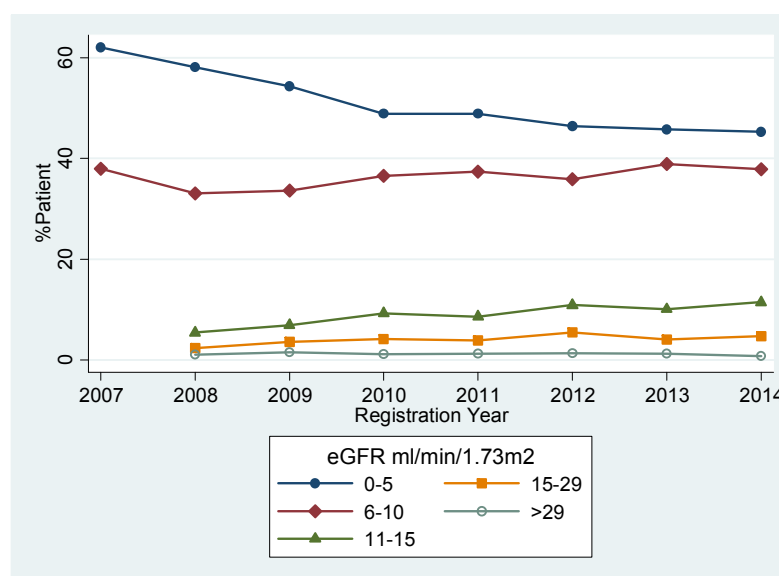
eGFR: estimated Glomerular Filtration Rate

From the decreasing trend of case fatality rates (CFR), we can infer that those who have ESRD were more likely to survive with the introduction of the RRT programme. However, this finding contrasted with the ESRD mortality rate which showed a reverse sign. The percentage of new ESRD patients per UCS population is a possible explanation as to why the results of the mortality rate and CFR were different. Figures in Table 6-15 suggest that there were growing numbers of new patients with ESRD diagnoses relative to the UCS population 2010-2012. Calculations of the ESRD death rate among UCS population[23] and

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[22] eGFR levels lower than 10ml/min/1.73m^2

[23] ESRD mortality rate= (Number of deaths from all causes among patients with ESRD x 100)/ Number of mid-year UCS members

CFR[24] employed same numerators but different denominators. When the denominators of CFR increased, the calculated figures of CFR decreased.

Moreover, looking at the share of new patients with an ESRD diagnosis in the UCS population (Table 6-15), there were growing numbers of patients with ESRD, in particular, among the elderly population (65 years old and above), who have a high risk of mortality. However, lower numbers of elderly patients were registered with the RRT programme. These figures may account for the high CFR in elderly ESRD patients between 2010 and 2012.

Table 6-15 Percentages of new ESRD diagnoses and overall UCS population, 2008-2013

Age	2008	2009	2010	2011	2012	2013
20-24	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%
25-29	0.02%	0.01%	0.02%	0.02%	0.01%	0.01%
30-34	0.03%	0.01%	0.02%	0.02%	0.02%	0.01%
35-39	0.03%	0.01%	0.02%	0.03%	0.02%	0.01%
40-44	0.05%	0.02%	0.03%	0.04%	0.03%	0.02%
45-49	0.07%	0.03%	0.05%	0.06%	0.05%	0.03%
50-54	0.13%	0.05%	0.09%	0.09%	0.08%	0.05%
55-59	0.18%	0.07%	0.13%	0.14%	0.14%	0.09%
60-64	0.25%	0.10%	0.19%	0.20%	0.19%	0.12%
65-69	0.32%	0.13%	0.25%	0.28%	0.27%	0.17%
70-74	0.40%	0.16%	**0.32%**	**0.37%**	**0.35%**	0.20%
75-79	0.46%	0.19%	**0.39%**	**0.44%**	**0.42%**	0.26%
80-84	0.42%	0.19%	**0.40%**	**0.45%**	**0.48%**	0.29%
85-89	0.31%	0.18%	**0.36%**	**0.41%**	**0.46%**	0.27%
Total	0.11%	0.05%	0.09%	0.11%	0.10%	0.06%

Note: bold figures represented relatively high percentages of elderly in comparison to overall UCS population, 2010-2012

Further comparison of new RRT registrations and numbers of patients with an ESRD diagnosis is shown in Table 6-16. Proportions of most age groups were increasing, with slight drops in 2010-2011. Despite rapidly growing proportions of new RRT registrations among young patients, less than half of patients aged 65 years and older enrolled in the RRT programme. This situation might explain the increase in all types of death rates in 2013.

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[24] CFR= Number of deaths from all causes among patients with ESRD x 100/ Number of all patients with ESRD

Table 6-16 Proportions of new RRT registrations as percentage of new ESRD diagnoses by year and age group

Age	2008	2009	2010	2011	2012	2013
20-24	51.0%	145.2%	83.8%	78.9%	100.0%	100.0%
25-29	36.5%	61.8%	46.8%	45.8%	60.7%	88.5%
30-34	32.3%	48.9%	46.4%	39.9%	54.4%	92.4%
35-39	32.1%	53.4%	41.9%	44.3%	49.6%	85.2%
40-44	31.1%	52.7%	42.5%	38.8%	50.0%	79.1%
45-49	28.7%	50.0%	39.6%	38.6%	49.8%	73.3%
50-54	27.1%	45.3%	35.3%	36.0%	43.0%	68.2%
55-59	24.7%	39.7%	32.7%	33.7%	37.8%	63.6%
60-64	23.1%	33.6%	28.4%	29.3%	33.7%	55.3%
65-69	21.0%	23.6%	20.9%	22.8%	25.7%	41.7%
70-74	16.8%	14.4%	15.7%	15.5%	16.8%	31.8%
75-79	13.1%	9.0%	8.4%	10.2%	10.8%	18.8%
80-84	11.3%	5.2%	5.8%	6.7%	7.2%	9.0%
85-89	8.8%	2.6%	4.2%	4.4%	4.2%	4.8%
Total	22.8%	31.7%	25.1%	25.3%	28.8%	47.3%

Note: bold figures represented relatively constant or low increasing percentages of elderly in comparison to overall UCS population, 2010-2012

6.4.4   Other evidence supporting the findings

This study used NHSO data routinely collected from its health care facilities to estimate numbers of patients with ESRD (chronic kidney disease stage 5), yielding an ESRD prevalence of 0.14% (in 2010) and 0.24% (in 2013) among the UCS population. Another study estimated the prevalence of chronic kidney disease (stages 1-5) in Thai adults by conducting a national survey in 2004 (Ong-ajyooth, Vareesangthip et al. 2009). The study collected samples of 3,117 of the Thai population aged 15 years and above in 2004. The different stages of kidney disease were assessed by laboratory tests[25] and the prevalence of ESRD stage 5 was reported as 0.2% (see Table 6-17). The national study was conducted in 2004, and therefore, current national figures should be higher. This finding may suggest that there might be a large number of UCS members who have chronic kidney disease stage 5 but have not been given ESRD diagnoses in the UCS databases during the study period (2005-2013).

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[25] Proteinuria and serum creatinine

In reality, the probability of giving an ESRD diagnosis might have increased over time after launching the RRT programme. This is because the availabilities of treatment and disease management of the RRT system (such as the patient identification, guideline protocols, payment mechanism, and coordinating system) provide incentives to providers to take patients into the programme. However, the number of patients with ESRD diagnoses in the UCS database might be lower than the reality for a number of reasons. Given the fact that chronic kidney disease is a silent disease, patients are likely to know they have this disease only when they are severely ill and at the late stage, generally when they are taken to hospital and given a diagnosis. In addition, RRT centres are mostly concentrated in urban areas, they might be beyond reach of some patients who live far away to receive care and be diagnosed.

Table 6-17 Chronic kidney disease stage 5 prevalence in Thai and UCS population

Age group	Thai population 2004(%)[1/]	UC population 2010(%)[2/]
15-29	0	0.03
30-44	0.2	0.06
45-59	0.2	0.16
>60	0.5	0.37
Overall	0.2	0.14

[1/]Prevalence of chronic kidney disease in Thai adults: a national health survey (Ong-ajyooth, Vareesangthip et al. 2009)

[2/]Results from this study

6.5 Conclusions

After launching the RRT programme in 2008, registration rates of all three RRT modalities showed fairly stable patterns in their first years followed by increasing trends in recent years. The RRT programme was able to enroll a higher percentage of young patients, in particular patients in the 55-54 age group. In contrast, access to care by patients aged 70 years and over was low, and tended to decrease with age, despite their high and growing proportion amongst those with ESRD diagnoses.

In terms of mortality, all-cause mortality rates of adult RRT patients increased over time through 2010, then tended to level off. In 2013, the age-standardised mortality rate (ASMR) for adult RRT patients reduced from its peak at 80 deaths per 1,000 patient-years at risk in 2010, to 60 deaths per 1,000 RRT patient-years at risk. Patients who received RRT had a significantly high mortality rate later in life compared to overall ESRD patients.

The disease management approach of the RRT programme appeared to link to these promising results, in the way ESRD patients were identified, registered, and received treatment. In addition, changes in the RRT benefit, UCS policy, and environmental events such as free erythropoietin for HD users, the harmonisation among the three public schemes, and flooding, could also affect numbers of patients entering into the RRT programme and their mortality rates.

6.6   Limitations

There are a number of limitations in this study which may influence the results. These limitations come from many sources including the databases used, patient subjects in the study, and data analysis methods.

6.6.1   ESRD coding

Most studies from developed countries use the number of patients who are treated with RRT to represent numbers of patients with ESRD (El Nahas and Bello 2005). There is doubt of whether the number of RRT patients can represent overall ESRD patients. As mentioned above, chronic kidney disease is a silent disease. There is a time lag between when patients start to have ESRD and when they are diagnosed and treated. This situation is true in Thailand despite the availability of a national UCS screening programme. Therefore, coding ESRD to everyone who has entered chronic kidney disease stage 5 is practically impossible.

In addition, the Thai Nephrology Society guidelines suggest that patients with ESRD diagnoses will be asked to start RRT when their GFRs have reached 6

mL/min per 1.73m^2. This means there will be patients who have an ESRD diagnosis but have not yet started RRT because they still have relatively good clinical signs and symptoms. A study by Limwattananon and Limwattananon (2013) showed that up to 41% of UCS patients who had an ESRD diagnosis were registered with the RRT programme. This finding reflects the problem identified; that using the number of patients undergoing RRT to represent numbers of patients with ESRD would be an underestimate, since there were a large number of patients who have end-stage kidney disease but did not use RRT for some reasons. This is why the current study employed the number of all patients who have an ESRD diagnosis, rather than the number of patients who use RRT, to represent the ESRD population.

6.6.2   Nature of data sources

There were some limitations in the use of NHSO databases. These databases are intended to be used in reimbursement for health services, and there are several causes of data inaccuracies. The first drawback of this use was that the claims data may not be completely up-to-date. Since the NHSO allows its health facilities to claim up to one year late, observations of patients in recent years, particularly in 2013, might not be the most up-to-date. Second, by using patients' citizen numbers to merge various databases and construct the main dataset, some records could not be matched with any citizen number and were discarded.

Next, there was an adjustment of ICD-10 coding of ESRD in 2012. This change might affect numbers of diagnoses used in this study. Furthermore, when information from all relevant NHSO databases was used to calculate numbers of patients with end-stage renal disease, the figures were lower than the national survey. This might indicate that there are a large number of patients who are not identified as they have not been diagnosed with ESRD in last 5-8 years.

Finally, providers might have changed their coding practice. This is because availabilities of treatment and disease management of the RRT system might motivate them to take more patients into the programme. As a consequence,

patients have higher probabilities to be diagnosed with ESRD than they were before the RRT programme started in 2008.

In addition to the diagnosis issue, patients who come to outpatient departments usually come with various symptoms and may not be diagnosed accurately. These patients are, therefore under-reported cases. All these reasons might affect numbers of patients with end-stage renal disease discussed in this study.

6.6.3   Account of patient characteristics

The next limitation came from the models, which did not take account of patient characteristics such as gender, and clinical measures, such as glomerular filtration rate or comorbidities. This is because this study lacks information on overall population estimates regarding the proportions of these clinical measures.

6.6.4   Study period

The short study period, from 2005 to 2013, was another limitation. Providing only 6-9 years of study, lines in cohort graphs (all figures b and d in descriptive analyses) are not long enough to compare and observe trends adequately across most cohort groups.

CHAPTER 7   Long term projections of RRT patients and costs of the RRT programme

7.1   Introduction

Prior chapters of this thesis looked at the renal replacement therapy (RRT) programme in terms of the response to a high-cost condition by people at various levels of the health system, the programme design, and its effects in terms of accessibility, and of mortality of patients who were diagnosed with end-stage renal disease. Results in Chapter 5 show that the RRT disease management programme has facilitated the growth of RRT units and dialysis professionals in order to increase access to RRT services and to reduce catastrophic health spending. Disease management was employed as an intervention to facilitate the use of care through a patient identification process and the use of a guideline protocol. It was evident in Chapter 6 that the number of patients enrolling on the programme has been growing. Meanwhile, the programme retained increasing numbers of patients, as receiving proper dialysis care resulted in extended life expectancy.

Many countries have achieved the universal health coverage goal of protecting patients (in this case, those suffering from end-stage renal disease) from catastrophic health spending. Nonetheless, they face the challenge of increasing care costs (De Vecchi, Dratwa et al. 1999; Soroka, Kiberd et al. 2005; Knauf and Aronson 2009; Su, Tsai et al. 2010). For this reason, many countries' focus has been on factors influencing costs of health care (Gerdtham and Jönsson 2000), and how to control them as they impact overall health spending.

A number of cost drivers have been described as being the cause for increases of health expenditure, including each country's disease burden, and investments in materials and machines (Karopadi, Mason et al. 2013). In addition, each RRT modality may be driven by different cost drivers. In the case of peritoneal dialysis, the main cost drivers are material expenses such as solutions and catheters. Costs for hemodialysis are driven by the fixed costs of facility space and staff salary (Just, de Charro et al. 2008). A study from Thailand

(Suksamran, Kongsin et al. 2012) reported that the cost of medications accounted for the largest proportion of transplantation costs (although the study did not provide a breakdown of costs).

From its beginning in 2008, the Thai Universal Coverage Scheme (UCS) RRT programme has achieved its aim to increase access to care and provide financial protection for patients against catastrophic spending. At the same time, the programme's numbers of patients and spending have both grown significantly, and the increasing demand for RRT may challenge the country's health care budget and human resources for health. In 2014 the total cost of the RRT programme to the UCS amounted to 4% of the total UCS budget[26], although individuals who were maintaining RRT accounted for only 0.07% of the general UCS members (NHSO 2014).

In addition to the small number of studies defining the major cost drivers to RRT, there are a limited numbers of cost studies conducted in developing countries from the perspective of the public payer. Moreover, there is a lack of recent studies forecasting the number of patients and budget needs for the RRT programme in Thailand, and none of the previous studies have defined cost drivers for this high-cost health condition.

This study draws evidence from the previous chapters to estimate the long term financial consequences of the RRT programme by developing a model for calculating 1) future numbers of patients in each RRT modality, 2) the unit cost of each RRT modality, and 3) publically-funded budget needs from the public payer's perspective over the next ten years (2014-2023). The chapter further uses RRT to identify effects of cost drivers on future expenditure of a high-cost treatment. The main cost drivers included here are: number of patients, labour costs, material costs, and capital costs.

Firstly, this chapter summarises the methodology, with a framework of data analysis. Next, it reports results of the two sections: forecast numbers of RRT patients and estimated costs of the RRT programme over the next ten years.

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[26]Total UCS budget including salary was 154,285 mBaht. Total spending on claims of the RRT programme was 6,023 mBaht.

Results from these two sections were drawn on to calculate the programme's budget needs during the period. A discussion and conclusions are provided at the end of this chapter.

7.2   Methodology

The methodology section is divided into three subsections: for forecasting numbers of patients; estimating costs of the RRT programme; and predicting future budget needs for the programme. It details how each model was obtained, how each component was calculated, and what assumptions were used.

7.2.1   Forecasting numbers of RRT patients

Numbers of patients needing RRT is important to estimate the budget for treating them. This section shows the method of forecasting numbers of RRT patients into the next ten years. The three RRT modalities were separately modelled and forecasted. The forecast method was based on the autoregressive integrated moving average (ARIMA) technique, which is the most widely used time-series approach in health research. It predicts future behaviour of a variable of interest by taking previous observations as the basis (Linden, Adams et al. 2003). There are four steps of the ARIMA modelling: 1) constructing the analytical dataset, 2) identification, 3) estimation and testing, and 4) forecasting.

7.2.1.1   Constructing the analytical dataset

NHSO databases provide observations of individuals of all ages who were registered and retained in the RRT programme between the fiscal year 2008-2013 (1st October 2007-30th September 2013) stratified by RRT modality and month of registration. Table 7-1 is a part of the analytical dataset. Differenced series[27] of PD, HD, and KT were produced in this stage. Numbers of PD, HD, and KT in columns 2-4 are cumulative numbers of live patients by month; they are summed in column 5. Differenced series of PD, HD, and KT are calculated by

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[27] For example, PD differenced series at time t=PD_t - $PD_{(t-1)}$

subtracting the number of patients in the previous month (t-1) from the number of patients in the present month (t). Differenced series were used to identify trends in time series plots.

Table 7-1 Selected ten observations from the dataset

Time	No.PD	No.HD	No.KT	Total No.RRT	PD differenced series	HD differenced series	KT differenced series
Jan2009	1,232	6,271	39	7,638	130	-86	7
Feb2009	1,429	6,280	47	7,881	197	9	8
Mar2009	1,621	6,240	56	8,056	192	-40	9
Apr2009	1,849	6,215	99	8,387	228	-25	43
May2009	2,054	6,170	116	8,591	205	-45	17
Jun2009	2,296	6,134	127	8,826	242	-36	11
Jul2009	2,533	6,083	148	9,068	237	-51	21
Aug2009	2,741	6,046	162	9,270	208	-37	14
Sep2009	2,976	5,978	178	9,464	235	-68	16
Oct2009	3,204	6,008	190	9,746	228	30	12

PD=peritoneal dialysis, HD=hemodialysis, KT=kidney transplant

7.2.1.2   Identification

The identification process was conducted to determine whether a transformation of the data was needed to stabilise the variance. For this, observations from each RRT modality were plotted against time. All RRT modalities showed non-stationary patterns, therefore the first differenced series were compared with the initial series in order to identify the right models.

7.2.1.3   Estimation and testing

The purpose of estimation and testing was to determine the most appropriate model. This step started by first, plotting the Autocorrelation function (ACF) and partial autocorrelation (PACF) to all RRT modalities and their differenced series, then determining numbers of appropriate AR(p) or MA(q) terms for the appropriate model. Finally, a number of statistics were produced to identify accurately fitted models. These were; i) unit root test, ii) autocorrelations test, iii) Akaike's Information Criterion (AIC), and iv) test of residuals.

i. Unit root

If a unit root presents, the series are non-stationary and need differencing. A unit root can be identified by the appearance of autocorrelations of the original series and their differenced series. If autocorrelations are positive to a high number of lags, the series may need one or more number of differencing (Nau 2014). Also, there is a formal test for the unit root, called the Dickey-Fuller test, where the null hypothesis is that there is a unit root (Fisher 2010).

ii. Autocorrelations

Autocorrelation is a statistical measure used to describe correlations between values of the time series at different time periods or time lags (Makridakis, Wheelwright et al. 1998). This study performed three tests to detect serial correlations including 1) the Durbin-Watson statistic, 2) Durbin's alternative test, 3) the Breusch-Godfrey test. Their null hypothesis is that there is no serial correlation.

iii. Akaike's Information Criterion (AIC)

The AIC provides a measure of goodness-of-fit to a model. It is commonly used with ARIMA models to decide the appropriate model order (Makridakis, Wheelwright et al. 1998). A model with the lowest AIC is preferred.

iv. Residuals

A well-fitted model is measured by the white noise of residuals. The Q statistic (Portmanteau test of autocorrelations) was performed to test the white noise. The null hypothesis is that the series are white noise. In addition, a cumulative periodogram was assessed to test the distribution and spread of the residuals. The residuals should have a mean of zero, constant variance, and be normally distributed (Hyndman and Athanasopoulos 2015).

Tests for unit root, serial correlations, white noise, and AIC are presented in Appendices 8-9.

7.2.1.4   Forecasting

After the preferred models had been identified, they were used to produce mean values for the next 120 observations, that is, monthly data of the next ten year period. The product of this step was predicted numbers of patients by RRT modality. They were used to calculate future budget needs in subsection 3 (7.3.3). Confidence intervals of 95% were applied to give upper and lower limits of mean values. All statistical analyses and graphical presentations in this section were conducted using Stata13. Figure 7-1 summarises how the predicted number of patients are obtained. Results from fitting ARIMA models (for PD, HD, and KT) are shown in Appendix 10.

Figure 7-1 Three steps in forecasting the number of patients
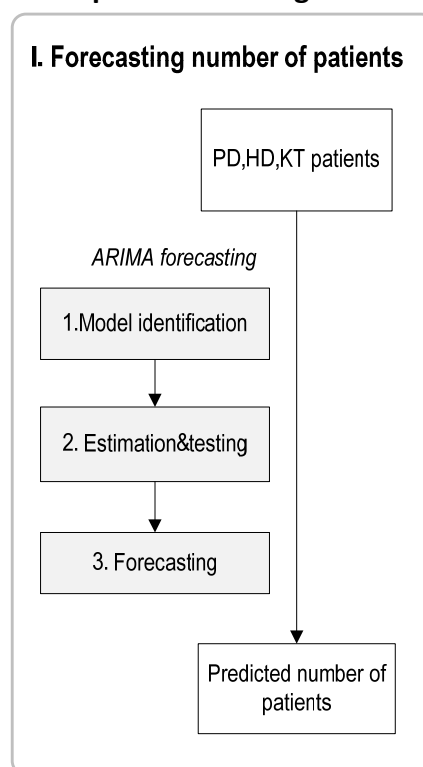
PD=peritoneal dialysis, HD=hemodialysis, KT=kidney transplant

7.2.2   Estimating the costs of the RRT programme

Information about costs of RRT services is important to inform policy decisions in many ways. For example, from the payer's perspective, hospital costs are important for determining reimbursement rates, and providers may want to compare the true cost of their services to the reimbursement that they receive.

