

POLICY NETWORKS IN HEALTHCARE POLICY: A CASE STUDY ON
THE NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE AND THE
APPRAISAL FOR BETA-INTERFERON TREATMENT FOR PATIENTS
WITH MULTIPLE SCLEROSIS

by

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ABSTRACT

The focus of this thesis was the study of the policy decision-making process in the healthcare services network in order to understand the behaviour of key actors involved in the UK health network. Additionally, the study examined about the use of the “policy networks” approach, and the application of the Dialectical Relationships Model in the healthcare service networks. A number of factors, internal and external to the network, are interacting and determine policy decisions while in turn influence the process and its outcome.

The research demonstrated that there were formal and non-formal rules within the network and actors interacted according to what was agreed. Actors worked and cooperated in order to produce a favourable outcome, and interacted accordingly in different situations. Another key research finding was shown to be the importance of individuals within organizations and within networks. The network was generally influenced by several factors: past conflicts, asymmetry in resources and power, the socio-economic and political context within which the network operated, governmental intervention were some; they were influencing the operation of the network and the role of actors and of individuals within actors. The application of the Dialectical Model had shown that the Model provided a general framework for studying policy making process.

Dedicated to my father Ioannis

my mother Efstathia,

and my dearest friend Tanja Kamin

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LIST OF ABBREVIATIONS

ABPI	Association of the British Pharmaceutical Industry
AC	Appraisal Committee
ACD	Appraisal Committee Determination
CHI	Committee for Health Improvement
DoH	Department of Health
DSU	Decision Support Unit
EOHCST	European Observatory of Health Care Systems in Transition
FAD	Final Appraisal Determination
HA	Health Authorities
HTA	Health Technology Assessment
MS	Multiple Sclerosis
MTA	Multiple Technology Appraisal
NCCHTA	National Collaborating Centre for Health Technology Assessment
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence ¹
PAD	Provisional Appraisal Determination
PCG	Primary Care Groups
PCO	Primary Care Organizations
PCT	Primary Care Trusts
RD	Research and Development
RRMS	Relapsing –Remitting Multiple Sclerosis
	Scottish Intercollegiate Network Health Technology Board for
SIGN	Scotland

SPMS	Secondary Progressive Multiple Sclerosis
STA	Single Technology Appraisal
WA	Welsh Assembly
WHO	World Health Organization

¹ At the period of study it was still National Institute for Clinical Excellence (NICE)

CHAPTER 1

INTRODUCTION

1.1 Introduction to the thesis

This thesis aimed to examine the policy decision-making process in healthcare services. It explored how healthcare policies are formulated and, more particularly, policies for the evaluation and the funding of different and new treatments with a case study on the funding of beta interferon treatment for patients with Multiple Sclerosis (MS).

The study used a relatively new approach that of policy networks. The health policy process has been discussed in terms of policy networks. Ferlie, Fitzgerald, McGivern, *et al.* (2011:307) discussed how there has been a shift from hierarchies to networks as modes for organising public services and public policy networks based governance.

1.2 The cost of healthcare

Policy and decision making in healthcare services have been very “sensitive” issues for the western, developed societies because of the importance and value of “health” and wellbeing of/for the people. One of the problems for governments, in these developed societies (and elsewhere), has been that “health” is costly and, as the cost of providing healthcare services has grown, this has forced cuts and reductions on the health Budget. There have been several concerns where costs had to be reduced but the provided health care services should not be cut down. Generally, it has been difficult for each government to make decisions while trying to manage its limited resources and, in parallel, to meet people’s health needs and achieve a good level of health status (Ferlie, Fitzgerald, McGivern, *et al.*, 2010; Rawlings and Culyer,

2004). Furthermore, each government also has had to adjust to the existing political-social-economic environment (setting) meaning the need for change could be argued to be strong not only in health services but in other Government departments, such as education and the economy.

As Pattison (prologue to Iles and Sutherland, 2001:7) argued “*the need for change to the health services is now widely recognised by public, by professions and by the government. The NHS Plan, issued last year, requires a fundamental change in thinking, practice and delivery of health care over the next decade*”.

The recognition of the need for change in health services, by the involved parties of “*the public, professions and the government*”, has been a first step. Questions on how and what kind of change should happen would be a next, second step that links to the logic of this