This section used information from NHSO reimbursement and payment to estimate the unit cost of each RRT modality. The unit cost was then broken down into three types of cost objects: material costs, labour costs, and investment costs using proportions from the reviewed studies on costing.

7.2.2.1   Unit cost per patient

NHSO reimbursement and payment in 2014 were used as the basis for estimating the unit cost of each RRT modality. The NHSO reimburses services relating to the RRT programme in various ways. This study divided them into three groups. They were (i) reimbursements for service bundles which relate to the amount used by a patient per year; (ii) medicines and medical devices, which are centrally purchased and allocated to RRT units; and (iii) additional reimbursements for services which are used by particular groups of patients. Only the first and second types (service bundles and medication/medical devices) were used to calculate the unit cost per patient per year. The third type (additional services) was used to calculate the future budget need in the last subsection.

Table 7-2 explains what is included in each group and how the unit cost is calculated. The PD service bundle was paid to RRT units on a per patient/per month basis. HD and KT payments were made per session and transplantation respectively. The second group of costs includes medicine and medical devices which were centrally purchased and allocated to RRT units on the basis of use. The third group comprises those PD patients who needed temporary hemodialysis before starting normal PD, vascular access which was applied to all new HD patients, erythropoietin for patients who were self-paying HD, and lifelong immunosuppressive drugs for patients at various stages of kidney transplant.

Table 7-2 Composition of NHSO reimbursements

(i) Service bundle	(ii) Medicine and medical device	(iii) Additional reimbursements
• PD • HD • Transplantation	• For PD: fluids, catheters, EPO • For HD: EPO • For KT: IS in the first year	• For PD: temporary HD • For HD: vascular access : EPO for self-pay HD • For KT: IS in subsequent years

PD=peritoneal dialysis, HD=hemodialysis, KT=kidney transplant, EPO=erythropoietin, IS= immunosuppressants

An NHSO administrator revealed in an interview (Chapter 5) that NHSO payment was intended to cover the full cost for caring for patients in the RRT programme. However, the payment is paid to RRT units in a total amount, details for each type of costs (such as salaries, drugs (excluding the second type that supported by the NHSO), and maintenance) were not clarified anywhere.

Unit costs of PD and HD

The unit cost per patient-year was estimated using the following steps. For PD and HD average use per patient was calculated from the total annual use divided by the number of using patients, see the formula below. For example, a figure of 72.43 EPO (erythropoietin) vials per month was calculated from the total vials dispensed per year, divided by the total number of patient claims.

$$Average\ use\ per\ patient\ per\ year\ = \frac{total\ use\ of\ all\ patients\ in\ 2014}{total\ patients\ in\ 2014}$$

The unit cost per patient per year was computed by working out the average use of each reimbursed item and then multiplying the average use by its reimbursement rate. Next, the unit cost per patient was the total of all results in the first and the second group of reimbursements, see the formula below.

$$Unit\ cost\ per\ patient\ per\ year\ =\ total\ of\ (average\ use * reimbursement\ rate)$$

Note that the NHSO divided HD patients into three categories: general HD patients, elderly HD patients who are reimbursed at different rates but costs to both groups were averaged here, and self-pay HD patients who pay out-of-pocket for HD sessions but are eligible to receive free erythropoietin from the NHSO. The average of HD bundles was worked out by (1) calculating average

reimbursement per patient per month by adding up all reimbursements in both age groups; (2) dividing this total by the total number of patients; and (3) adding the cost of all claims per patient-month to gain the total claims cost per patient-year.

Unit cost of KT

The unit cost of KT was calculated by a different method. Instead of using the average use per patient, the total number of claims of each item for transplantation (for both donors and recipients and extra claims for complications) were used and multiplied by their reimbursement rates, and then summed to produce the total payment per year (2014). The unit cost of KT was calculated by dividing this total by the total number of successful transplant operations, see formula below.

$$Total\ payment\ per\ year\ =\ total\ of\ (number\ of\ claims * reimbursement\ rate)$$

$$Unit\ cost\ =\ \frac{total\ payment\ per\ year}{total\ KT\ operations}$$

7.2.2.2   Material cost, labour cost, and capital cost

As mentioned above, NHSO payments and reimbursements are intended to cover all costs for patient care. This would imply that they include salaries (for everyone working for the RRT unit), medications, consumables, overheads, and investments (excluding patients' travel costs, carers, and lost wages); but this has never been specified anywhere.

This study used the calculated unit cost to estimate the components of material, labour, and capital costs by using the unit cost per patient-year and proportions from the reviewed studies. These studies were conducted in Thailand using the activity-based costing method where all departments, namely cost centres, relevant to RRT services were included. These cost centres allocated direct costs (material, labour and capital costs of the RRT unit) and indirect costs (material, labour and capital costs of other supporting departments such as administration, laboratory, and laundry) to each RRT modality.

For peritoneal dialysis, figures from the study by Laonapaporn, Punthunane et al. (2014) were used. This is because this study was recent and included detailed costs of each service. In this study, proportions of material cost (MC): labour cost (LC): capital cost (CC) were at a ratio of 74:25:1. For hemodialysis, various figures were available. The proportions of MC:LC:CC equalled 43:40:17 in the study of Tisayaticom, Patcharanarumol et al. (2003). Although the study was not the most recent, it was conducted across a wide range of health facilities across the country. In addition, proposed proportions seem to be consistent with the fact that hemodialysis relies heavily on skilled professionals in comparison to home dialysis such as PD. For kidney transplant, the proportions of LC:MC:CC were 79:18:3. This was taken from the study of Suksamran, Kongsin et al. (2012) to estimate the amount of material, labour, and capital costs contributing to one case of kidney transplantation.

In this study material costs comprise the cost of medications/devices which are centrally purchased and distributed to RRT units, and costs of other medicines and materials that hospitals purchase and use them for providing RRT services. Labour costs refer to remuneration given to everyone working for providing RRT services. Capital costs refer to depreciation and maintenance costs of equipment and buildings in the care of RRT.

The product of this stage was the unit cost per patient in each RRT modality per year consisting of estimated amounts of material costs, labour costs, and capital costs. The unit cost represented the initial cost in 2014 (the initial year of the forecast period), and was used to calculate annual budget needs from the payer's perspective over the next ten years in the next section. Figure 7-2 summarises how the unit cost, material costs, labour costs, and capital costs were calculated.

Figure 7-2 Summary of the unit cost calculation
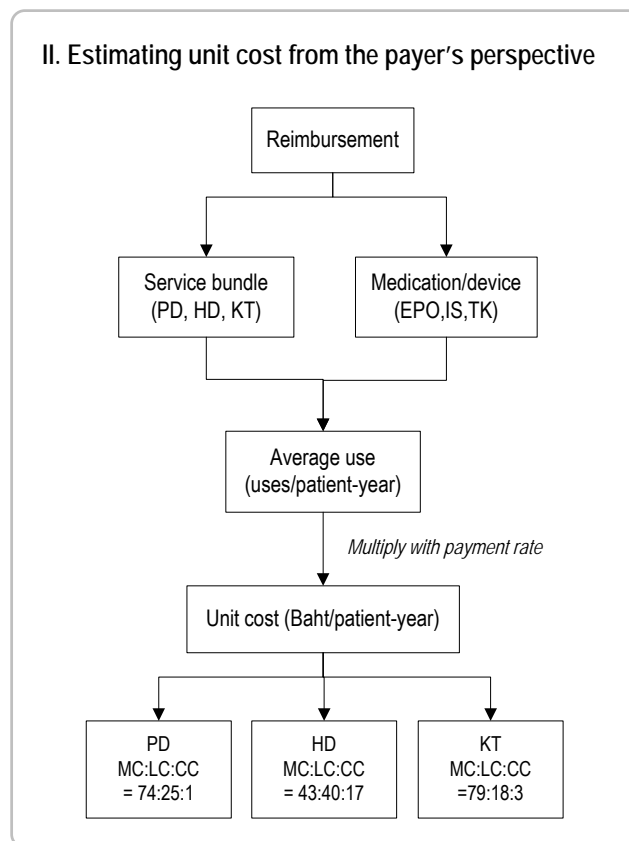
PD=peritoneal dialysis, HD=hemodialysis, KT=kidney transplant,
TK= Tenckhoff catheter, EPO=erythropoietin, IS=immunosuppressive drugs,
MC=material costs, LC=labour costs, CC=capital costs

7.2.3   Budget needs in the future

This section used results from previous sections to calculate the final results. They were: 1) the total RRT programme budget needs 2014-2023 and 2) effects of cost drivers: number of patients, labour costs, material costs, and capital costs. The latter is to explain effects of these drivers: how they influence the unit cost of each RRT modality, and to suggest ways to control care costs during such ten-year period.

The section first provides information on the selected scenarios. After that it explains how costs were calculated. The forecast figures are presented and discussed in terms of 2014-constant Baht.

7.2.3.1   Future scenarios

It is possible that the unit cost will, in the next ten years, deviate from what it was in 2014. Chapter 5 provided insights into what future scenarios could be,

and three scenarios which are likely to happen were selected. All three scenarios used numbers of projected future patients to model cost. There were three costing parameters: material costs, labour costs, and capital costs. While labour costs and capital costs were the same in all scenarios, material costs were varied, Table 7-3.

Table 7-3 Variations of costing parameters in three scenarios

Scenario	Material cost	Labour cost	Capital cost
1	≈	↑	≈
2	↑	↑	≈
3	↓	↑	≈

↑= increasing, ↓ = decreasing, ≈ = unchanging

A number of assumptions were employed to propose scenarios, thus the selected scenarios were close to the real process of government's budgets. All three selected scenarios assumed the numbers of patients in each RRT modality would be as projected in subsection 7.3.1.

This section assumed that the capital cost would behave like a fixed cost, and therefore the total capital cost of treating the patient population of 2014 would not vary as the patient number increases. It is possible that the payer may want to control RRT spending by keeping the cost of new investment stable during a time period. The total capital cost supported by the NHSO was assumed to be a flat rate annually for the total patient population and remains unchanged from the cost in 2014 over the next ten-year period.

Labour costs and material costs were assumed to behave like variable costs, increasing as the number of patients rises. In reality, staff salaries and wages increase each year. For this reason, this section assumed wage rates would grow by 7.2%-7.9% in real terms annually as Sakulpanit, Jitsuchon et al. (2015) projected for wage growth in the public service sector, therefore the total labour cost increases as a consequence of increasing patients (and more staff needed) and wage growth.

Material costs of each reimbursed item were varied across scenarios 1 to 3. In scenario 1, material costs per patient-year would remain unchanged in 2014-

2023. In scenario 2, it was assumed that pharmaceutical companies want to gain more profits and would not keep their prices of medicines and devices stable, meaning material costs per patient-year would increase at 10% per year in real terms, as reported by Sakulpanit, Jitsuchon et al. (2015).

In the future, it is likely that PD solutions, erythropoietin, and immunosuppressive drugs will be made locally by the Government Pharmaceutical Organization (GPO). When locally made, costs of transportation and bulk storage would be cheaper, and therefore large savings would be expected. A study by Akaleephan, Wibulpolprasert et al. (2009) reported that a generic brand would cost approximately 30%-80% of its innovator brand in the first year of substitution. The third scenario (that generic brands are used in 2014-2023) took the figure of 80% of the original 2014 price to calculate material costs per patient-year for each reimbursed item.

7.2.3.2 Cost calculation method

The two previous sections estimated numbers of future patients and costs per patient-year. Referring to Table 7-2, reimbursements were divided into three groups: (i) reimbursements for service bundles, (ii) medications/devices, and (iii) reimbursements for additional payments; these were separately calculated. Reimbursements for service bundles and costs of medications/devices (group 1 and group 2) were combined in order to calculate the unit cost per patient. In this section, the total cost to the payer for each RRT modality was estimated into the future. Figure 7-3 summarises the calculation process for assessing future financial implications.

First, the unit cost per patient from the previous section was broken down into three cost objects: material costs, labour costs, and capital costs. Next, the cost object was varied for three selected scenarios. At this stage, each cost object was multiplied by the predicted number of patients in each RRT modality to give the total cost of each cost object. Finally, the total cost to the payer was calculated by adding up all the computed cost products by each RRT modality.

The third group of reimbursements (additional services) was computed to identify its total cost in the same way as the other two groups, but only the relevant number of patients was used. For example, to calculate the total material cost of temporary hemodialysis sessions used by new PD patients, the number of relevant patients was new PD patients (not all PD patients). Additionally, throughout the next 10-year period, it was assumed that:

- temporary HD was assumed to be used only by new PD patients and the average use of temporary HD sessions by new PD patients would remain unchanged,
- the cumulative number of self-pay HD patients would increase at a decreasing rate, and the rate used in calculations would be equal to those of HD patients each year,
- the number of old case KT patients[28] would remain unchanged.

7.2.3.3 Effects of cost drivers

To identify the effects of cost drivers, the individual estimated unit costs from 2014 to 2023 were calculated by dividing the total costs to the payer by the total number of patients in each modality. This was to show the changing trend of unit costs by RRT modality over the next ten-year period in the selected scenarios. However, these unit costs were not intended to provide unit cost projections in the future.

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[28] Meaning patients who had transplantation by self-financing or other means before the start of the RRT programme in 2008. These patients are supported with free EPO by the NHSO.

Figure 7-3 Framework for assessing budget needs, numbers of patients, and future financial implications
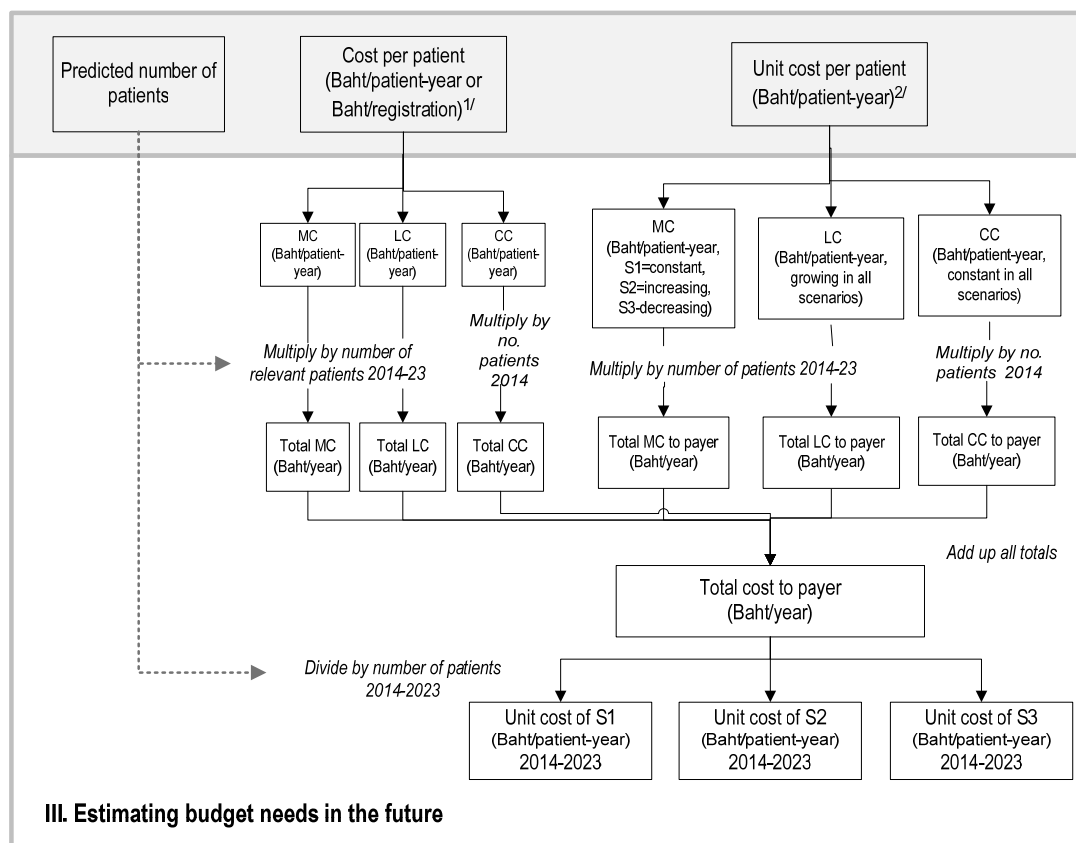
[1/]cost per patient of the third group (see Table 7-2), [2/] unit cost per patient of the second group (see Table 7-2)

  MC=material cost, LC=labour cost, CC=capital cost, S1=scenario 1, S2=scenario 2, S3=scenario 3

7.3   Results

This section presents results of cost estimations, forecasting numbers of patients and projecting budget needs into the next ten years.

7.3.1   Forecasting numbers of patients

Historical data for PD, HD, and KT patients were plotted against time from the beginning of 2008 to the end of 2013, Figure 7-4. Although there is a slight drop in numbers, PD patients have shown a constant increase. By the end of 2013, the figure increased to 12,000 patients. HD patients showed slowly increasing rates until mid-2013. After that the rate increased at similar rates to PD. In December 2013, there were 10,000 patients using HD (Figure 7-4a). Numbers of KT were increasing but the figures were much lower in comparison to those of PD and HD. At the end of 2013, there were approximately 800 patients who

had had a kidney transplant, Figure 7-4b. Note that low figures of dialysis patients during 2013 might be a consequence of 1) merging several databases and 2) claims data given from 2013 may not be completely up to date.

Figure 7-4 Numbers of patients by RRT modality
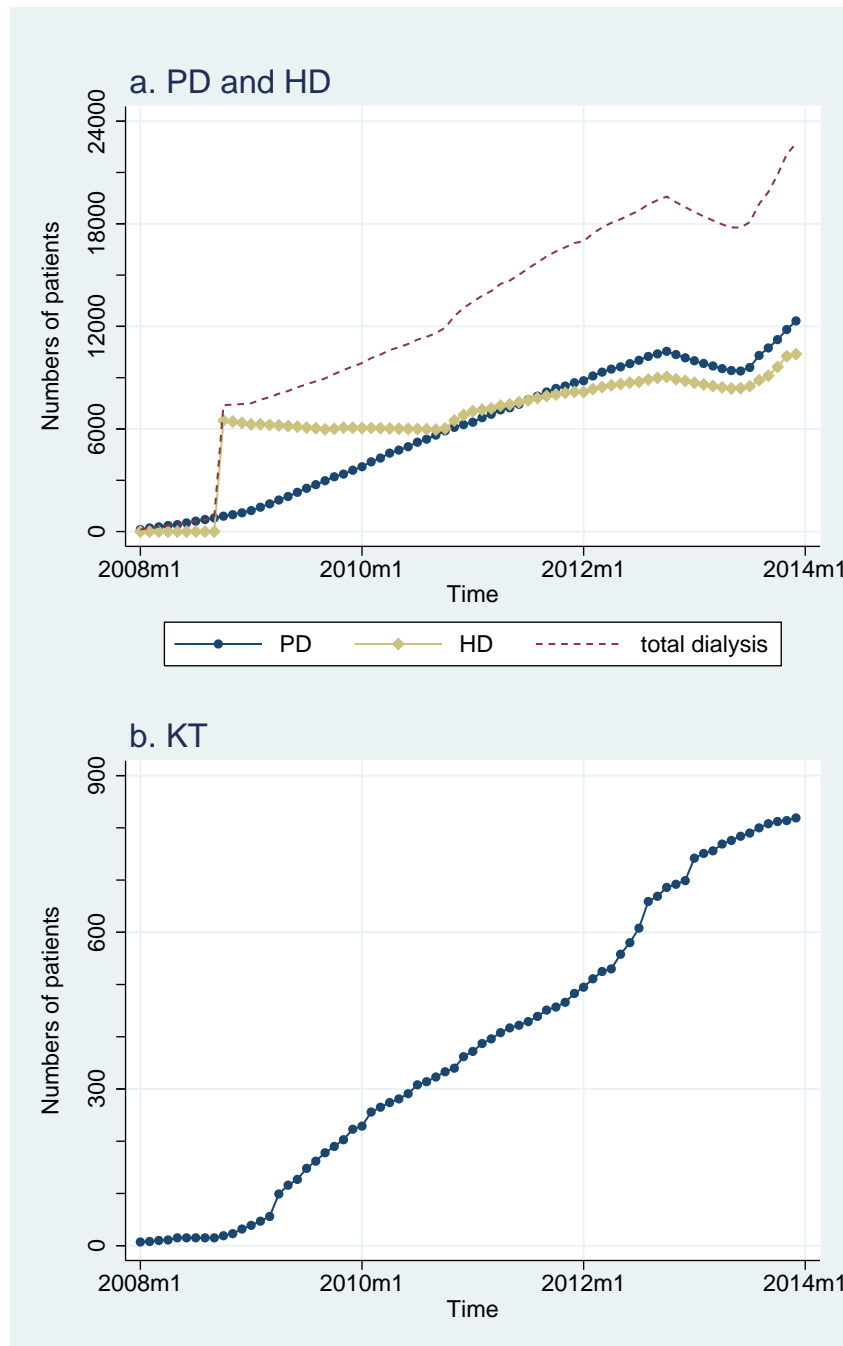
PD=peritoneal dialysis, HD=hemodialysis, KT=kidney transplant

7.3.1.1   Model identification

It is clear from Figure 7-4 that trend patterns exist in the time series plots of PD, HD, and KT. To statistically measure these nonstationary patterns, unit root tests for stationarity in time series were performed. Results show the presence of unit roots in all models, see Appendices 8 and 9. These results suggest that each model needs at least one differencing.

Next, autocorrelation function (ACF) and partial autocorrelation (PACF) plots were used to identify the number of autoregressive (AR) and moving average (MA) terms in each model. Results from the original series were compared against the differenced series.

i.   ACFs and PACFs of peritoneal dialysis

Figures 4a and b are ACF and PACF of the original series, while Figures 4c and d are those of the differenced series. ACF plots of the original series decay very slowly (Figures 4a) and the ACF of the differenced series (Figures 4c) shows a cut-off at lag 1. PACF plots of both original and differenced series are infinite and dominated by dampened sine waves (Figures 4b and 4d). All these features indicate the model ARIMA(0,1,1).

Figure 7-5 ACFs and PACFs of peritoneal dialysis
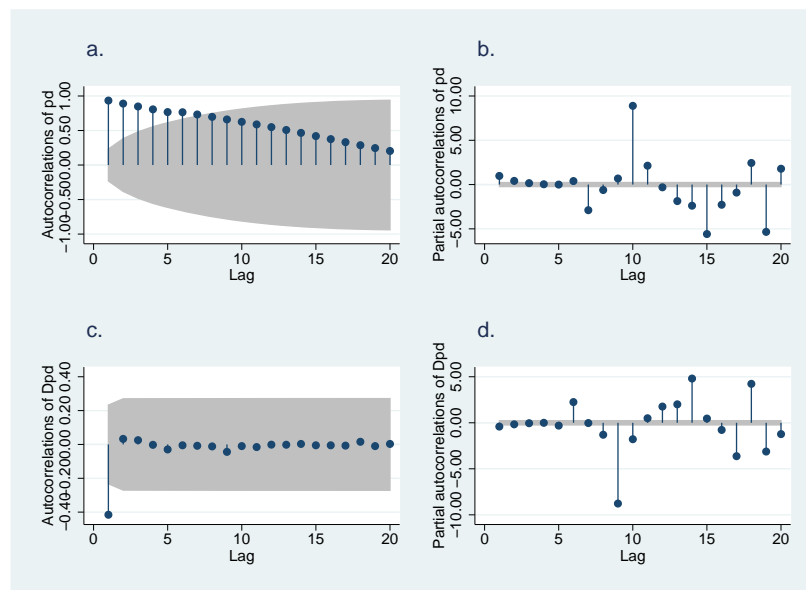
pd=peritoneal dialysis, Dpd=differenced series
Shaded areas represent 95% confidence bands

ii. ACFs and PACFs of hemodialysis

Figure 7-6a and b are the ACF and PACF of the original series, and Figures 5c and 5d are those of the differenced series. From Figure 7-6a, we can see that the ACF of the original series decays to zero and the PACF shows a significant spike at lag 1 then a cut-off (Figure 7-6b). Both ACF and PACF of the differenced series show insignificant lags as there are no lag spikes out of the 95% confidence bands (Figure 7-6c and d). Because the ACF plots of the differenced series are all negative and show no patterns, differencing might not be necessary. Therefore, the model with one AR term and without differencing, AR(1) was selected.

Figure 7-6 ACFs and PACFs of hemodialysis
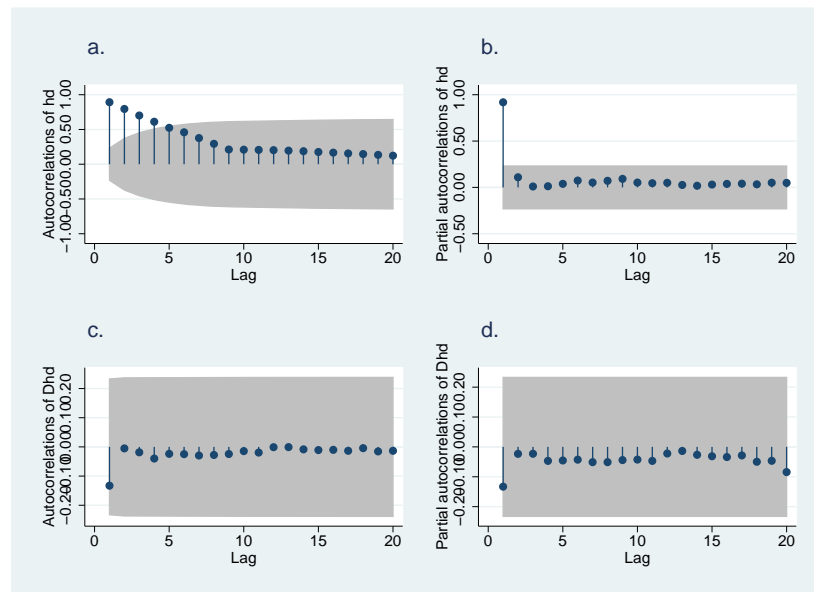
hd=hemodialysis, Dhd=differenced series of hemodialysis
Shaded areas represent 95% confidence bands

iii. ACFs and PACFs of kidney transplant

Similar to those of the PD models, ACF plots of the original series gradually decay (Figure 7-7a) and the ACFs of the differenced series display a sharp cut-off, significant at lag 1, Figure 7-7c. PACF plots of both original and differenced series are infinite, and are dominated by dampened sine waves (Figure 7-7b and 6d). This feature suggests the ARIMA(0,1,1).

Figure 7-7 ACFs and PACFs of kidney transplant
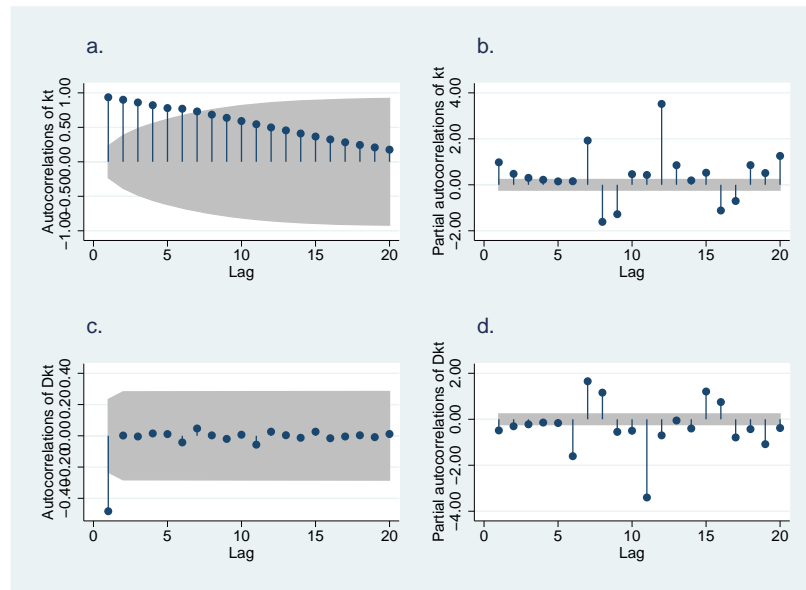
kt=kindey transplant, Dkt=differenced series of kidney transplant
Shaded areas represent 95% confidence bands

7.3.1.2   Estimation

i. PD model and KT model: ARIMA (0,1,1)

The equation for an ARIMA(0,1,1) is

$$\hat{Y}_t \ = \ \mu \ + Y_{t\text{-}1} - \theta_1 e_{t\text{-}1}$$

where $\hat{Y}$ denotes forecast value at time t, μ is the constant (PD model =167.44 and KT model=11.79), and θ is the moving average parameter (PD model =-0.48, KT model=-0.76). The term $e_{t\text{-}1}$ is the error term at time t-1 (see details in Appendix 10).

ii. Hemodialysis: ARIMA(1,1,0)

A model with one AR term seemed to fit the data best. However, *p-values* of all coefficients of this model were insignificant (see Appendix 10). When trying to fit a mixed model ARIMA(1,1,1), all parameters were significant. Makridakis, Wheelwright et al. (1998) and Nau (2014) explained that it is possible that the AR term and the MA term cancel each other's effects even though both may appear significant in the model when judged by the *p*-value of their coefficients. Furthermore, fitting the model ARIMA(1,1,1), the parameter estimation process

took many iterations to converge. In this case, reducing one AR or MA term might be appropriate, as suggested by Nau (2014). Consequently, the ARIMA(1,1,0) was selected.

The equation for a differenced series of ARIMA(1,1,0) is

$$\hat{Y}_t \; = \; \mu + Y_{t-1} + \phi \; (Y_{t-1} - Y_{t-2})$$

where $\hat{Y}_t$ represents the expected number of patients at time t. The term μ is the constant (146.32) and ϕ denotes the autoregressive coefficient (-0.131).

iii. Tests of residuals

Cumulative periodograms of all models remain close to the 45 degree line and within the confidence band, while the residuals show no deviation to white noise (see Appendix 11).

7.3.1.3   Forecasting

Figure 7-8 shows the actual historical and predicted numbers of RRT patients according to the selected models. It was estimated that by the end of 2018, numbers of PD, HD, and KT patients would increase to 22,364 ±1,683; 19,155±1,716; and 1,526±126 patients respectively. After that, by the end of 2023, these figures were forecast to be 32,410 ±1,683; 27,935±1,716; and 2,234±126 respectively. It is clear that confidence intervals of PD and KT are very close to their predicted lines, which might be because these two modalities showed strong, stable historical trends. For this reason, only the central numbers of the three RRT modalities will be used in calculations from here on.

Figure 7-8 Actual and predicted PD, HD, and KT patients to the year 2024
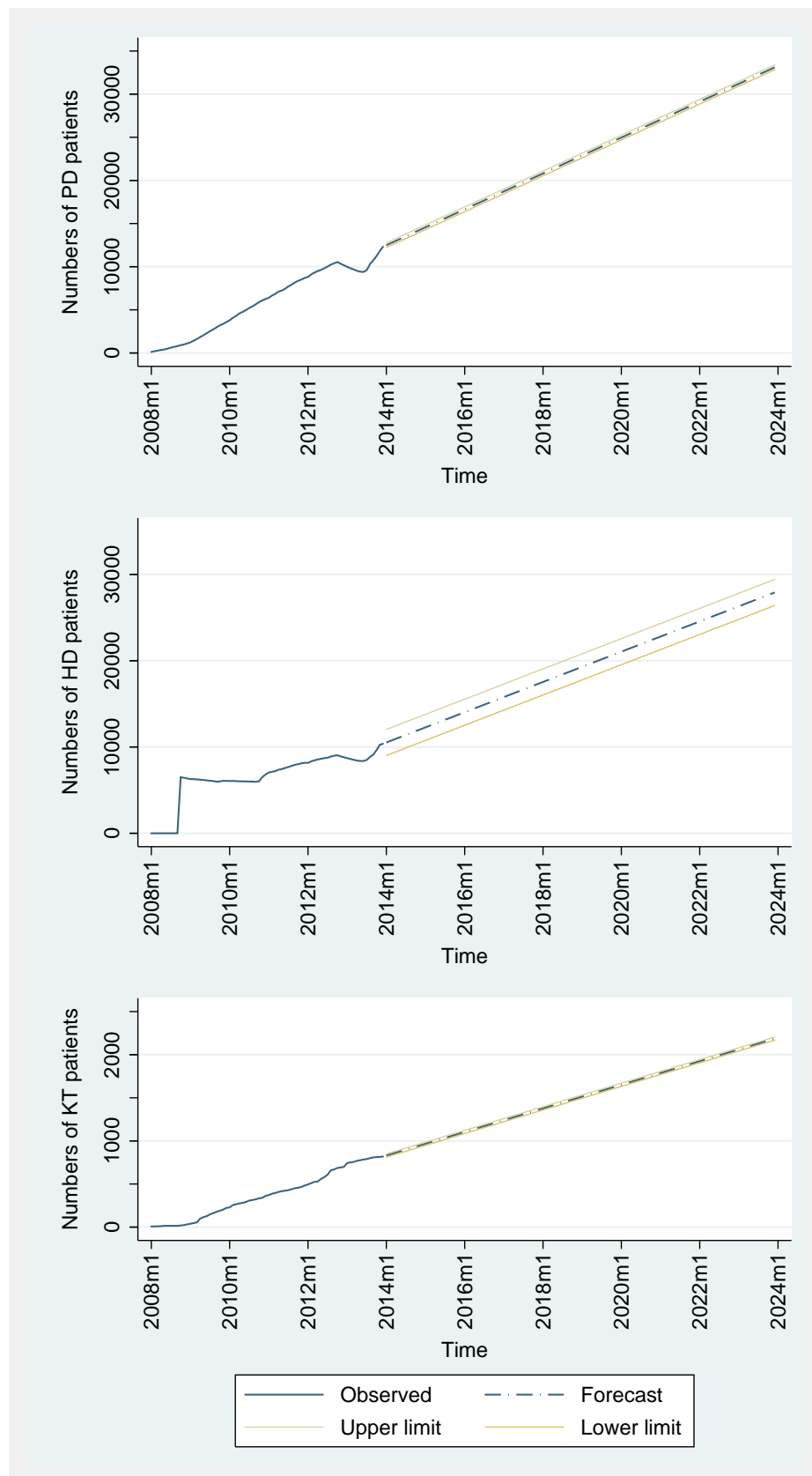
PD=peritoneal dialysis, HD=hemodialysis, KT=kidney transplant

Forecast values for all RRT modalities at the end of each year from 2014-2023 are given in Table 7-4. Over the next ten years, numbers of PD, HD, and KT patients were expected to grow with decreasing rates. The ARIMA models predicted that the number of RRT modalities, PD, HD, and KT would increase by 14.0%, 14.5%, and 14.7% respectively in 2015 and by 6.6%, 6.7%, and 6.8% respectively in 2023. Their average increases were 10.2%, 12.5%, and 10.6% annually. The total number of patients in 2023 was forecast to be 62,579.

Table 7-4 Forecast total numbers of patients by RRT modality from 2014 to 2023

Year	PD	HD	KT	Total
2014	14,327	12,132	960	27,420
2015	16,336	13,888	1,102	31,326
2016	18,346	15,644	1,243	35,233
2017	20,355	17,399	1,385	39,139
2018	22,364	19,155	1,526	43,046
2019	24,373	20,911	1,668	46,953
2020	26,383	22,667	1,809	50,859
2021	28,392	24,423	1,951	54,766
2022	30,401	26,179	2,092	58,672
2023	32,410	27,935	2,234	62,579
% average annual growth rate	10.2	12.5	10.6	10.3

PD=peritoneal dialysis, HD=hemodialysis, KT=kidney transplant

7.3.2   Costs of the RRT programme

7.3.2.1   PD cost calculation

NHSO reimbursements of PD were divided into three components. They consisted of reimbursements for temporary HD, PD services, and erythropoietin injections. Table 7-5 shows calculated costs by activity, as well as the total cost that the NHSO expected to pay for a PD patient in 2014. The total cost was 224,514 Baht per PD patient-year, of which the cost of the PD solution accounted for the largest proportion of the total cost, at 78%. This amount, however, did not include reimbursements for temporary HD sessions (HD sessions given to some patients before they start permanent PD). In 2014, new

patients registering with the PD programme used an average of 7.45 sessions before they started PD. This amounted to 11,175 Baht per patient.

Table 7-5 Annual payment for activities for one PD patient in 2014 (in Baht)

Activity	Reimbursement	Average use	payment/patient·year
Temporary HD*	1,500 Baht/session	7.45 sessions	N/A
PD service	2,500 Baht/month	12 times/year	30,000
PD solution (bag)	120 Baht/bag**	1,460 bags/year	175,200
EPO	200 Baht/vial**	72.43 vials/year	14,486
EPO administration	50 Baht/time	47.34 times/year	2,367
Tenckhoff catheter	4,172 Baht/catheter**	0.59 catheters/year	2,461
Total (Baht)			224,514

HD=hemodialysis, PD=peritoneal dialysis, EPO=erythropoietin
*Temporary HD was classified as additional cost to the NHSO and excluded in the unit cost per patient-year calculation
**Prices that NHSO purchased in 2014

7.3.2.2   HD cost calculation

For HD, there were four components to be reimbursed; reimbursements for undergoing a vascular access, HD sessions, erythropoietin, and erythropoietin administration. The vascular access is done just once before a patient starts hemodialysis. This activity, however, was not included in the total cost per patient-year calculation. In practice, there are two types of reimbursements for HD sessions; 1,500 Baht for patients aged 0-60 years and 1,700 Baht for elderly patients or those who have complications. This study used an average HD cost of 1,529[29].

The total cost for HD patients was calculated as 219,132 Baht per patient-year. This amount is dominated by reimbursements for hemodialysis sessions. Apart from general HD patients, the NHSO also supports provision of erythropoietin to HD patients who self-pay. These costs amounted to 17,788 per patient-year, Table 7-6.

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[29] The amount was calculated from the total claim cost of HD sessions divided by the total number of claims

Table 7-6 Annual payment for activities for one HD patient in 2014 (in Baht)

Activity	Reimbursement	Average use	Payment/patient·year
Vascular access*	5,000-12,000 Bath/operation	1 time	N/A
HD session	1,529.34 Bath/session**	131.65 times/patient-year	201,344
EPO	200 Baht/vial	77.55 vials/patient-year	15,510
EPO administration	50 Bath/time	45.56 times/patient-year	2,278
Total (Bath)		General HD	219,132
		Self-pay HD	17,788

HD=hemodialysis, EPO=erythropoietin
*Vascular access was classified as additional cost to the NHSO and excluded in the unit cost per patient-year calculation,
**Calculated from total claims costs divided by total number of claims

7.3.2.3   KT cost calculation

For KT, costs covered operations for both donors and recipients. There were four protocols of kidney transplant operations which varied in complexity. If there were complications, an extra 23,000-500,000 Baht per patient may have been spent for additional treatments. In 2014 the total number of successful operations was 183 operations. On average, one transplant operation cost 960,000 Baht (see Table 7-7).

Table 7-7 Payment for a kidney transplant procedure in 2014 (in Baht)

Activity	Total payment
Living donor pre-operation and nephrectomy	27,200,300
Deceased donor nephrectomy	9,300,300
Recipient's transplant programme[30]	39,421,280
Kidney transplant operation	
• Protocol 1	5,788,900
• Protocol 2	12,216,500
• Protocol 3	2,928,000
• Protocol 4	38,190,680
Transplant with complications	
• ARC_A	1,865,000
• ARC_B	3,600,100
• AMR_A	6,605,700

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[30] Including panel reactive antibody, an immunological laboratory test routinely performed on the blood of people awaiting transplantation

Activity	Total payment
• AMR_B	9,328,600
• DGF_A	12,776,000
• DGF_B	1,804,800
• DGF_C	4,709,400
Total payment to 183 operations	175,735,560
Unit cost per operation	960,304

All patients who have had a kidney transplant need immunosuppressant drugs after they go back to daily life. The reimbursement depends on which stage the patient is in. For a patient who is in the first six months after the operation, the RRT unit received 30,000 Baht per month and after the second year, the reimbursement decreased to 15,000 Baht. Overall in 2014, a total of 35,695,000 Baht went to 1,815 claims of patients in various stages, Table 7-8.

Table 7-8 Reimbursements (in Baht) of immunosuppressant drugs in 2014

	Reimbursement	Total payment/patient-year
IS in first 1-6 months	30,000/month	
IS in next 7-12 months	25,000/month	330,000
IS in next 13-24 months	20,000/month	240,000
IS after 24 months	15,000/month	180,000

IS = immunosuppressants

The total costs for PD, HD, and KT per patient are all summarised in Table 7-9. The total cost of each RRT modality was broken down into material costs, labour costs, and capital costs. Material costs included costs of consumables; laboratory tests and medications[31]. Labour costs included remuneration of professionals for work in the RRT unit. Capital costs refer to depreciation and maintenance costs of equipment and buildings in the care of RRT.

A large proportion (96%) of PD costs was spent on materials. For HD, 47% and 37% of the total cost went on material and labour costs, respectively. Total costs of PD and HD were comparable, at approximately 225,000 Baht and 219,000 Baht per patient-year respectively. The total cost of KT was much

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[31] Medications here assumed to include both items that were purchased in bulk quantities at the central NHSO then allocated to hospitals and items that hospitals bought by themselves.

higher than the other two modalities in the year of transplantation. The total cost of KT (1,290,000 Baht) is for one kidney transplant and medication (immunosuppressants) given to a patient in the first year of transplantation. The total cost for transplantation alone was 960,000 Baht.

Table 7-9 Estimated costs per patient-year for each RRT modality (in Baht)

	PD (%)	HD (%)	KT (%)
Material cost	216,099 (96)	103,068 (47)	467,931 (46)
Labour cost	8,092 (4)	81,449 (37)	172,855 (38)
Capital cost	324 (<1)	34,616 (16)	28,809 (16)
Total cost	224,514 (100)	219,132 (100)	1,290,304*(100)

PD=peritoneal dialysis, HD=hemodialysis, KT=kidney transplant
*Figure represents costs for donor nephrectomy, recipient's transplant programme, PRA test, transplantation with complications, and immunosuppressant in the first year.

Figure 7-9 is a graph comparing each cost component of the three RRT modalities. Self-pay HD and KT patients in their second year and above were included in the graph to show the costs of medication. It is clear that costs of PD and HD were comparable and cost just one-sixth of KT in the first year. After the first year of transplantation, however, costs for patients who maintain KT were significantly lower. In the second and third year and beyond, only immunosuppressants were supported for KT patients, meaning total reimbursements after the second year would be slightly lower than those of PD and HD.

Figure 7-9 Comparison of costs and their components
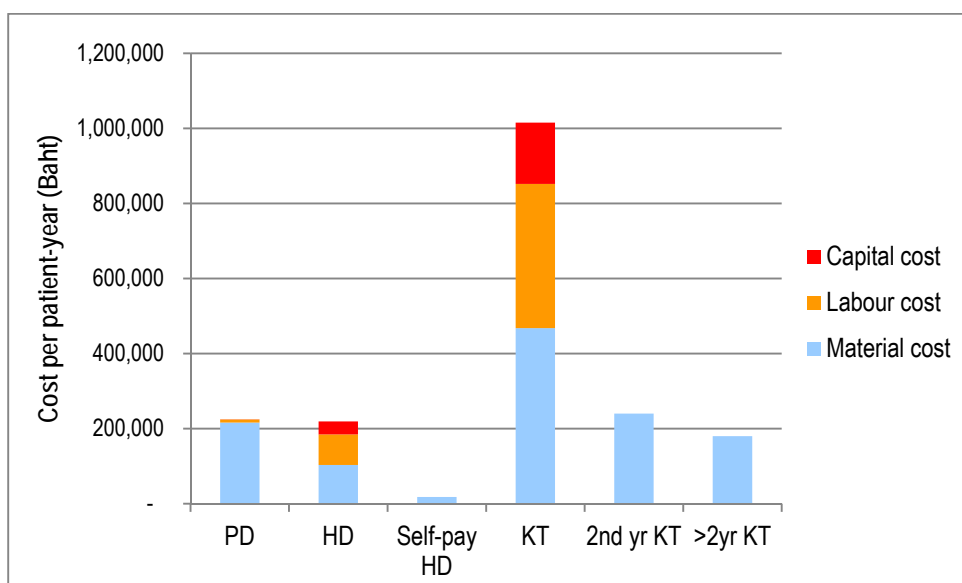
PD=peritoneal dialysis, HD=hemodialysis, KT=kidney transplant

7.3.3   Future budget needs of RRT programme

7.3.3.1   Scenario 1

In this scenario, reimbursement rates were adjusted for wage increases at 7.2%-7.8% annually. Reimbursements for material and investment costs would remain unchanged. Budget needs in 2014-2023 were projected as shown in Table 7-10. In 2023, reimbursements of PD, HD, and KT costs were predicted to be 7,500 million Baht, 8,000 million Baht and 700 million Baht respectively, giving a total cost of 16,200 million Baht. Overall the total RRT budget need was expected to grow by a mean annual rate of 11%.

Table 7-10 Forecast budget needs in Scenario 1 (million Baht)

Year	PD	HD	KT	Total
2014	3,239	2,773	411	6,422
2015	3,700	3,195	439	7,334
2016	4,164	3,649	467	8,280
2017	4,632	4,137	494	9,263
2018	5,104	4,660	522	10,286
2019	5,581	5,227	550	11,358
2020	6,063	5,835	578	12,476
2021	6,551	6,503	606	13,660

Year	PD	HD	KT	Total
2022	7,046	7,226	635	14,907
2023	7,547	8,009	664	16,220
% average annual growth rate	10	13	6	11

PD=peritoneal dialysis, HD=hemodialysis, KT=kidney transplant
Note: numbers were rounded to the nearest million, in terms of 2014-constant Baht

7.3.3.2 Scenario 2

If reimbursements were adjusted for wage increase at 7.2-7.8%, and for material increase at 10% each year, a greater budget would be spent on dialysis, particularly on PD. In 2023, the various RRT modalities would incur a total of 30,700 million Baht. PD was expected to cost at around 17,000 million Baht. Both dialysis modalities would require 95% of the total RRT budget. KT would spend less budget at around 1,500 million Baht (see Table 7-11). In this scenario the total budget need would grow at the highest rate in comparison to the other two scenarios, at around 19% annually.

Table 7-11 Forecast budget needs in Scenario 2 (million Baht)

Year	PD	HD	KT	Total
2014	3,239	2,770	411	6,420
2015	4,054	3,343	480	7,877
2016	4,999	4,004	557	9,560
2017	6,091	4,760	646	11,497
2018	7,351	5,623	747	13,721
2019	8,803	6,611	861	16,275
2020	10,469	7,732	991	19,192
2021	12,381	9,017	1,138	22,535
2022	14,570	10,474	1,305	26,349
2023	17,071	12,126	1,494	30,691
% average annual growth rate	20	18	15	19

PD=peritoneal dialysis, HD=hemodialysis, KT=kidney transplant
Note: numbers were rounded to the nearest million, in terms of 2014-constant Baht

7.3.3.3   Scenario 3

If the PD solution, erythropoietin, and immunosuppressants can be manufactured locally, substantial budget could be saved, particularly on PD. In the situation that these subsidised medications would be replaced by locally made types, the possible percentage saving was estimated at 20% of the 2014 purchase price. Costs of all RRT modalities, PD, HD, and KT, would increase slowly and reach the amounts of 6,100 million Baht, 7,400 million Baht and 500 million Baht respectively in 2023. All three RRT modalities would incur a total of 14,000 million Baht. The total RRT programme budget would be expected to grow by a mean of 9% each year.

Table 7-12 Forecast budget needs in Scenario 3 (million Baht)

Year	PD	HD	KT	Total
2014	3,239	2,770	411	6,420
2015	2,992	2,889	357	6,238
2016	3,369	3,304	380	7,053
2017	3,750	3,753	402	7,906
2018	4,135	4,237	425	8,798
2019	4,526	4,766	448	9,739
2020	4,921	5,335	471	10,727
2021	5,322	5,964	494	11,780
2022	5,730	6,648	518	12,896
2023	6,144	7,393	542	14,078
% average annual growth rate	8	12	3	9

PD=peritoneal dialysis, HD=hemodialysis, KT=kidney transplant
Note: numbers were rounded to the nearest million, in terms of 2014-constant Baht

Figure 7-10 compares estimated figures from the three scenarios. It is clear that PD would be influenced the most if there were changes in material costs and it would benefit most from switching to generic substitutions in scenario 3. Estimated savings would be in the region of 700-1,400 million Baht in comparison to scenario 1 (in which purchase prices of medications would remain unchanged). In contrast, if material prices of PD are uncontrollable, the total cost of PD would increase rapidly and would rise faster than the other two modalities.

Figure 7-10 Comparison of reimbursement costs from three different scenarios
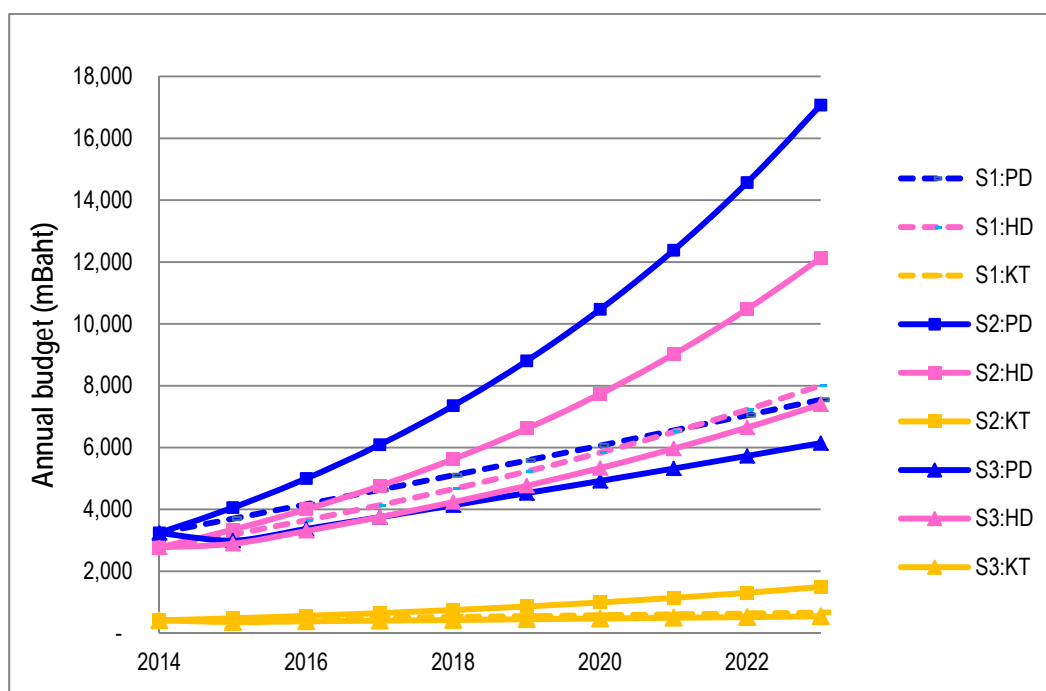
S1=scenario 1, S2=scenario 2, S3=scenario 3, PD=peritoneal dialysis, HD=hemodialysis, KT=kidney transplant

7.3.3.4   Estimated unit cost in the future

Behaviours of the three cost drivers were explained by the estimated unit costs over time of PD, HD, and KT from scenarios 1 to 3 (Figure 7-11). Scenario 1 assumed that labour costs would increase approximately 7% each year with unchanged material and capital costs. Estimated unit costs of PD and HD would gradually decrease, in contrast to that of KT, whose unit cost would increase over time (Figure 7-11). In scenario 2, material costs were assumed uncontrolled and would increase at 10% annually, while labour and capital costs would act as described in scenario 1. All estimated unit costs would increase over time.

In scenario 3, material costs were assumed to decrease by 20% in 2015. These savings would make each unit cost of RRT modalities decrease from its original scenario 1 value, then reach a low point. After that, the unit costs of PD would remain rather stable over time. However, unit costs of HD and KT would increase after reaching a low point in 2015.

Figure 7-11 Estimated unit costs of PD, HD, and KT from scenarios 1 to 3 2014-2023
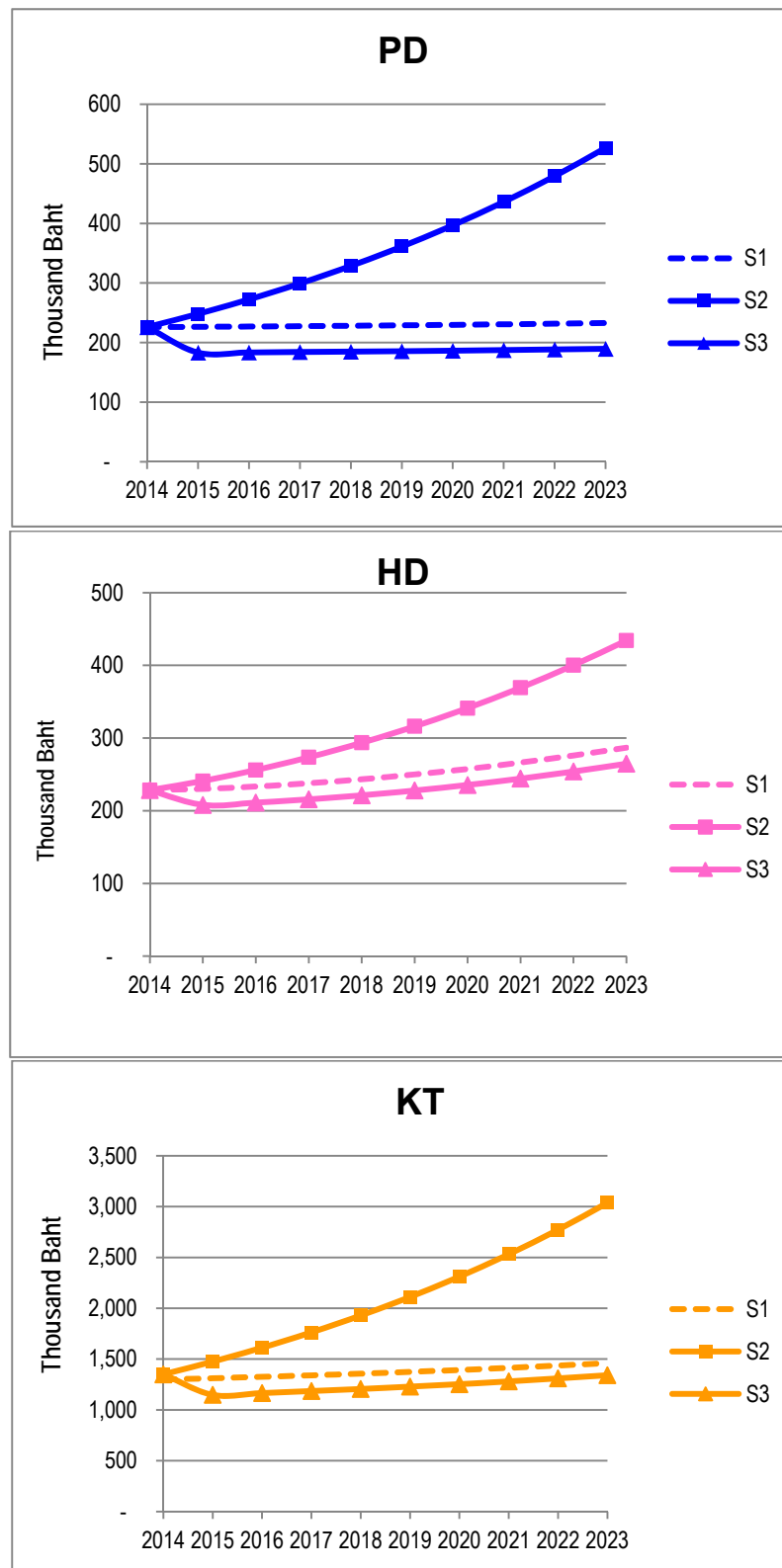
S1=scenario 1, S2=scenario 2, S3=scenario 3

PD=peritoneal dialysis, HD=hemodialysis, KT=kidney transplant

231

7.4   Discussion

This section summarises and discusses results on the predicted number of RRT patients, their unit costs, and budget needs in the future. It then relates the findings of the cost drivers to how to control care costs of the RRT programme. Finally it compares the study's findings with others conducted in Thailand and other countries.

7.4.1   Future numbers of patients

This study predicted that the number of RRT patients would increase at around 10% annually for the next ten-year period. There are various factors influencing the increase of RRT patients at this rate. Firstly, the high number of ESRD patients can be a consequence of the growing prevalence of ESRD risk factors in the general population. A national survey in 2004 in Thailand (Ong-ajyooth, Vareesangthip et al. 2009) found that age, diabetes, hypertension, and body mass index were strongly associated with chronic kidney disease. In this regard, a report from Thai Health (2014) confirmed the increasing body mass index. Also, the Chronic Diseases Surveillance of the Ministry of Public Health (Tonghong, Tepsitta et al. 2012) reported the increasing prevalence of diabetes and hypertension among the Thai population.

Secondly, comparing these findings to studies from other countries which focused on hemodialysis found similar results. For example, a study in Australia's Northern territory (projected between 2001 and 2004 in the Aboriginal population) suggested that the number of HD patients would grow at a decreasing rate, giving an average increase of 12% per year respectively. This similarity might relate to the fact that patients are in the early phase of access to the RRT programme. In countries where there is a long history of RRT benefit, growth in the prevalence of RRT patients is much lower. A study in Ontario, Canada (Quinn, Laupacis et al. 2009) (projected between 2005 and 2011) and a study in the US (Gilbertson, Liu et al. 2005) (projected between 2010 and 2015) expected annual increases of 5.5% and 3.8% respectively.

Thirdly, the treatment guidelines may affect the number of patients entering into the programme by changing nephrologists' practices. For instance, it is evident in Chapter 6 that at present, patients who are recruited into the RRT programme have a low level of eGFR, less than 15 ml/min/1.73 m². If the threshold level is raised, the number of RRT patients will increase significantly.

Finally, changes in the payer's policy could influence the popularity of RRT modalities, affecting numbers of patients and therefore the expenditure of the RRT programme. In a prior example from 2012, the NHSO started reimbursing all types of HD for erythropoietin, which resulted in a significant increase in numbers of HD patients (see details in Chapter 6).

In contrast to the projections of increases in RRT patients, a more positive outlook is possible. This could be due to effective prevention and screening programmes of ESRD risk factors, all of which are essential to manage these risk factors and to decrease the number of patients entering into the RRT programme. Along with the RRT programme, the NHSO provides a screening programme for the risk factors of diabetes and hypertension to all Thai adults over 30, regardless of their health insurance status. A secondary prevention programme is also given to those who are already diagnosed with diabetes and hypertension. Coverage of these programmes, together with effective public health campaigns to reduce risk behaviours, will help reduce the growth in the RRT patients (James, Hemmelgarn et al. 2010), and therefore the growth in long term health care expenses.

Despite being a more cost-effective RRT modality over PD and HD, KT suffers from the low numbers of donated kidneys for transplant. In each year, around 7% of all patients (including patients from the other two public schemes) who were waiting for a kidney were able to have transplantation. Additionally, until now only 11% of all patients who had transplantation were UCS members (Thai Transplantation Society 2014). A study has pointed out that the major flaw is because the organ donation system in Thailand suffers from a lack of concrete policy and guidelines to support the system (Onsuwan, Bunnak et al. 2015). Despite KT being more cost-effective, because of limited numbers of organ

donors, the increasing numbers of patients with RRT needs have been put on dialysis modalities. This study predicted that in 2023 there would be thirty times more patients on dialysis than KT patients.

7.4.2   How to control programme costs?

The concept of economies of scale provides ways to control programme costs. They are the circumstance that the unit cost of a service decreases with increasing output as its fixed costs are spread across more units of output. According to McPake, Normand et al. (2013) economies of scale in health care may be achieved by two ways: 1) increasing output with constant fixed costs. This is because increases in numbers of outputs, although resulting in the increase of the total material cost, may not affect fixed costs such as labour costs and capital costs and 2) using available capacity intensively, for example by sharing resources such as professionals and care units to fill spare capacity.

It is possible that future costs of RRT modalities will change from what they are presently. This study suggested three possible scenarios and explained how the RRT programme might grow in the next ten years and how to control care costs by focusing on four cost drivers: number of patients, labour costs, material costs, and capital costs. In all scenarios numbers of patients and labour costs would increase each year, at around 10% and 7%, in real terms respectively, and capital costs would remain constant across the study period. Material costs were varied: remain constant in scenario 1, increase in scenario 2, and decrease in scenario 3.

Findings from this study suggested that the total costs in scenarios 1-3 were estimated to grow by 9-19% annually. Despite increases in the total budget, some scenarios showed that the unit cost may be lower or may increase slowly by focusing on the four cost drivers, see Figure 7-11.

7.4.2.1   Number of patients

The number of patients is one of the most powerful cost drivers of the RRT programme. Its effect is notable when comparing the total cost of KT to PD and HD costs. The unit cost per patient-year of KT is large, at 1.3 million Baht, while

PD and HD were both at 220 thousand Baht in 2014. However, the number of KT patients is minimal in comparison to PD and HD, and their amounts of total costs become more distanced from each other over time.

KT requires high investments in professionals and equipment, and the low number of patients is an obstacle to increasing the efficiency of KT units. Other cost drivers (material, labour, and capital costs) show minimal effects on unit costs of KT. It is evident in Figure 7-10 that total KT costs would remain low in comparison to costs of dialysis in all scenarios. The unit cost of KT per patient, however, is high, and would not decrease in any scenarios, in contrast to the other two RRT modalities (see Figure 7-11). One explanation for this is that the denominator used to calculate the unit cost of KT was the number of new transplant cases[32], which was projected to be stable across the studied period. Many more patients have to undertake transplantation in order to spread the total cost and reduce the unit cost of KT.

Apart from the need to promote numbers of donated kidneys for transplantation, filling spare capacity might be a solution to control costs of KT. In Thailand, although there is no study assessing spare capacity of operating theatres in hospitals, a nationwide charity campaign in 2006 showed that the number of kidney transplantation could be boosted to over 200% of its target[33]. This suggested that there might be spare capacity in the KT system. Filling the capacity with optimum use of existing theatres with a large pool of specialist services may help RRT units control costs, and in addition it was reported in a study (Bowers and Mould 2002) that concentrating health services in operating centres which had more surgical specialists might increase quality of care by providing more opportunities for ongoing specialty training.

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[32] Old transplant cases were assumed that they have exited from the system and were not included in the denominator, unlike PD and HD that denominators were cumulative cases.

[33] http://www.kidneythai.org/newsdetail30.php

7.4.2.2 Material costs

Material costs account for the largest proportion in the total costs of PD, HD, and KT. It is, therefore, the most important cost to contain from the public payer's perspective. In scenarios 1 and 3, material costs per patient over the study period were assumed unchanged and decreased respectively. As a result, unit costs of PD would be lower with increasing numbers of patients. However, the result of this study shows that this would not be the case for HD and KT. This is because HD comprises high staff costs and numbers of KT patients are too low and it would not affect the large amount of its total cost as explained above. Although unit costs of HD and KT would not be lower with increasing numbers of patients, they would increase at slow rates.

Controlling the price of materials is central to a cost containment strategy. This was evident in scenario 3, in which the cost of PD benefited the most because it contains a large proportion of material cost (74%), and the majority of materials were assumed to reduce in price once locally made. KT costs also comprised a large proportion of material cost (79%) but just a small number of patients would have transplantation, and therefore the total cost of KT would not benefit much from this strategy.

7.4.2.3 Labour costs and capital costs

The labour cost is a small proportion of PD and KT costs, at 25% (Laonapaporn, Punthunane et al. 2014) and 18% (Suksamran, Kongsin et al. 2012) respectively. All scenarios in this study assumed that wages would vary with increasing patients and grow at 7% annually, but total costs of PD and KT were dominated by changing material costs and effects of the labour cost did not show clearly. The costs of HD contains a significant proportion of labour cost (40%), because of this the noticeable effect in this study was that the total cost of HD increase slowly but would not gain much advantage from switching to locally made brands, compared to the total cost of PD.

HD also has slightly higher labour and capital costs than PD and KT. This is in line with the fact that HD units have to invest more in salaries in order to hire

professionals, dialysis machines, and areas in the dialysis unit to care for patients. With an increase in HD patients, the costs of professionals and investments are likely to grow proportionally. In contrast, an increase in PD patients may not require more PD nurses, machines, or areas. This is because PD is home-based dialysis and, because patients rely mainly on their self-care management, is less labour-intensive (Liu, Gao et al. 2014).

7.4.3   Comparison to the prior study of the UCS

Predictions for the growth of RRT patients and budget needs of the RRT programme were previously reported in the study of Kasemsap, Prakongsai et al. (2006). At the time, the UCS RRT programme was not yet set up, and the study used a number of assumptions (incidence rates from the US renal registry and survey prices from Thai RRT providers) to estimate numbers and budget needs of the RRT programme. Predictions from this study were far from the reality, which might be due to imprecise cost and incidence estimations.

Survey prices of dialysis procedures and medications were much higher than real reimbursement rates and purchase prices of medication in the RRT programme. For example, the price per HD patient-year, excluding EPO, was calculated at 272,190 Baht (current study=209,344 Baht); the price per PD patient-year excluding EPO was 276,708 Baht (current study=218,836 Baht). The greatest variation between this study and reality was that the price of EPO in 2001 was anything from 80%-95% higher than the current price.

Incidence, which refers to the number of new patients, was another cause of imprecision in the previous study. The previous study employed the ESRD incidence rate of 300 per million population (pmp) per year and assumed all new ESRD patients would enter the RRT programme. However, this current study (Chapter 6) found the true incidence rate of RRT patients in the UCS was just 197 pmp per year in 2013 and that around half of the diagnosed patients entered the RRT programme.

7.4.4   Cost comparison to other countries

Direct comparison of RRT costs between countries is not very straightforward. This is because costs from each study might be calculated from a different perspective (such as payer's, provider's, or societal perspective). Also, items included in cost calculations may vary. In addition to these differences, the characteristics of a country play an important role in the preferred RRT modality, and therefore the costs of RRT may vary significantly across the world. These characteristics (Karopadi, Mason et al. 2014) include gross domestic product per capita, health care resources, how provision is split between public and private, financing structures, and reimbursements for providers of RRT care.

For example, from the payer's perspective, reimbursements in high income countries such as Germany, the US, and the UK are costly. For PD and HD, reimbursements per patient-year range from 27,000-58,000 US$ and 36,000-61,000 US$, respectively (Vanholder, Davenport et al. 2012). Looking at other countries which belong to the same middle-income group and same region as Thailand (Asia), costs of each RRT modality are different depending on each country's specific characteristics and which perspective is assessed (see Table 7-13). Note that costs for PD and HD in Table 7-13 include direct costs for dialysis services, professional fees, medications, and routine laboratory tests excluding hospitalisation. KT costs are only for transplantation and exclude dialysis and medication after transplantation. For Mexico and Brazil, costs were assessed from the provider's view, and reimbursements from their insurance schemes may be different. For example in Brazil, reimbursements (in October 2006) were US$52.40 per HD session and US$716 per month for PD.

Table 7-13 Average annual cost (US$) per patient-year in selected countries

	PD	HD	KT
Thailand (current study)*	7,242	6,968	30,009
Mexico (2013)**	8,695	N/A	N/A
Brazil (2013)**	23,404	23,411	N/A
India (2012, 2013)***	6,275	6,382	Up to 12,924

*Figures were calculated from the payer's perspective
** Figures were calculated from the provider's perspective including medical costs and professional fees excluding costs for emergency visits and hospitalisation
***Costs for out-of-pocket payment
Sources: Mexico: Cortés-Sanabria, Paredes-Cesena et al. (2013); Brazil: de Abreu, Walker et al. (2013); India: PD and HD from Jeloka, Upase et al. (2012), KT from Ramachandran and Jha (2013)

7.5 Conclusions

Results of this study are expected to provide new insights into how the RRT programme would grow over time, in terms of the number of patients and budget needs over the next ten years.

In the next ten years the number of RRT patients was forecasted to grow at around 10% annually. These patients would need a large amount of the UCS budget, and the total amount of the RRT programme was estimated to increase in the region of 9-19% annually. The unit cost per patient of PD could be lower than its price in 2014 and the unit costs per patient of HD and KT could increase at slow rates. This would depend on whether costs of technologies, in particular expensive medications, can be lower or remain unchanged in the next ten years, regardless of normal increases in the number of health staff and wage rate at around 7% annually.

Although these predictions may not provide exact calculations, they can be an approximation to the health care payer for planning future budget, health facilities, and human resources relating to the RRT programme, and how to adjust the plan as new information becomes available. Comparing the actual expenditure of the RRT programme against historical predictions provides an idea to policy makers of whether the programme has performed as it was planned, and if not, what may contribute to such results.

In addition to this, examining behaviours of the four cost drivers (the number of patients, material costs, labour costs, and capital costs) can help policy makers decide which proportions of the RRT payment can be regulated to suit the actual situation and the government's available budget. For example, if cost components are adjusted, at what percentages or at what prices this should be done. Also, the study described which cost components can be contained and suggestions for how to do so.

A number of components in the disease management approach may have helped the UCS control health care costs. These include the focus on a target population (ESRD) and the guideline protocols that are linked with predefined payment rates. These components provide information on the number of patients and budget needed to run the RRT programme, and help control the programme payment to fit the available RRT budget.

7.6   Limitations

7.6.1   Quality of data

This study employed the most recent data available. The limitation of this use was that the claims may not be the most up to date. Since the NHSO allows its health facilities to claim up to one year post-expenditure, more claims for the fiscal year 2014 can be expected.

7.6.2   Threats to validity

The time-series approach is used to project numbers of patients in the renal replacement therapy programme because it controls most factors that other population approach designs cannot control for (Linden, Adams et al. 2003). However, there remain two issues of validity to discuss: internal validity and external validity.

i.   Internal validity: long term effect

The advantage of the time-series approach is that it can eliminate the effects of other factors that may influence the variable of interest. However, the approach

depends substantially on historical values. This means that the closer the projected values are to historical values, the more precise they are.

ii. External validity: generalisability

Since the RRT programme is designed to serve a specific population, the result is not meant to explain or be used in other groups of patients.

7.6.3   Proportions and assumptions used

Another limitation was that this study used results of the past studies to estimate costs of material, labour, and investments for each RRT modality. Some of these studies were conducted on a large scale but some were conducted in just one hospital. Additionally, some cost objects may have different definitions in other settings and may include different items. For example, overhead costs were one of the most difficult items to identify because sometimes they included training, education, and research, in addition to costs for hospital administration, interest, and housing. This is why results from different settings may give different figures.

Predictions in this study are vulnerable to inaccuracies due to a number of factors. Most importantly, assumptions used have an effect on the estimated budget needs. If what happens in reality deviates substantially from what was assumed, it threatens the accuracy of the forecasts. Finally, on some occasions a patient encounters an infection due to the dialysis, generating costs which the NHSO has to pay for, but they are not covered in this study.

CHAPTER 8   Discussion

8.1   Introduction

In the previous chapters, this study reviewed high-cost conditions, their impacts on households and health systems, and empirical evidence from population-based disease management programmes. Research gaps were then identified and used to formulate the research questions, aims, and objectives of this study.

Disease management has a number of uses, for example to control increasing health care costs, promote quality of care, and reduce fragmentation in the health system. This study viewed the approach as an intervention to increase access to a high-cost treatment (renal replacement therapy, or RRT) in the Universal Coverage Scheme (UCS), Thailand. This study aimed to use RRT as a tracer to explore the introduction and functioning of a high-cost health benefit programme of the UCS, and then to assess how a disease management approach has facilitated the inclusion of RRT in the UCS benefit package.

There were three objectives. The first was to describe the rationale behind the initiation of a high-cost health benefit programme and the application of the disease management approach. It employed qualitative methods to triangulate evidence from multiple data sources. These methods included document review, semi-structured interview, focus group discussion, and structured observation. The second objective was to assess the output and outcome of the RRT programme: access to RRT services and mortality. It identified changing patterns of access to RRT services and mortality of patients who were diagnosed with end-stage renal disease (ESRD), both those who were maintaining any modality of RRT and those who were living without RRT, by using the age-period-cohort analysis. The third objective was to carry out long term projections of the RRT programme, in terms of the number of future patients and estimated budget from the public payer's perspective. This study employed cost modelling and time-series analysis methods. Possible future scenarios were identified to define cost drivers of the RRT programme.

This chapter synthesises findings from analytical chapters and embeds them within the context of the literature review and research questions. These accounts lead to the discussion of approaches to the monitoring and evaluation of disease management programmes, and how the study methodology can be used and applied. They also raise issues of the study strengths and weaknesses in relation to the interpretation of overall results.

8.1   Methodological issues

This study applied both qualitative and quantitative methods to cope with the complex nature of the disease management programme and they complemented each other. This section summarises the methodologies used and links them to a broader range of designs and methods for disease management programme evaluation.

8.1.1   Qualitative approach

Qualitative methods are essential in the early phase of any research, in particular for data collection, qualitative description and result interpretation (Murphy, Dingwall et al. 1998). In disease management programme evaluation, they are even more important because most disease management programmes always have complex designs, multifaceted interventions, and participatory and collaborative practices.

Chapter 5 of this study used qualitative approaches to collect data from multiple sources including reviews, interviews, a focus group discussion, and observations. Findings from the qualitative analysis were used to explain the RRT programme in greater detail, and provide evidence on the application of disease management interventions and the links between various stakeholders in the health system.

Results from qualitative methods in Chapter 5 were also used as preliminary to the quantitative method. They supported findings from the quantitative method in Chapter 6 in terms of outputs and outcomes by revealing why around half of patients with ESRD diagnoses decided not to register with the RRT programme.

The qualitative approach also offered insights into how best to support these patients with their opt-out choice.

In previous literature, the in-depth interview and focus group discussion were conducted to probe patients', providers', or other stakeholders' attitudes (Blakeman, Macdonald et al. 2006), beliefs and concerns (Jerant, von Friederichs-Fitzwater et al. 2005), as well as patients' quality of life (Dongbo, Ding et al. 2006). Qualitative information was also used to describe disease management interventions and to support analysis of the programme's effect as assessed by quantitative methods (Weingarten, Henning et al. 2002).

8.1.2 Quantitative approach

The selected quantitative methods in this study are recognised as powerful tools. The age-period-cohort analysis in Chapter 6 is a modelling technique to summarise and report routinely collected information from administrative records or disease registries (Carstensen 2007). The ARIMA modelling in Chapter 7 is the most widely used time-series approach in health research (Linden, Adams et al. 2003). The use of administrative data detailed to the individual level of this study provided strength to the quantitative analysis since they did not need a population estimate and NHSO payment estimate since this used information derived from the true UCS population and patients. This therefore helped increase the validity of the study.

8.1.2.1 Data source

This study used the facility-based administrative data that were collected from routine services of UCS health facilities across the country. This use allowed the study to undertake a facility-based analysis of patients who had ESRD diagnoses from three types of databases: outpatient, inpatient, and the RRT disease management programme.

The UCS administrative data used in this study included all patients who sought care from such services from 2008, both those receiving RRT and those who were not, although these might not represent the entire prevalent population of patients with ESRD and the total UCS population. This is because there may be a

number of the UCS members who have never used any UCS service (but may receive care elsewhere in private facilities), or never been diagnosed as ESRD, and therefore were left out of the UCS databases.

In addition to the advantage of the UCS databases, they provided citizen identification numbers that were encoded before handing to any third party. The use of encoded citizen identification numbers allowed matching between databases without violating patients' confidentiality.

Chapters 6 and 7 provided examples of using administrative data for programme monitoring and evaluation purposes. Administrative data or claims data result from the health care delivery system by registering members into health schemes or programmes and reimbursing for health care costs. They contain demographic characteristics, diagnoses, and procedures given to patients and are often used in health care evaluation (Iezzoni 1997). This study used NHSO administrative data and gained a number of benefits. Firstly, the databases were readily available to the NHSO and were inexpensive to acquire for research purposes. Secondly, they were frequently updated due to the reimbursement process. Thirdly, they encompassed a large group of populations, that is, the UCS population and RRT patients which were relevant to this study's aims and objectives. Finally, databases were computerised, the International Classification of Diseases (ICD) system was used as a standard diagnosis tool, and they contained encoded patients' citizen identification numbers. These allowed the merging of various databases into analytical datasets.

The Thailand Renal Replacement Therapy Registry was a potential data source but it was not used in this study for a variety of reasons. The renal registry covers information on various aspects of all patients who are maintaining RRT in Thailand, including patients who are beneficiaries of the other two public health insurance schemes. However, the focus of this study was only on the access to RRT of ESRD-diagnosed UCS members, not RRT patients in general. Information in the renal registry, therefore, is not enough to fulfill the study's aims and objectives. In addition, the database did not include individuals'

citizen identification numbers which were the key variable for combining databases in this study.

The NHSO administrative data have limitations. Despite containing rich information, administrative data lack precise patient socioeconomic information which is one of the factors determining the use of health care (Aday and Andersen 1974), therefore this may undermine comparisons of access to health services amongst different social classes in future research.

Data quality is another challenge of using administrative databases: there are several causes of data inaccuracies. Firstly, their main purpose is administrative function. Consequently, fields which are not relevant for claims processing are frequently incomplete. The use for other purposes such as assessing health indicators and the performance of the system can be limited. Secondly, claims data sent to obtain reimbursement for treatment may not be completely up to date, since the NHSO allows its health facilities to claim up to a year later. Finally, DRG (diagnosis related group) creep in order to increase hospital income has been a major concern of diagnosis procedure in Thailand and elsewhere (Pongpirul, Walker et al. 2011).

To deal with these problems, the NHSO has introduced an audit process with incentives for providers if there are no coding errors found, and penalties are given to mistakes.

8.1.2.2   Study design

In general, methods used in disease management programme evaluation vary greatly and they can affect studies' findings. The literature review in Chapter 3 found that many population-based disease management evaluations had moved towards more practical study designs of non-experimental studies aiming to evaluate programme effectiveness. Most of these reviewed studies compare effects of an intervention group (patients in disease management programme) against a control group (usual care group) using a number of measures, such as costs of care, service utilisation, and patients' health outcomes. Results from these studies, however, were mixed and inconclusive. This might because

limitations in study designs meant that they could not control for possible biases, confounders, and the multifaceted characteristics of disease management interventions.

Chapter 6 of this study assessed the RRT disease management programme, in terms of the changing patterns in access to RRT services and ESRD patients' all-cause mortality. The method introduced in this chapter was the age-period-cohort analysis. The analysis modelled effects of age, year of registration (or death), and birth cohort intended to assess the changing patterns of RRT programme registration rates and all-cause mortality rates among UCS members overtime in particular years against the reference year. Modelling effects of such variables eliminated the identifiability problem that occurs from the relation: period = age + cohort, faced by other linear models as they have two variables as well as their sum in the same model.

The age-period-cohort analysis has been adopted by many studies to model and describe trends in mortality rates and incidence rates from routinely collected databases and disease registries (Carstensen 2007), however it has had limited use in chronic kidney disease or renal replacement therapy. Many longitudinal studies on patients with chronic kidney disease frequently used the cohort study design to assess longitudinal effects, and all-cause mortality was often included as a primary outcome. For example, those were conducted by O'Hare, Choi et al. (2007); Wen, Cheng et al. (2008); and Neovius, Jacobson et al. (2014).

There are numerous studies conducted to quantify costs and financial implications relating to RRT. These studies varied considerably, in particular in terms of cost components included. This is due to variations in which perspective (payer, provider, or societal) is assessed and in definitions used to define each cost item. For example, 'overheads' may refer to dissimilar items in different studies.

Chapter 7 estimated the future financial implications of the RRT programme by using cost modelling and time series projection. It chose the payer's perspective to estimate the unit cost of each RRT modality. The study then calculated future numbers of patients in each RRT modality using the ARIMA time series

technique. Finally, the study used the calculated unit cost and the projected patient numbers to estimate the long term financial consequences of the RRT programme.

This study found a number of methodological issues that might affect accuracies of forecast values. First, time series modelling required a large number of observations (such as at least 60 observations in a row) to perform an ARIMA time series analysis. This can be a challenge to a newly launched programme such as RRT because if using monthly data as in this current study, there have to be data available for at least five years. In addition, this approach depends substantially on historical values. This means that the closer the projected values are to historical values, the more precise they are.

Secondly, costs were conducted from the payer's perspective using NHSO reimbursements and payments as the basis. The NHSO assumed that they covered the full cost for providing RRT care. In reality there might be some type of costs that were not taken into account. For example from the providers' perspective there might be some costs incurred from the care process which were not covered in NHSO payments.

Finally, this study used information from past studies and a number of assumptions to estimate future costs of the RRT programme. Some of these past studies were conducted on a limited numbers of hospitals and might not represent the whole country which has various kinds of RRT units. The assumptions used might affect the future budget need in a way that if what will happen in the future differs from these, it threatens the accuracy of the forecasts.

8.1.2.3   Designs used by other studies evaluating disease management programmes

The selection of data collection methods can affect studies' findings (Linden, Adams et al. 2003) and the data obtained in a disease management programme evaluation can roughly determine the methodology used and indicators to be assessed (Busse and Stahl 2014). Routinely collected sources such as

administrative data, claims data, or patient records are often used to assess the care process, utilisation, outputs, and outcomes; while newly collected sources such as surveys and interviews are mostly used to probe patient and provider experiences (Busse and Stahl 2014).

Studies assessing the disease management approach have used a range of methods to evaluate the effects of nationwide disease management programmes. According to a review by Conklin and Nolte (2013), the cross-sectional (pre-post or post only), observational study design was the most frequently used. This is because experimental studies, particularly randomised control trials, are considered the gold standard for evaluating the effectiveness of an intervention, but are controversial in practice. This is because experimental studies may be unlikely in disease management programmes that are implemented nationwide. Additionally, there are issues about ethical considerations, since providers may hesitate to offer better services to a subgroup of patients (Nolte, Conklin et al. 2012).

Comparing the effects of disease management with a reference group, or before and after launching the programme, is a common strategy for assessing disease management programmes. Conklin and Nolte (2013) conducted a review and pointed out that the reference groups can be the general population or patients with the same health condition but who received conventional care or typical care instead of disease management interventions. Using an external reference group as a benchmark was another comparison strategy and the groups selected varied greatly. They included, for example, international or interregional comparison, performance targets, and a national or regional standard (Conklin and Nolte 2013). Selecting which comparators to use, however, is a key challenge for assessing disease management programmes due to the nature of study subjects. They are likely to change over the study period as a result of the nature of progressive chronic diseases (Linden, Adams et al. 2003).

Some specific approaches, referred to as statistical techniques, can be used to evaluate the effects of a programme. For example, the difference-in-difference

approach compares changes in the outcome of interest in the control (or pre-intervention) group with changes in the intervention (or post-intervention) group in the same time period (Athey and Imbens 2006). An example of this method is a study conducted in Medicaid diabetes disease management programmes (Conti 2013). The study used administrative data to compare inpatient costs and the number of emergency admissions in three states of the US against those in states without such programmes. An interrupted time series is a rather powerful quasi-experimental design to evaluate longitudinal effects of interventions. The segmented regression analysis of an interrupted time series uses statistical models to estimate level and trend pre- and post-intervention (Wagner, Soumerai et al. 2002). An example of this study design is the assessment of the effect of a new payment system on quality of care and clinical outcomes for patients with hypertension in the UK (Serumaga, Ross-Degnan et al. 2011).

8.2   Discussion on the research findings

In this section, the research findings are summarised and discussed. It starts with an introduction to the functioning of the UCS RRT programme. It is followed by the effects of the disease management approach on patients including patient decision making, changes in access to care, and changes in all-cause mortality of ESRD patients. Finally, the future financial implications of the programme are discussed.

8.2.1   What are the rationale and functioning of the RRT programme?

The RRT programme is the result of attempts from various stakeholders to respond to the implications of high-cost conditions. This study highlighted the combination of leadership roles from three elements: the academicians who gather new information, public actions, and politicians who push ahead the new RRT policy.

The programme is one of the few UCS disease management programmes that has all the basic interventions of the disease management concept. This section summarises and discusses the definition of high-cost and catastrophic

conditions, then covers the introduction and functioning of the RRT programme focusing on the UCS disease management approach.

8.2.1.1   High-cost and catastrophic definitions

Exploring the introduction of the RRT benefit of the UCS found that RRT fell into the definition of a high cost condition as proposed by Wyszewianski (1986). This is because the health budget spent on caring for a small number of patients with ESRD accounted for a significant proportion of the health care budget. In 2014, the total cost of the RRT programme to the UCS amounted to 4% of the total UCS budget, although individuals who were maintaining RRT accounted for only 0.07% of general UCS members (NHSO 2014). Evidence from other countries suggests similar results. In the UK, around 1-2% of the annual NHS budget goes to treat 0.05% of individuals with renal failure (Baboolal, McEwan et al. 2008; Kerr, Brey et al. 2012). In the US, ESRD patients comprising less than 1% of the total Medicare population received 6% of the annual Medicare budget in recent years (United States Renal Data System 2014).

Seeking treatment for kidney failure can cause a patient and family financial catastrophe, especially the poor and those without effective insurance coverage. When patients pay out-of-pocket for dialysis care, and the amount exceeds their ability to pay, they have to reduce normal consumption of food and other necessities. Some families use up savings, sell property, raise loans, or stop their children's education. Many patients decide not to use care simply because they cannot afford it. These effects are evident in countries (Sakhuja and Kohli 2006; Prakongsai, Palmer et al. 2009; Luyckx, Naicker et al. 2013; Ramachandran and Jha 2013) where RRT services may be available but are not covered by health insurance.

While the focus of Wyszewianski (1986)'s definition of high-cost conditions is on cost containment by policy makers, the concern over catastrophic conditions is more about protecting patients against excessive payment of care costs.

8.2.1.2   Response to ESRD by stakeholders

End-stage renal disease is an example of a chronic condition that can rapidly bring a patient without insurance coverage into financial catastrophe. This happens because each episode of treatment is expensive and treatment is needed regularly to sustain a patient's life. This is in marked contrast to other chronic conditions such as hypertension and diabetes, where most of the health spending is likely to be covered by a benefit package of health insurance.

The commencement of the RRT programme in the UCS was a result of the response to ESRD by people at various levels in the health system. Before the RRT programme started in 2008, patients and families paid all they had, with some taking out loans or making distressed sales of property to finance their treatment. Some patients gathered into a patient group and called for their rights to affordable health benefits. Policy makers and providers took into account the consequences of these conditions and the financial catastrophe they cause for patients. Together with the patient group, they created knowledge, societal movement, and got politicians involved, and eventually were successful in the introduction of the RRT benefit.

In particular, the introduction of the RRT programme was a move that went with the creation of knowledge, the public, and the strong ministerial leadership as proposed by Wasi (2000). This move was essential to protect UCS patients and their families from catastrophic health spending. It differed from most countries (for example the UK, continental European countries, and Japan) that have implemented universal health coverage with RRT included from the outset. An example of another country that attempted to make a change to its health care benefit was the US. The federal government led the move to extend Medicare benefits to cover RRT in 1972. From that point, patients with ESRD were defined as disabled by their chronic illness and were covered in Medicare regardless of age (Iglehart 1993).

The move to introduce the RRT benefit in Thailand and the US may be explained by inequities in access to essential health care, as with many countries when they introduced their universal health coverage. Before commencing the UCS

RRT programme, the right to equal access to care was raised and compared with the other two public health schemes: the CSMBS and the SSS. In Thailand and also in Mexico, another developing country implementing universal health coverage, unequal access to the treatment of end-stage renal disease has been mentioned as a cause of fragmentation in the health system (Kierans, Padilla-Altamira et al. 2013). One study (Garcia-Garcia, Renoirte-Lopez et al. 2010) argued that extending the Mexican Seguro Popular health insurance scheme to cover the treatment for end-stage renal disease nationwide would be one strategy to reduce the existing inequality in that country.

8.2.1.3   Disease management approach of the RRT programme

Bringing a high-cost treatment into the health benefit basket may be a challenge to any developing country. It is essential to separate a high-cost programme from the mainstream in order to facilitate patient access to care. This is because the payment in the mainstream system may not motivate providers to take patients into the programme and provide expensive care. In addition, Thailand and a number of developing countries (Van Bui 2007; Jha 2008; Odubanjo, Oluwasola et al. 2011; Luyckx, Naicker et al. 2013), in particular, share some limitations in the service system including the shortfall or geographically skewed distribution of specialists, nurses, and health facilities. They also lack effective guidelines and the database management system which are crucial for working between departments or sections of providers and different sectors in the health system.

8.2.1.4   Which of disease management interventions works?

Components of disease management were used as interventions in the UCS RRT programme to overcome the system's inadequacies and set up the service provision nationwide, where it was once hard to reach for UCS beneficiaries. The key interventions used by the NHSO were the evidence-based guideline protocol and reporting system. The evidence-based guideline set up by the NHSO laid down the procedure for the providers, based on medical evidence. The guideline was bound with the payment mechanism and led to other components of disease management which were: patient identification,

collaborative practice, reporting system, and self-management by patients and families.

Disease management programmes that had wider support such as a national policy or protocol have been found to be more successful and sustainable than those programmes that were stand-alone and dependent on a local champion (Schang L, Thomson S et al. 2016). Other disease management interventions and contextual factors can provide support for ongoing disease management programmes. Programmes with multifaceted interventions are more likely to show positive outcomes (Brusamento, Legido-Quigley et al. 2012; Smith, Soubhi et al. 2012). In the case of the UCS RRT programme, patients with an ESRD diagnosis are targeted and selected to enroll for the programme according to the guideline protocol and are then trained and educated about self-care management. Payments are paid back to RRT units by the reporting system. The collaborative practice is an integral part of the RRT programme between and within the groups: policy maker, provider, and patient. Interviewees mentioned this practice, in that it contributed to the rapid expansion of RRT facilities across the country. UCS interventions are regarded as a means of increasing access to care and improving the quality and efficiency of care for patients with end-stage renal disease. These interventions are in line with the finding of a systematic review (Comino, Davies et al. 2012) of interventions to increase access to health care for patients with chronic conditions. The latter study reported that the combining of disease management interventions facilitated access to health services.

Linking provider payment to the standard protocol is a key strategy to promote programme implementation and patient identification, and therefore access to care. In countries where disease management programmes are implemented nationwide, like Germany, the national standard protocol which links to payment mechanisms has been highlighted as an important factor in facilitating the success of nationwide implementation of disease management programmes. In contrast, the programme in Austria lacks a national standard protocol, implementation is limited in some regions and there are low numbers of newly registered patients (Schang, Thomson et al. 2016). Meanwhile, the introduction

of routine reporting of GFR[34] and financial incentives as a part of disease management programmes caused increases in the identification and referral of patients with chronic kidney disease stages 3-5 in primary to secondary care in the UK (Richards, Harris et al. 2008) and Canada (Hemmelgarn, Zhang et al. 2010).

Disease management interventions, however, are complex and multifaceted, so individual intervention components should not be linked with specific outcomes (Smith, Soubhi et al. 2012).

8.2.2   What are effects of the RRT disease management programme?

After the RRT programme has commenced there are many issues to be considered, as they influence the programme's efficiency and sustainability: firstly whether this programme was costly to start and maintain, and should it be kept separate from the mainstream system; secondly, whether this programme has reduced the patients' difficulties paying for care costs, improved patient access to care, and facilitated quality health services; thirdly, on the provider and payer sides, how much amount of budget is needed to spend on RRT services, and whether there is a way to adjust it to suit provider and payer preferences.

8.2.2.1   Starting and setting up the RRT programme

From the beginning of the RRT programme, its administrative functions and financing system have been separated from the UCS mainstream. This is intended to promote patients' access to this high-cost care. Inevitably, the programme required initial investment in setting up and then getting the programme to a steady state. The programme began with specific expenses relating to arrangements of target patients, protocol guidelines, and information system for the programme's maintenance and monitoring process. These contributed to a high amount of administrative costs to the programme initiation and maintenance of all programme processes.

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[34] a kidney function indicator

At present the RRT programme is still separate from the mainstream system and its administrative costs are ongoing as the programme has not yet achieved its aims to eliminate poor patient access to care and to prevent catastrophic payment from care costs. By linking these aims and findings from this study, the steady state of the RRT programme may include 1) providing good programme coverage nationwide; 2) reducing treatment costs by ensuring the exploitation of lower cost production of materials; 3) ensuring treatment costs are reasonable and do not prevent providers from giving services; and 4) ensuring affordable access for patients.

8.2.2.2   Effects on patients

This section summarises and discusses findings from Chapters 5 and 6. Qualitative studies of Chapter 5 provided insights into patient decision making, catastrophic payment, and alternative therapy for ESRD patients. The age-period-cohort analysis in Chapter 6 provided knowledge on the changing trends of patients' access to care and their all-cause mortality. Ideally, evaluating a disease management programme should be conducted by a study design that provides a counterfactual to demonstrate that the changing trends were the effect of the programme. This study did not address the counterfactual due to limitations in the study setting and available data. It showed evidence on improvements in patients' entry into the RRT programme and their all-cause mortality after commencing the RRT programme in 2008.

i.   *Patient decision making, catastrophic payment, and alternative therapy*

In this study, most patients with an ESRD diagnosis who were referred to the RRT unit in the university hospital intended to use RRT to prolong their life. Patients were eligible for free health services, however, some of them mentioned difficulties such as travel cost and opportunity cost to themselves as well as family members. These costs could bring a patient to incur financial catastrophe.

In the PD first policy, PD patients reported advantages of PD that it increased their self-reliance, reduced travel for treatment, and allowed patients to manage their daily life almost as usual (Chaudhary, Sangha et al. 2011; Liu, Gao et al. 2014). A systematic review of patient views on whether to undergo dialysis concluded that patients considered impacts of treatment on their lifestyle to be more important than the medical outcome (Morton, Tong et al. 2010).

At the community level, there were numbers of patients with ESRD diagnoses who refused to start dialysis in the RRT programme. Patient characteristics played an important role in decision making for living without dialysis. These included advanced age, having multiple comorbidities, belonging to an underprivileged family, low levels of education, and no carer. This study also found that being the sole person responsible for family members and social norms could hinder starting dialysis. A qualitative study in the UK reported a number of reasons that patients gave as to why they chose not to have dialysis. These included that they felt too old, had difficulty travelling to the dialysis unit, fear of dialysis, multiple illnesses, and insufficient information about dialysis (Noble, Meyer et al. 2009). Patients who initially opted to live without dialysis in England, however, reported in a study that they might have changed their decision and started dialysis (Rayner, Baharani et al. 2014).

Although not included in the RRT programme protocol, the community hospital in this study established conservative therapy for patients with chronic conditions. Patients with ESRD diagnoses living in this community had a choice between dialysis or conservative therapy. Conservative therapy for chronic kidney disease by a multidisciplinary team has been developed in a number of countries as an alternative to dialysis (Morton, Turner et al. 2012; O'Connor and Kumar 2012). It may include careful attention to fluid balance, treatment of anemia, correction of acidosis and hyperkalemia, and monitoring blood pressure and calcium/phosphorus metabolism (O'Connor and Kumar 2012). In the UK's chronic kidney disease programmes, ESRD patients without dialysis are given multidisciplinary nephrology care before they pass away (Rayner, Baharani et al. 2014). It was evident in a systematic review that elderly ESRD patients with multiple comorbidities who were on conservative therapy had

equal quality of life to those who were maintaining dialysis (O'Connor and Kumar 2012). A study in the UK found that elderly people with conservative therapy might have better survival and lower acute hospital admissions in comparison to those on RRT, and be more likely to die at home or in a hospice (Hussain, Mooney et al. 2013). Conservative management of ESRD, therefore, could be a practical option for certain groups of ESRD patients in the UCS. This includes elderly patients or patients with multiple comorbidities and burdens who have made an explicit choice not to have dialysis.

Even in developed countries, where the role of a multidisciplinary team has long been highlighted, there are limitations to this practice that deter development and assessment. Firstly, there is a lack of common terminology and definitions, meaning arrangements vary greatly (Okamoto, Tonkin-Crine et al. 2015). Secondly, despite the importance of conservative management as an option for patients with ESRD, many clinicians are unfamiliar with this approach and lack the information to properly counsel patients and families. Consequently, many dialysis patients are not aware of conservative therapy as an option (O'Connor and Kumar 2012; Okamoto, Tonkin-Crine et al. 2015). Finally, the scale of implementation is limited, and a single centre may have to be responsible for patients from a vast geographical area (Bowen 2014).

ii. Access to care

After launching the RRT programme in 2008, there was a sudden increase in the registration rate as those who were previously unrecognised were identified and registered. A steady state of registration rates in all RRT modalities developed in the 18 months following the introduction of the programme. Around half (53%) of newly diagnosed ESRD patients were unable to use or refused to start RRT. This proportion was slightly lower than an estimate in the previous study (64%) (Limwattananon and Limwattananon 2013), but was much higher than those reported in the UK and Australia (both at 14% of ESRD patients) (Morton, Turner et al. 2012; Rayner, Baharani et al. 2014).

Examining the proportion of RRT patients to ESRD patients by age group (see Table 6-15), the RRT programme was able to enroll a higher percentage of

young patients needing RRT, in particular patients younger under 70. The 55-64 age group had the highest registration rates. In contrast, access to care by patients aged 70 years and over was low, and their registration rates tended to decrease with age, despite the high and growing proportion of those with ESRD diagnoses in this age group (see Table 6-14). This finding corresponded to that of the previous chapter (Chapter 5) and some prior studies (Morton, Tong et al. 2010; Morton, Turner et al. 2012; Rayner, Baharani et al. 2014) that elderly people (approximately >75 years) with ESRD, who had multiple illnesses and lack family support, were likely to refuse to start dialysis.

The RRT programme provides three RRT modalities: peritoneal dialysis (PD), hemodialysis (HD), and kidney transplant (KT). PD has the highest number of new registrations as there is the 'PD first policy', which means PD is the preferred modality under the UCS. In the study period, 2008 to 2013, some circumstances might influence registration rates on the RRT programme. For example, flooding affected major cities of Thailand and clearly brought down the number of new registrations. The abolition of co-payment for HD, including fees for dialysis and erythropoietin, appeared to have boosted new HD registrations.

Results from other literature have indicated that HD is the least cost-effective treatment option, while PD and KT represent more cost-effective approaches (Sennfalt, Magnusson et al. 2002; Kontodimopoulos and Niakas 2008; Haller, Gutjahr et al. 2011). In addition, the cost of KT contributes both to a significant reduction of future costs and to a greater number of expected patient life years (Kontodimopoulos and Niakas 2008). However, rates of kidney transplantation remain low globally and in Thailand due to the limited number of organ donors (White, Chadban et al. 2008; WHO 2012).

A cross-country comparison among 104 countries reported that numbers of kidney transplants performed each year in Thailand was 5 per million population (pmp), comparable to others in South-East Asia (4 pmp), but significantly lower than Continental European countries (25 pmp) and the UK (30 pmp)(WHO 2012). Moreover, the proportion of UCS patients who

underwent KT accounted for just one-third of all kidney transplants in Thailand (Thai Transplantation Society 2014), despite the fact that the UCS is the largest public health scheme and covers 76% of all Thais.

This study confirmed the low number of transplants each year and projected that this situation would remain unchanged in the next decade, but did not explore this further. Some prior studies have provided the explanation that the organ donation decision is complex and based strongly on personal beliefs, such as religious and cultural beliefs, which are often mentioned as reasons for a refusal to donate (Irving, Tong et al. 2012). There are some other complex issues, such as disincentives for living organ donation, distrust of the medical system for deceased donors, and failure to arrange an effective organ donation system, in particular donation after death (Klein, Messersmith et al. 2010; Irving, Tong et al. 2012).

A number of countries, such as Singapore, Switzerland, Norway, Italy, Austria, France (Kwek, Lew et al. 2009) and the UK, have introduced the presumed consent system. In this system individuals are presumed to have agreed for their organs to be donated after death unless they opt out. A systematic review study concluded that presumed consent legislation contributed to higher organ donation rates. However, the extent might vary depending on country characteristics. These included rates of mortality from road accidents, numbers of transplant centres, gross domestic product per capita, and health expenditure per capita (Rithalia, McDaid et al. 2009). In Thailand, there has been very little research assessing people's attitudes towards organ donation and how to increase the number of donors in the future.

iii. Deaths of ESRD and RRT patients

All-cause mortality rates among RRT and ESRD patients were used as indicators to assess patients' health status within the RRT programme in this study. All-cause mortality rates in ESRD patients increased exponentially with age after patients reached their late forties. However, if patients received RRT, the rapid increase of mortality rates arrived later in life, after patients reached their seventies (see Figures 6-8a, 6-10a, and 6-13a). It is interesting to look at trends

in death rates over time. Although the number of deaths increases (as dialysis is not a true cure) and the programme constantly accepts more patients, all-cause mortality rates in patients with ESRD diagnoses and patients who used RRT show decreasing trends since 2009. These behaviours reflect demographic, ESRD epidemiological and health care changes in access to RRT among UCS members.

The results of this study correspond to findings from a number of studies that, after the mid sixties, ESRD patients had much higher risks of death in comparison to younger patients (O'Hare, Choi et al. 2007; Hallan, Matsushita et al. 2012). Additionally, adjusted rates of all-cause mortality are 7 to 20 times greater for RRT patients than for individuals in the general age-matched UCS population. In comparison to other countries, adjusted mortality rates in UCS RRT patients were much lower than those in all age groups who received RRT under Medicare (United States Renal Data System 2014). Crude mortality rates on RRT in UCS patients were higher than those in the UK (Steenkampa, Raoa et al. 2014) but comparable to dialysis patients in Sweden (Neovius, Jacobson et al. 2014). These variations may reflect underlying differences among countries in factors such as epidemiology of ESRD and the management of the condition.

8.2.2.3 Financial implications in the future

Costs for arranging and delivering RRT services may put a challenge to the health care budget in the long term. This study has sought to explain behaviours of the four cost drivers (numbers of future patients, material cost, labour cost, and capital cost) towards future programme costs. From the public payer's perspective, material costs accounted for the largest proportion of the costs of PD, HD, and KT. In the long term, it represents the most powerful cost driver for the total costs of PD and HD. Referring to Figure 7-11, in the scenario that material costs of the three RRT modalities increase, the unit cost of all RRT modalities will increase rapidly in the future. In contrast in another scenario where the costs of materials are assumed to be controllable, and would not cost more than the purchase price in 2014 as a result of central purchasing or the use of locally made medications, the unit cost of PD will be lower in the future.

This is because the unit cost is derived from dividing the total cost (the sum of material costs, labour costs, and capital costs) by the number of patients, and in the next ten years, the number of patients was projected to increase over time. Increases in labour and capital costs do not affect the unit cost.

Apart from the material cost, numbers of patients is another powerful cost driver. Transplant numbers are projected to be constant, not increasing over the next ten years. These numbers were low relative to the amount of their total costs, which were large and increasing each year. The unit cost of KT (equals to the total cost divided by number of transplants) would not decrease like that of PD but would instead increase as wages increase, independent of the material cost.

Labour costs are a concern among policy makers; that is, the growing level of wages as Thailand has become richer. This study has shown that if labour costs increase by the increasing number of patients and wage growth at not more than 7% each year, it would not have much effect on the size of the unit cost of PD and KT. As HD requires a high proportion of staff costs, cheap material costs may not contribute to the low unit cost in the future as that of PD, however the total HD budget would increase slowly, see Figure 7-10 and Figure 7-11.

A prior study (Kasemsap, Prakongsai et al. 2006) which projected RRT programme's future expenses, overestimated the likely budget of the programme by 2.3-4.5 times (£287-£480 million instead of £87 million in 2013). This result provides insights into cost containment strategies and emphasises the significance of controlling a programme's material costs and numbers of patients. There are some possible explanations for this lower cost that link to the disease management approach. First the guideline protocol controls types of reimbursable RRT services and their reimbursement rates, therefore reduces unnecessary items. In addition, the protocol has made RRT services, in particular PD, become commonplace in the UCS. This provides the NHSO with increased bargaining power in central purchasing of a range of medicines and medical products.

From the beginning of the RRT programme, the NHSO has used its purchasing power to obtain many medications and medical devices at best prices. For example, the current price of erythropoietin is cheaper by 80%-95% than its original price. In addition, the NHSO is able to purchase PD solutions at the lowest price in the world (Karopadi, Mason et al. 2014). However, the primary and secondary prevention programmes have yet to prove whether they can reduce enrollment of new patients with ESRD diagnoses on the RRT programme as well as reducing programme costs over the long term.

8.3   Strengths and weaknesses of the study

This study was conducted to explore the introduction and functioning of a high-cost health benefit programme as part of a universal coverage scheme. There were limitations from the data and methodology used, detailed in the end of Chapters 4-7. This section summarises the strengths and discusses the weaknesses of the study in relation to the overall interpretation of the results.

8.3.1   Strengths

The strengths of this study have been mentioned in the methodological issues section of this chapter. They are outlined as follows:

- This study focused on multiple aspects of the RRT disease management programme. These included;
    - Input: rationale for using disease management and the introduction of the RRT programme
    - Process: the functioning of the disease management interventions in the RRT programme
    - Output: programme registration rates
    - Outcome: mortality of patients with ESRD
    - Future implications: number of patients and budget needs
- The mixed-method approach of both qualitative and quantitative methods was applied to cope with the complexity of the disease management programme, since one approach could not provide all the

information required. The study methods complemented each other and led to improved study validity.

- The facility-based study enhanced validity by capturing most individuals of interest and results were representative of the studied population.

- Electronic databases containing patient diagnoses and encoded citizen identification numbers allowed the merging of databases from various sources without violating patients' anonymity.

- The quantitative method used, namely age-period-cohort analysis, is regarded as a powerful tool in modelling and analysing routinely collected information from administrative records or disease registries. Also, the ARIMA modelling technique is the most widely used time-series approach in health research.

8.3.2   Weaknesses

An experimental study design was not possible in practice for this study setting, in which a nationwide disease management programme was implemented. This might lead to the major weakness of this study; it could be questioned whether the conclusions derive from the true effects of the disease management interventions (Nolte, Conklin et al. 2012). Additionally, it lacked comparison or control groups, a strategy used in most disease management evaluations (Conklin and Nolte 2013) when assessing effects of the RRT programme. This study applied the age-period-cohort analysis, a descriptive tool to describe changes in the key measures, which were numbers of registrations and deaths in any study period, and compared them against those of the reference year. The analysis did not directly demonstrate causal relationships between the disease management interventions and outputs or outcomes. Similarly to other age-period-cohort studies, it is essential to provide and interpret the study results with environmental circumstances (such as commencing the RRT programme and new RRT benefits, flooding in Thailand) to explain the likely causes of the changes found in the studied period.

The other two public health insurance schemes, namely the Social Security Scheme and the Civil Servant Medical Benefit Scheme, could possibly be used as

comparison groups, because no disease management programmes operated in these two schemes. However, some reasons hindered the use of their data. First, patients in these two schemes represent different demographic and socioeconomic conditions, and use of care, from those of UCS patients. Additionally, the two schemes had very different proportions of RRT patients from the UCS, and were mainly treated with hemodialysis not peritoneal dialysis.

Another weakness was generalisability, the degree to which the results can be applied to a wider population of interest. Since the RRT programme was designed to serve a specific population, it has unique characteristics in terms of the policy support, delivery system, and community participation; the findings were not meant to explain results for other groups of patients with different disease management interventions. In addition, this study had few opt-out patient interviewees, and all of them share some characteristics including residing in a rural area, living in poverty, and low literacy levels. Ability to generalise conclusions to a wider group of opt-out patients can be limited, in particular those who are better off or living in urban areas.

CHAPTER 9   Conclusions and policy recommendations

This study set out to explore the introduction and functioning of a high-cost UCS health benefit programme, using the renal replacement therapy (RRT) programme as a tracer. It then aimed to assess how a disease management approach can facilitate the inclusion of RRT in the benefit package, now and in the longer term, and with what results. The findings of this study are intended to build evidence to highlight the role of the disease management approach in supporting a policy of including a high-cost health benefit such as RRT in the context of a developing country.

This chapter summarises what this study has accomplished. It next brings in the contribution to knowledge, then identifies the policy implications for disease management of high-cost health conditions. Finally, the chapter draws out suggested directions for future research.

9.1   Conclusions of findings

This study emphasised the significance of the definitions of high-cost and catastrophic spending, and the policy implications suggested by Wyszewianski (1986). RRT is an example of the treatment that is both high cost and can cause catastrophic spending. Before the commencement of the RRT programme in the UCS, RRT was recognised as a high-cost treatment that could impoverish a patient and their family. At the time concerns were focused on how to introduce the health care benefit to protect the patients from such consequences and on how to increase access to this high-cost health care.

Despite resource constraints, governments in every country have a responsibility to ensure that their citizens are looked after and have the care and treatment they need when they fall ill. The expense of health treatment can hinder people from receiving essential services; either patients stop using services they cannot afford, or continued treatment pushes patients and their families into poverty.

In the commencement of the UCS in 2001, there was a concern on the scheme's fiscal constraints and an unprepared system. As a consequence, UCS policy makers decided not to include RRT in the benefit package. Later in 2008, RRT was added in the UCS benefit package, as a result of efforts from various stakeholders responding to the implications of high-cost conditions. This study highlighted the combination of leadership between three components: the scholars who create knowledge, public actions, and politicians who push ahead the new RRT policy.

There were two key reforms to the new RRT programme. First, the RRT payment system was separated from mainstream UCS services. This is because capitation and diagnosis related group (DRG) with global budget payment tended to prevent providers from providing high-cost treatment such as RRT and the shift to a fee schedule aimed to encourage provision of RRT services among providers. Second, the disease management approach was not only used in the RRT service delivery at the provider level, but also in arranging the entire RRT system by incorporating a range of interventions: i) population identification, ii) evidence-based guidelines, iii) reporting systems, iv) process and outcome measurements, v) collaborative practice, and vi) self-care management support.

Results from this study pointed out that, since the introduction of the RRT in the UCS, patients diagnosed with end-stage renal disease (ESRD) had better access to care. Overall, after a stable period between 2009 and 2011, new adult ESRD patients registered in all RRT modalities had a significant increase. Particularly, there was considerable success in taking up patients in younger age groups. In 2013, the proportion of adult ESRD patients newly starting RRT was 47% of all newly diagnosed ESRD patients. The rest had not yet started RRT for some reasons. In the next ten years, the total number of RRT patients was projected to increase by 10% annually.

After launching the RRT programme in 2008, the all-cause mortality rate of adult RRT patients increased over time through 2010. Now it tends to have leveled off. In 2013, the age-standardised mortality rate (ASMR) for adult RRT

patients reduced from a peak at 80 deaths per 1,000 patient-years at risk in 2010, to 60 deaths per 1,000 RRT patient-years at risk.

RRT continues to account for a high proportion of the government health budget. Consequently, the policy concern around RRT has shifted from protecting patients against catastrophic spending to controlling health care costs to the government. In the near future, the RRT programme budget is expected to increase in the region of 9-19% annually.

Results from long term projections, however pointed out that RRT costs can be made more affordable to the health care payer. Controlling cost per unit in the RRT programme can be achieved by 1) for KT, filling spare capacity of operating theaters and 2) for PD and HD, controlling or reducing material costs while labour costs are increased as normal and capital costs are kept constant.

Interviewing policy makers, providers, and patients in all types of RRT modalities, including patients on conservative therapy, revealed interesting results. The majority of RRT patients reported a good quality of life, which it was possible with sufficient knowledge and self-care management skills. Some interviewees mentioned difficulties with the care process and dialysis-related costs that patients still had to take on. Patients living with conservative therapy reported that poverty, frailty, and weak or no family support deterred them from starting dialysis. Nonetheless, these issues demonstrate a potential for development of the RRT benefit and care process to better suit the needs of all patients, those living close to town centres and those in remote areas.

This study also found that although there is now RRT coverage, it still has the characteristics of a high-cost and catastrophic condition, although the catastrophic effect on patients is diminished. The remaining effect is generally a consequence of some types of costs outside coverage, for instance, frequent journeys to dialysis units, out-of-pocket costs relating to dialysis, and patients' or families' opportunity costs.

9.2   Contribution to knowledge

The focus of previous studies worldwide has been on the cost-effectiveness of health care interventions, or quantifying numbers of households with catastrophic spending: there has been less study on how to prevent patients' impoverishment due to high-cost but essential health services.

The number of and investment in disease management programmes is growing, but programme evaluations have mainly been conducted in the US and European countries. In these countries, disease management has been used as a means to improve quality of care in patients with chronic conditions. Although treatment costs for these conditions are not expensive, multiple episodes of treatment sum to a large amount and can be a burden on countries' health care budget in the long term. The aims of disease management programmes are generally to improve health and cost outcomes, while in the UCS, disease management was used with a different aim. In the context of a developing country, Thailand encountered a challenge on equal access to high-cost treatments and the aim of applying UCS disease management programmes was to increase access to high cost health care. In this instance, the rationale, process, performance, and effect of these programmes were unknown.

When a government decides to support patients' access to high-cost treatment by using public money, there may be concerns about 1) what tools to use and how to use them, and 2) whether the results will be measurable, those intended, and represent value for money. This study has highlighted the application of the disease management approach as an intervention to arrange service provision and to promote patients' access to less-accessible and expensive treatments that may otherwise lead patients into impoverishment in the context of one condition and one developing country.

The study was conducted in Thailand, a developing country achieving universal health coverage. Various so-called disease management programmes have been implemented, and these programmes need continued monitoring and evaluation to feed back into the policy formulation process. By focusing on the health care payer's perspective, this study has filled a knowledge gap about the

rationale, process, output, and outcome of a UCS disease management programme for a high cost disease (the RRT programme) from beginning to end.

This study shows that investments in the RRT programme have returned promising results. After launching the RRT programme, more than half of patients with ESRD diagnoses are able to start RRT and that makes them more likely to survive. The study further contributed to estimating the long term financial consequences of the RRT programme and identifying potential cost drivers of high-cost disease management programmes and suggested ways to adjust payment to suit the preferences of both health care providers and the payer.

The study introduced approaches to monitoring access to care and the health status of patients. It further provided a cost modelling method for projecting future financial implications and defining cost drivers of such high-cost programmes. This study also revealed some limitations of disease management programme evaluation if purely quantitative methods are used. Disease management administrative data and disease registry data account for patients who seek care and are registered in their databases. In reality, many patients with ESRD diagnoses never start dialysis. Qualitative methods in this study, such as in-depth interview and focus group discussion, supported quantitative findings by providing insights to why patients refuse dialysis.

Despite being a middle-income country, Thailand is an innovator in a number of areas relating to universal health coverage. Strong leadership of the NHSO and of the policy community plays an important role in pushing ahead for continuous improvements to ensure members' equitable access to care. The RRT programme is an example of this. Experiences from the management of high-cost diseases in Thailand can provide lessons learned to other countries seeking interventions to arrange service provision for high-cost diseases. Findings from this study can be beneficial to the process of health policy formulation, especially where a government needs to know what should be invested for a benefit package which covers high-cost conditions.

9.3   Policy recommendations

This section proposes policy recommendations related to high-cost treatment in two main areas: 1) general recommendations for any country looking for ways to introduce a high-cost health benefit and 2) specific recommendations, regarding high-cost conditions and disease management programmes, for the UCS context.

9.3.1   Recommendations for other countries

Each country has a different context which contributes to differences in resources, people's health needs, and the organisation of health care. Experiences from this study can provide lessons learned to any country with or without universal coverage, as long as their health system has limitations in funding, health workforce, and infrastructure.

I. Including high-cost treatment in a benefit package

This study has provided an example on making a policy change to include a high-cost treatment (RRT) in a benefit package. The key processes are summarised here and could be a general guideline for other countries.

First, a group of scholars gathered evidence on 1) what other countries do to provide this benefit, 2) available infrastructure of the system: workforce and facilities, 3) estimated numbers of patients who will use this treatment and budget needs, 4) Studies on cost-effectiveness of the treatment, 5) public opinion of the new benefit. Next, relevant stakeholders were invited to participate at an early stage, these included medical professionals, scholars, patient groups, and politicians including the Minister of Public Health. These people got involved in designing the RRT benefit in many ways, both formal and informal. After the stakeholder participation had been carried out, the result was first implemented in a pilot project to review possibilities of large scale arrangements regarding staffing and service provision. Finally the RRT programme was launched. The overall process took about three years and a half to finish.

II. Disease management approach

Disease management has various forms and definitions. Components used in the UCS, although different from disease management approaches used in many developed countries, have been shown in this thesis to be effective in arranging service provision for a high-cost condition. These may help other countries assess the value of disease management for them. The key effective components are highlighted as follows.

i. Population identification processes to select patients

The term target population refers to individuals that have the same health needs or have the selected condition; they are selected by frontline providers according to an agreed guideline protocol. For this reason, setting criteria for patient selection is important, and patients are prospectively identified from routine review of patient profiles. This study found that the population identification process is the starting point for providers to include patients in the RRT programme. For the payer, this process helps to identify the number of patients who are expected to use services and therefore to estimate the budget need.

ii. Nationwide evidence-based protocol linked to provider payment

An evidence-based protocol is essential to lay down the working procedures for providers. The protocol should be based on clinical practice guidelines that are adjusted to suit the local context of individual countries. In addition, the protocol should be linked to the payment mechanism in order to ensure providers are paid at predefined rates once services are provided to patients. This study found that a fee schedule suits payment to providers better than a capitation payment, as it provides incentives for providers to scale up service provision. However, making a guideline protocol that suits everybody's preference can be a challenge to policy makers, in particular when linking a protocol with payment. In addition, it needs frequent updates, and any new information should be clear to providers, including what they should do to fulfill their duty.

iii. Collaborative practice which includes health care teams and external stakeholders

It is impossible for the health care payer to work alone: there must be collaborative practice from the beginning when setting up a high-cost health benefit and organising the service provision. Collaborative practice is likely to be central to a sustainable system. In this study, the collaboration included people at all levels. For example, providers and academicians identified the system capacities and developed working protocols for the health staff. The protocols were based on clinical practice guidelines adapted to the country context. Patients groups were supported in order to create links between the payer, providers, and local communities; in these groups patients were able to voice their needs and exchange useful information.

iv. Routine reporting system and ongoing process/outcomes measurement and evaluation

A routine reporting system provides administrative data which is used for reimbursement purposes and as an essential source of information for the monitoring and evaluation process. Computerised databases would provide more utilisable data than paper based reports.

The monitoring and evaluation process is important in order to ascertain whether the programme has yielded the preferred results, and whether those results represent value for money. In addition, findings from the programme evaluation can be used to improve future provision and inform any expansion to provision of other high-cost conditions.

In the disease management programme monitoring and evaluation, this study found challenges about data inaccuracies in administrative data. This can be because of the data recording process and the nature of these data that are not meant to be used for monitoring and evaluation purposes. An effective audit system is therefore essential to assess recording practice among providers. It should be in place as a continuing process, similar to that of the monitoring and evaluation process. This is to ensure and maintain the quality of reporting sent

back to the payer, since it affects the accuracy of claims data used for reimbursements, as well as the production of monitoring and evaluation reports.

> ### v.   Self-care management and educational programmes that may include raising awareness of secondary prevention, adherence to treatment, and behaviour modification

The literature review of this study found that in most other disease management programmes, patient education and/or patient reminders are basic strategies used to prompt patient self-care in order to better control conditions and reduce care costs. This component, although not highlighted as a key feature of the success of the UCS RRT programme, helps patients with managing their condition and maintaining everyday life. It also complements other disease management components by facilitating collaboration between patients and their health care professionals.

9.3.2   Recommendations for UCS policy makers

The recommendations proposed in this section are obtained from evidence from the RRT disease management programme. Section i provides recommendations for disease management programmes in general. Sections ii-v focus on arrangements for and management of the RRT programme in the UCS, but some recommendations can be applied to other disease management programmes.

> ### i.   Future directions of the UCS disease management programmes

The UCS has introduced many so-called disease management programmes. However, most of these have only a few components of the disease management approach and are not focused on service delivery. This study found that the RRT programme encompassed all components, and has benefited from each one. It has also achieved its aims to increase access to care and prolong patients' lives.

The research implies that implementing just a few components of a disease management programme that is not focused on arranging service provision is

likely to incur unfavourable results. For example, without a clear target population and protocol, a programme budget cannot be estimated, and payers and providers may be unsure how to begin and roll out the programme.

There have been many disease management programmes in the UCS. Each of them needs to be reviewed in terms of efficiency and effectiveness. Programmes that produce unpromising results could be terminated, while more successful programmes could be expanded until there is good coverage and costs of technologies are reduced. It may not be necessary to manage these programmes separately; they could be brought into mainstream UCS services, for which criteria need to be developed.

ii.   Decreasing the need for dialysis

Controlling numbers of patients retained in the RRT programme might be the best solution to deal with the increasing cost of the programme. This can be done by decreasing numbers of patients taken into the programme, delaying entry, and boosting numbers of patients exiting the programme via transplantation.

Early detection and effective intervention in the early stages of kidney disease are essential to prevent or delay the development of chronic kidney disease. At the moment, the NHSO has set up several primary prevention programmes that focus on improving health and reducing risk factors contributing to chronic diseases, and a secondary prevention programme that consists of measures for early detection in those who have already developed diabetes mellitus and hypertension in order to prevent the progression of the disease and reduce or delay long-term complications such as chronic kidney disease. Given that chronic kidney disease is a silent disease, a patient may be living unaware of the condition until it reaches an advanced stage. A guideline focusing on educating and taking patients into the prevention programmes, particularly those residing in remote areas, is needed.

This study found that there have been low numbers of kidney transplants and this situation may continue if no action is taken. The study did not explore the

solutions to this situation. Possible suggestions may include establishing an effective and reliable organ donation system in accordance with international guidelines (WHO 2009). Although many developing countries have introduced presumed consent, the majority of Thai people still have limited information about and negative attitudes towards organ donation. Therefore, implementation of this system at the moment would be controversial, and likely unsuccessful. Promoting positive public perceptions of organ donation is therefore a high priority and may address the most difficult issues in the organ donation process.

iii. Promoting conservative therapy at the community level

This study found many patients of a community hospital chose not to start dialysis, but instead accepted ongoing support by a multidisciplinary team including general practioners, nurses, a pharmacist, a nutritionist, and a physiotherapist. Conservative therapy is therefore another option for ESRD patients apart from the three RRT modalities as the RRT programme continues to expand. Conservative therapy should be promoted and implemented in community hospitals nationwide to ensure that opt-out patients are not completely abandoned, but are supported by the health care team until the end of their life. Overall this could reduce or delay entry into the RRT programme and help reduce the high cost of dialysis treatment within the RRT programme, since many patients may never start.

iv. Controlling costs of materials and setting up optimal payment proportions

The results of this study suggested that the material cost influenced the unit cost of each RRT modality, and it can be adjusted to control programme costs. The material cost of medications such as dialysis solutions, catheters, and erythropoietin, should be controlled by introducing local manufacturing of or controlling purchase prices. Labour costs can be increased annually to fit the wage rate of the local labour market in order to persuade and motivate providers. Reimbursements for machines and buildings can be increased then

fixed for their life cycle periods. Altogether, proportions of these three cost drivers: material, labour, and capital costs can be adjusted in order to set the optimal payment rate.

v. Investing in effective information systems for monitoring and evaluation

An effective information system is central to programme administration. The information system should include continuous monitoring of the working processes of frontline providers and of the central NHSO. Examples of such monitoring include: inspecting DRG coding manipulation, measuring accuracy and completeness of patient records stored in claims data, measurements of programme outputs, and coverage of disease management programmes.

In addition, there is a need for updated research studies to provide evidence from assessing disease management programmes, whether they have achieved their ultimate aims and whether they represent value for money. This is explained in greater detail in the next section.

9.4 Areas for future research

There is a constant need for updated research studies to provide new evidence to inform policy changes and support, monitor, and evaluate existing policy decisions. This study has provided some examples, there are questions that this study has not yet answered and could therefore provide scope for future research. Potential areas for future studies are described here.

9.4.1 High-cost and catastrophic definition

Wyszewianski (1986) differentiated between the terms high-cost and financially catastrophic. Although sometimes used interchangeably, in fact they affect policy formulation in different ways. This study used Wyszewienski's definitions to give an example of a high-cost and catastrophic condition (ESRD) and to describe how ESRD affects patients, providers, and policy makers in this sense.

A number of conditions fall under the definition of 'high-cost', referring to conditions that affect small numbers of patients but account for a significant proportion of the health care budget. From the provider's perspective, identifying the most expensive conditions and the patient characteristics that predispose to expensive treatments would be essential in order to effectively select conditions or groups of patients to manage in this way.

9.4.2   Costs and costing of treatment for chronic kidney disease

The provision of treatment for chronic kidney disease is costly. There is a need for further research on the costs of treatment for chronic kidney disease. From the providers' perspective, detailed costing of each activity is required. Comparing costs with other hospitals, or comparing to past hospital performance, reveals opportunities for efficiency improvement. From the payer's perspective, costing of treatment is important in order to estimate its impact on the health care payer's budget. Also, costs can be used as an input to set the prices for the programme reimbursement rate.

Assumptions used in this study came from the reviewed studies, which were quite old or used data collected from small numbers of health facilities. Large-scale studies are needed to estimate the true cost to hospitals (the providers' perspective).

9.4.3   RRT programme monitoring and evaluation

Increasing access to care is the main aim of the RRT disease management programme and this should be an ongoing process. From the literature review in this study, there are numbers of ways to measure access to care and other health outcomes.

This current study provided examples of these but it lacked a comparator to demonstrate a cause-and-effect relationship for disease management interventions. Future research may consider adding a comparison strategy to interpret results. This might include a comparator group (internal, external, or general population) and benchmarks (general population or target). Suggested topics might include whether variations in access to care or other health

outcomes are likely to be explained by differences in geographical regions, social classes, age structures and health schemes. In addition, this study found a number of patients in a remote area had made the decision not to start dialysis. It should be explored further in a wider group of population about factors and patient characteristics that might influence this decision.

9.4.4 Kidney transplant

Kidney transplant is the most preferred and cost-effective treatment modality for ESRD patients. However, the potential to increase the number of transplantations has been limited by a shortage of donated kidneys. This study confirmed the low number of transplants each year and projected that this situation would remain unchanged in the next decade, however the study did not explore this further. In addition, there have been limited published papers in Thailand about kidney transplant. These could be opportunities for future research to identify ways to increase organ donations. Possible topics may include, for example attitudes towards organ donation among different groups of people, system barriers, and attitudes towards the presumed consent system.

Filling spare capacity of operating theatres is a way that this study suggested to increase efficiency of the KT system. This study assumed that spare capacity existed but has not proved it. This could be another area to explore, that is the extent to which operating theatres are managed and used, whether there is spare capacity and what impacts are.

9.4.5 Human resource for RRT programme

Apart from sufficient budget to care for patients with ESRD, increasing needs for RRT may also challenge human resources for health. This study has projected future numbers of patients by RRT modality. This information could be used as a basis to estimate numbers of health professionals required in the RRT system, and whether the available workforce will be enough to meet this need.

9.4.6   New technologies in dialysis

The dominant modes of dialysis in Thailand are in-centre hemodialysis and continuous ambulatory peritoneal dialysis. In addition to these, there are other types of dialysis such as automated peritoneal dialysis (in which dialysis solution is changed at night when patients are asleep) and home hemodialysis. Both are popular in many developed countries (Nitsch, Steenkamp et al. 2011; Vanholder, Davenport et al. 2012) but are rarely used in Thailand. None of these types is perfect, they have advantages and disadvantages.

Due to the limited use of other types of dialysis, studies relating to them, in terms of costs, clinical outcomes, and patients' quality of life, are rare. This knowledge gap could be addressed by future research to assess the potential for adopting other types of dialysis as part of the UCS benefit package. This would also provide a chance for patients to have the dialysis method that best suits their personal situation.

9.4.7   Approaches to implement disease management programmes

Disease management has been used in the UCS as an intervention to cope with patients' difficulties and inequities in access to health services. However, this study found a number of remaining challenges within the RRT programme. For example; many patients in a remote area decided not to start RRT; some patients were maintaining RRT and facing very high indirect costs; the use of a multidisciplinary team produced positive results in a community hospital and there may be a way to scale up this practice.

Implementation research applied to these instances could support existing policy decisions and provides information as to whether the disease management components work, which would work best, how best to adjust them, and how to expand the use of a disease management approach to some other UCS services that encounter similar problems.

9.5   Conclusions

In the UCS, the aim of disease management programmes is different from that of the US and European programmes. In Thailand, disease management is an answer to managing high-cost and catastrophic conditions. It is a tool for policy makers to increase access to care for particular health conditions and reduce catastrophic patient payments. Key features of the Thai programme include the guideline protocol, linked to a payment system that focuses on a specific population group. The protocol links to other components affecting patients' access to care: collaborative practice, routine reporting, monitoring and evaluation systems, and self-care management.

The RRT programme and the UCS have achieved their aims in terms of protecting many Thai households from health-care payments which may drive them into poverty (Evans, Chowdhury et al. 2012), while at the same time promoting access to essential health services and likely improving health outcomes. Lessons learned from the disease management approach might be extended to other high-cost conditions within the UCS and can be applied to other developing countries.

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Appendices

Appendix 1 EMBASE search results

No.	Terms	Number retrieved
1	"disease management".ti,ab.	13,216
2	effect$.ti,ab.	6,600,707
3	nation$.ti,ab.	544,626
4	region$.ti,ab.	1,487,746
5	sickness fund.ti,ab.	226
6	decentral$.ti,ab.	6,866
7	(county or counties).ti,ab.	59,065
8	countr$.ti,ab.	378,593
9	3 or 4 or 5 or 6 or 7 or 8	2,314,026
10	1 and 2 and 9	923
11	limit 10 to (abstracts and english language and yr="2003 - 2015")	768

Appendix 2 Interview questions for policy makers and health care providers

Main question	Additional question
I. general questions	
1. What are your job descriptions/responsibilities?	• How many year you've been working on this job?
II. High cost disease	
2. From your experience, have you ever seen a patient who paid for health care until bankrupted	• What kind of disease the patient had, general disease(s) or chronic disease(s)? • What was the main reason?
3. In your opinion, what are the characteristics of a disease that can cause the patient bankrupt?	• Before the existing of NHSO and after NHSO, are they different?
III. Disease management of RRT programme	
4. How do you diagnose a patient having last stage of chronic kidney disease (ICD10=N185)?	• In the case that you or the patient does not want to start a dialysis at the moment, how do you diagnose that patient?
5. How about the referral system?	• From community hospital to higher level • From health centre to community hospital
6. How do you manage the HR for the PD first programme)	• How many nephrologist, GPs, nurses, and patients you have?
7. In your opinion, what are advantages and disadvantages of separating the RRT programme from other treatments which are paid by capitation payment.	• Increase access to high cost treatment? • (keyword: Patient identification, payment, guideline protocol
8. What about the reporting system?	

IV. Holistic care/ palliative care	
9. Do you offer both holistic care/ palliative care to CKD patients?	• What kind of activities you have? • Can you describe the flow/patient journey? • Do patients who have dialysis and patients who choose conservative therapy (no RRT) receive the same palliative care?
10. In what stage that a patient can deny RRT	• Generally, who is the one who makes decision (GP/nurse/patient/family)
11. How do you evaluate a patient and get him ready for the conservative therapy?	• Are there any processes of counseling and asking patient's feedback?
12. From the beginning of the RRT programme, what changing pattern do you observe?	• Eg. No of patients on PD in comparison to HD and KT • Withdrawal and refusal of RRT in the first place • Effects of new policies
13. Quality of life of ESRD patients	• Dialysis/KT/conservative patients
14. Community supports	
IV. Opinion on RRT programme	

: interview questions for patients

Main question	Additional question
1. Ask general questions about …	• Age, place of birth, career, source of income, education, history of illness, and carer
2. How did you about your condition (ESRD)?	• When was that and who told you? • Were you worried, what about? • How did you cope with the condition?
3. Before that have you got screening tests?	• In which hospital, how and by who?
4. After you know about your condition, what happen then?	• What did you/family think? • Did you go to receive the treatment?
5. Could you tell about the decision making process?	• Did you/family have an opportunity to make decision about your treatment? • Did you know 'PD first'?
6. (If received treatment) when did you register with the programme?	• Did it take long to start the treatment? • How about your treatment? • How do you come to the hospital, how often, and anyone come along? • Are there any things you have to pay from your pocket? • Have you experienced a complication?
7. (If not received treatment) what is the main reason of denying the treatment?	• Who made the decision, you/family/doctor? • Did doctors give you enough information? • Is there any form of support you are given?
8. How about your quality of life at the moment?	

Appendix 3 Observation checklist

Name: Address: Date of collection:

1. Socio-economic information

Age	
Sex	☐ Male ☐ Female
Birthplace	(Province)
Marital status	☐ Married ☐ Single ☐ Widow/separate
Highest education	☐ Primary or lower ☐ Secondary ☐ Bachelor's or higher
Career	
Household size	Person(s)
Household income	Baht/month
Main carer	

2. History of illness

Month/year diagnosed with ESRD	
Month/year starting dialysis	
Complication(s) from dialysis	☐ No ☐ Yes, ……………………..
Comorbidity(ies)	

3. Features of the house

House type	☐ House ☐ Flat ☐ Other
Patient's bedroom	Own bedroom? ☐ Yes ☐ No Good air flow? ☐ Yes ☐ No Cleanliness? ☐ Conform ☐ Not conform
House's perimeter	Cleanliness? ☐ Conform ☐ Not conform Hygiene? ☐ Conform ☐ Not conform Pet? ☐ No ☐ Yes, kept away from exchange area ☐ Yes, kept near exchange area
Water source	☐ Tap water ☐ Ground water ☐ Rain water ☐ Other
Exchange area	Have a separate room? ☐ Yes ☐ No Cleanliness? ☐ Conform ☐ Not conform
Stock of dialysis bags	Separate area? ☐ Yes ☐ No Good air flow? ☐ Yes ☐ No Direct sunlight ☐ Yes ☐ No Cleanliness? ☐ Conform ☐ Not conform

Remaining bags	

4. Changing practice

1) General information

How often do you do exchange?	
How do you get dialysis bags?	☐ Srinagarind hospital ☐ Health centre ☐ Home delivery
Normally, who do the changing?	☐ Yourself ☐ Carer

2) Equipment

1. Table/ flat surface	☐ Have	☐ Don't have
2. Liquid soap	☐ Have	☐ Don't have
3. Alcohol	☐ Have	☐ Don't have
4. Hand towel	☐ Have	☐ Don't have
5. Cotton ball	☐ Have	☐ Don't have
6. Water resistance, adhesive bandage	☐ Have	☐ Don't have
7. Hook/pole with hook	☐ Have	☐ Don't have
8. Hanging scale	☐ Have	☐ Don't have
9. Bucket to place empty bag in	☐ Have	☐ Don't have
10. Bucket to place used hand towel in	☐ Have	☐ Don't have
11. Sink with single lever faucet	☐ Have	☐ Don't have

3) Exchange technique

1. Arranging equipment	☐ Correct	☐ Incorrect
2. Hand washing	☐ Correct	☐ Incorrect
3. Surface cleaning	☐ Correct	☐ Incorrect
4. Checking the unused bag	☐ Correct	☐ Incorrect
5. Combining and connecting exchange devices	☐ Correct	☐ Incorrect
6. Weighing of used dialysis solution	☐ Correct	☐ Incorrect
7. Updating health records	☐ Correct	☐ Incorrect
8. Waste disposal	☐ Correct	☐ Incorrect
9. Arranging equipment	☐ Correct	☐ Incorrect
10. Hand washing	☐ Correct	☐ Incorrect
11. Surface cleaning	☐ Correct	☐ Incorrect
12. Checking the unused bag	☐ Correct	☐ Incorrect
13. Combining and connecting exchange devices	☐ Correct	☐ Incorrect

5. Exit site

Cleanliness	☐ Clean	☐ Infected
Dressing technique	☐ Correct	☐ Incorrect

Appendix 4 Coding framework

Root code	Sub code
High-cost disease	View on high-cost disease
	Coping high-cost disease
Chronic renal failure	Reason to select chronic renal failure to manage
	Reason to separate from other diseases
	How to select disease
HR	HR allocation knowledge
	View on HR allocation
Payment	Reimbursement knowledge
	Motivation from payment
	View on payment
Protocol	Guideline/protocol knowledge
	View on guideline/protocol
Reporting/M&E	Report, M&E knowledge
	View on report, M&E
Collaboration practice	Provider-patientpractice
	Purchaser-providerpractice
	View on collaborative practice
Family/community support	View on family support
	View on community support
Patient journey	Patient journey knowledge
Patient characteristics	Demographic
	Socio-economic
	Beliefs
Patients' decision making	Reasons
	By whom
Patient self- management	Location
	Equipment
	Technique

Appendix 5   Ethical approval

Ethics Committee

Institute for the Development of Human Research Protections (IHRP)

Building 8 Floor 7 Room 702 Department of Medical Science Ministry Public Health Nonthaburi Thailand 11000

Certificate of Approval

Title of Project: Can a Disease Management Approach Facilitate the Inclusion of High-cost Conditions in a Benefit Package?: The Case of Renal Replacement Therapy in Thailand. (Version 2/20 August 2014)

Principal Investigator: Mrs.Noppakun Thammatacharee

Responsible Organization: Health Insurance System Research Office, Ministry of Public Health.

The Ethics Committee of Institute for the Development of Human Research Protections (IHRP) had reviewed the research proposal. Concerning on scientific, ICH-GCP and ethical issues, the committee has approved for the implementation of the research study mentioned above.

(Dr.Vichai Chokevivat)
Chairman

(Dr.Pramote Stienrut)
Committee and Secretary

Date of First Meeting: July 28, 2014
Date of Approval: February 25, 2015

Appendix 6   Research articles conducted to advocate including the RRT
benefit in the UCS

	Dimension	Aim	Type/Method	Results
1.	Access to RRT (Kasemsap, Tangcharoensathien et al. 2001)	To raise the importance of the problem	Review articleof situations in Thailand and other countries	Access to RRT was limited only to those who were well-off, at around 23% of all ESRD patients
2.	Access to RRT (Tangcharoensathien, Teerawattananon et al. 2001)	To give possibilities of including RRT benefit into the UCS	Policy analysis	There is a need to take action on planning of service provision of RRT(including resources:HR/unit/budget), as well as programme expenditure
3.	Cost-effectiveness of RRT(Chewchanwattana, limwattananon et al. 2003)	To compared costs of 2 mode of dialysis (HD and CAPD)	Cost-utility analysis	Using secondary data input from the US. renal data system (2002), ICER of CAPD in comparison to HD was 6.15 million Baht per QALY
4.	Supply (physician/nurse/HD machine/health facility) of the RRT(Krairittichai, Supaporn et al. 2003)	To report current situations regarding infrastructures of the RRT	Annual report of TRT registry	Thailand Registry of Renal Replacement Therapy started its mission in 1997. Until 2003 there were201 registered RRT units. Incidence and prevalence of ESRD in 2001 were 23.4 and 112.7 pmp respectively.
5.	Cost-effectiveness of RRT (Teerawatananon 2006)	To compared costs of 2 mode of dialysis (HD and CAPD) and without treatment	Cost-utility analysis	CAPD had more cost-benefit and(Kasemsap, Teerawatananon et al. 2006) cost-utility in comparison to HD in all age groups. Both dialysis modes were not cost-effectiveness when using GDP or 3 times GDP as indicators.
6.	Demand of the programme (Kasemsap, Teerawatananon et al. 2006)	To estimate numbers of patients who need to use RRT	Calculations of incidence rate and survival rate	Under the circumstance of every ESRD patients can use RRT, there were 14,000 patients in 2005, would increase to 50,000 in 2009.
7.	Public opinion (Tangcharoensathien, Vasavid et al. 2006)	To seek opinion from the public regarding the RRT benefit of the UCS	Descriptive analysis of the survey	Most Thais supported including the RRT benefit into the UCS. Just half of respondent agreed about paying a small amount of contribution (of less than 800 Baht -approx.£17-per month)
8.	Budget impact (Kasemsap, Prakongsai et al. 2006)	To estimate budget needed for programme implementation	Budget estimate	In the first year of the programme, it would require 4,000-6,500 mBaht/year. These amounts would increase to more than 50,000mBaht/year in the 14th year.
9.	Access to RRT(Prakongsai, Tangcharoensathien et al. 2006)	To provide policy options regarding RRT benefit	Literature review/qualitative analysis/policy analysis	Including the RRT benefit into the UCS was essential to protect its beneficiaries from financial catastrophic due to service costs. Prioritising to those with more health needs

```
replace CRange=1971 if C>=1971&C<1976
replace CRange=1966 if C>=1966&C<1971
replace CRange=1961 if C>=1961&C<1966
replace CRange=1956 if C>=1956&C<1961
replace CRange=1951 if C>=1951&C<1956
replace CRange=1946 if C>=1946&C<1951
replace CRange=1941 if C>=1941&C<1946
replace CRange=1936 if C>=1936&C<1941
replace CRange=1931 if C>=1931&C<1936
replace CRange=1926 if C>=1926&C<1931
replace CRange=1921 if C>=1921&C<1926
replace CRange=1916 if C>=1916&C<1921&C!=.

*PERIOD RANGES
gen PRange=.
replace PRange=2005 if P>=2005&P<2006
replace PRange=2006 if P>=2006&P<2007
replace PRange=2007 if P>=2007&P<2008
replace PRange=2008 if P>=2008&P<2009
replace PRange=2009 if P>=2009&P<2010
replace PRange=2010 if P>=2010&P<2011
replace PRange=2011 if P>=2011&P<2012
replace PRange=2012 if P>=2012&P<2013
replace PRange=2013 if P>=2013&P<2014&P!=.
tempfile x
quietly save `x', replace

*DESCRIPTIVE HD POPULATION
use `x',clear
keep D ageRange PRange
egen pop=sum(D), by(PRange ageRange)
label define ageRange 20"20-24" 25"25-29" 30"30-34" 35"35-39" 40"40-44"
45"45-49" ///
50"50-54" 55"55-59" 60"60-64" 65"65-69" 70"70-74" 75"75-79" 80"80-84"
85"85-89"
label value ageRange ageRange
label variable ageRange "Age"
contract pop ageRange PRange
drop _freq
rename ageRange Age
rename PRange Year
sort Year Age
reshape wide pop, i(Age) j(Year)
forvalue i=2008/2013 {
quietly format pop`i' %5.0fc
}
**APC ANALYSIS
*POPRISK
use `x',clear
poprisktime using popESRD_Allnewdata_r2, age(A) period(P) cohort(C)
cases(D) ///
agemin(20) agemax(89) permin(2008) permax(2013) missingreplace
drop if Y==0
drop if Y==.
label variable Y "Poprisktime"

*APC FIT: AP MODEL,REFERENCE PERIOD=2010,DF=5
apcfit, age(A) period(P) cases(D) poprisktime(Y) nper(1000) refper(2010)
param(AP)

*CREATE GRAPH FOR AGE
twoway (rarea agefitted_uci agefitted_lci A, sort pstyle(ci) color(orange)
fintensity(inten50)) ///
       (line agefitted A, sort lc(cranberry) clpattern(solid)) ///
     , yscale(log)  name(A,replace) title("HD" "c.",position(11))
legend(off) ///
         ylabel(2 5 10 20, angle(h)) xlabel(20(20)80) ///
```

```
        xtitle("Age") ytitle("Rate per 1,000 ESRD diagnosis-years")
scheme(sj)

*CREATE GRAPH FOR PERIOD
twoway (rarea perfitted_uci perfitted_lci P, sort pstyle(ci)
color(eltgreen)  ///
        fintensity(inten50)) (line perfitted P, sort lc(emerald)
clpattern(solid)) ///
        ,legend(off) name(P,replace) title(" " "d.",position(11)) ///
        xtitle("Calendar Time") ytitle("Rate Ratio") yscale(log) ///
            ylabel(1 2 4 15 50) xlabel(2009 2011 2013)
*COMBINE AGE AND PERIOD GRAPHS
graph combine A P, nocopies imargin(2 2 2 2) scheme(sj) ysize(4) xsize(8)
name(hd,replace)


**DESCRIPTIVE GRAPHS OF ACCESS TO HD (ESRD INCEDENCE AS DENOMINATOR)
clear
clear matrix
set more off
cd "D:\..."

*CONSTRUCT ANALYTIC DATASETS
use "ESRD_OPIP_HDPDKT_2008to2013r2",clear
keep if rrt==1
keep pid C dateRegister
gen P=year(dateRegister)
drop dateRegister
gen A=P-C
label variable A "Age at Registration"
sort pid
display _N
keep C P A
contract P A C
rename _freq D
label variable D "Number of HD registration"
drop if A<20
drop if A>89
sort P A C
tempfile a
quietly save `a',replace

**DESCRIPTIVE GRAPHS
use popESRD_Allnewdata_r2,clear
sort P A C
merge 1:1 P A C using `a'
keep if _merge==3
drop _merge
drop if P>2013
display _N
tempfile hd
quietly save `hd', replace

*1)GRAPHS RATE VS AGE BY PERIOD
use `hd',clear
egen Dpa=sum(D), by(P ageRange)
egen Poppa=sum(pop), by(P ageRange)
contract P ageRange Dpa Poppa
drop _freq
gen Rate=Dpa*100/Poppa
format Rate %5.0f
keep P ageRange Rate
reshape wide Rate, i(ageRange) j(P)
graph twoway (connected Rate* ageRange,sort name(HDdes1,replace) ///
        title("Hemodialysis" "a",position(11)) ///
        ytitle("Rate per 100 new ESRD diagnoses", margin(l=3 r=3)) ///
        xtitle("Age at Registration") ///
```

```
      ylabel(0(10)30) xlabel(20(10)85) ytick(5(5)30) msymbol(O D T S Oh Dh
Th Sh) ///
      clwidth(medthick medthick medthick medthick medthick medthick
medthick medthick medthick) ///
      legend(label(1 "2008") label(2 "2009") label(3 "2010") label(4
"2011") label(5 "2012") label(6 "2013")  ///
            rows(4) colfirst subtitle("Calendar Year")))

*2)GRAPHS RATE VS AGE BY COHORT
use `hd',clear
egen Dca=sum(D), by(ageRange CRange)
egen Popca=sum(pop), by(ageRange CRange)
contract ageRange CRange Dca Popca
drop _freq
gen Rate=Dca*100/Popca
format Rate %5.0f
keep CRange ageRange Rate
reshape wide Rate, i(ageRange) j(CRange)
graph twoway (connected Rate* ageRange,sort name(HDdes2,replace) ///
      title(" " "b",position(11)) ///
      ytitle("Rate per 100 new ESRD diagnoses",margin(l=2 r=2)) xtitle("Age
at Registration",margin(t=1 b=1)) ///
      ylabel(0(10)30) xlabel(20(10)85) ytick(5(5)30) ///
      msymbol(O D T S + Oh Dh Th Sh X o d t s p smplus)  ///
      clwidth(medthick medthick medthick medthick medthick medthick
medthick medthick medthick ///
      medthick medthick medthick medthick medthick medthick medthick) ///
      legend(label(1 "1916-20") label(2 "1921-25") label(3 "1926-30")
label(4 "1931-35") ///
            label(5 "1936-40") label(6 "1941-45") label(7 "1946-50")
label(8 "1951-55") ///
            label(9 "1956-60") label(10 "1961-65") label(11 "1966-70")
label(12 "1971-75") ///
            label(13 "1976-80") label(14 "1981-85") label(15 "1986-90")
label(16 "1991-93") ///
      rows(4) colfirst subtitle("Birth Year") symxsize(6)keygap(0)))

*3)GRAPHS RATE VS PERIOD BY AGE
use `hd',clear
egen Dpa=sum(D), by(P ageRange)
egen Poppa=sum(pop), by(P ageRange)
contract P ageRange Dpa Poppa
drop _freq
gen Rate=Dpa*100/Poppa
format Rate %5.0f
keep P ageRange Rate
reshape wide Rate, i(P) j(ageRange)
graph twoway (connected Rate* P,sort name(HDdes3,replace) title(" "
"c",position(11)) ///
      ytitle("Rate per 100 new ESRD diagnoses", margin(l=3 r=5))
xtitle("Calendar Year",margin(t=1 b=1)) ///
      ylabel(0(10)30) xlabel(2008(1)2013) ytick(5(5)30) ///
      msymbol(O D T S + Oh Dh Th Sh X o d t s) ///
      clwidth(medthick medthick medthick medthick medthick medthick
medthick ///
            medthick medthick medthick medthick medthick medthick
medthick) ///
      legend(label(1 "20-24") label(2 "25-29") label(3 "30-34") label(4
"35-39") label(5 "40-44") ///
            label(6 "44-49") label(7 "50-54") label(8 "55-59") label(9
"60-64") label(10 "65-69") ///
            label(11 "70-74") label(12 "75-79") label(13 "80-84") label(14
"85-89") rows(4) colfirst ///
            subtitle("Age at Registration") symxsize(9)))

*4)GRAPHS RATE VS COHORT BY AGE
use `hd',clear
egen Dca=sum(D), by(CRange ageRange)
```

```
egen Popca=sum(pop), by(CRange ageRange)
contract CRange ageRange Dca Popca
drop _freq
gen Rate=Dca*100/Popca
format Rate %5.0f
keep CRange ageRange Rate
replace Rate=. if Rate==0
reshape wide Rate, i(CRange) j(ageRange)
graph twoway (connected Rate* CRange,sort name(HDdes4,replace) title(" "
"d",position(11)) ///
     ytitle("Rate per 100 new ESRD diagnoses",margin(l=2 r=2))
xtitle("Birth Year",margin(t=1 b=1)) ///
     ylabel(0(10)30) xlabel(1915(10)1990) ytick(5(5)30) ///
     msymbol(O D T S + Oh Dh Th Sh X o d t s) ///
     clwidth(medthick medthick medthick medthick medthick medthick
medthick ///
          medthick medthick medthick medthick medthick medthick
medthick) ///
     legend(label(1 "20-24") label(2 "25-29") label(3 "30-34") label(4
"35-39") label(5 "40-44") ///
          label(6 "44-49") label(7 "50-54") label(8 "55-59") label(9
"60-64") label(10 "65-69") ///
          label(11 "70-74") label(12 "75-79") label(13 "80-84") label(14
"85-89") rows(4) colfirst ///
          subtitle("Age at Registration") symxsize(8) keygap(0)))

*COMBINE 4 GRAPHS AND SAVE
graph combine HDdes1 HDdes2 HDdes3 HDdes4,row(2) col(2) ycommon imargin(b=1
t=1) iscale(.4) ///
graphregion(margin(l=0 r=3)) ysize(11) xsize(8)
```

Appendix 8 Test for unit root, serial correlations, white noise in the error terms, and AIC before differencing

Test	Model		
	PD	HD	KT
Dicky-Fuller *	0.804	0.244	0.824
Durbin-Watson d-statistic**	0.057	0.110	0.061
Durbin's alternative**	<0.001	<0.001	<0.001
Breusch-Godfrey LM**	<0.001	<0.001	<0.001
Portmanteau (Q) statistic***	<0.001	<0.001	<0.001
AIC	1388.328	1345.492	1008.531

*H_0=No presence of a unit root

**H_0=no serial correlation

***H_0=No presence of a white noise

Appendix 9 Test for unit root, serial correlations, white noise in the error terms, and AIC after first differencing

Test	Model		
	PD	HD	KT
Dicky-Fuller *	<0.001	<0.001	<0.001

Test	Model		
	PD	HD	KT
Durbin-Watson d-statistic	N/A	N/A	N/A
Durbin's alternative**	<0.001	0.266	<0.001
Breusch-Godfrey LM**	<0.001	0.263	<0.001
Portmanteau (Q) statistic***	0.999	1.000	0.982
AIC	1163.646	1169.222	1171.975

*H_0=No presence of a unit root

**H_0=no serial correlation

***H_0=No presence of a white noise

Appendix 10   Results from fitting ARIMA models

PD

```
------------------------------------------------------------------------------
             |                 OIM
        D.pd |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
pd           |
       _cons |   167.4371   48.15384     3.48   0.001     73.05733    261.8169
-------------+----------------------------------------------------------------
ARMA         |
          ma |
         L1. |  -.4828109   .1099371    -4.39   0.000    -.6982837   -.2673381
-------------+----------------------------------------------------------------
      /sigma |    773.312   64.89882    11.92   0.000     646.1126    900.5114
------------------------------------------------------------------------------
```

HD

```
------------------------------------------------------------------------------
             |                 OIM
        D.hd |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
hd           |
       _cons |   146.3224   93.61479     1.56   0.118    -37.15922     329.804
-------------+----------------------------------------------------------------
ARMA         |
          ar |
         L1. |  -.1310408   .1168015    -1.12   0.262    -.3599675    .0978858
-------------+----------------------------------------------------------------
      /sigma |   890.7188   74.74747    11.92   0.000     744.2164    1037.221
------------------------------------------------------------------------------
```

KT

```
------------------------------------------------------------------------------
             |                 OIM
        D.kt |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
kt           |
       _cons |   11.79115   1.514517     7.79   0.000     8.822747    14.75955
-------------+----------------------------------------------------------------
ARMA         |
          ma |
         L1. |  -.7633019   .1043864    -7.31   0.000    -.9678955   -.5587082
-------------+----------------------------------------------------------------
      /sigma |   50.95865   4.278565    11.91   0.000     42.57282    59.34449
```

Appendix 11 Cumulative periodograms of the residuals

PD

HD

KT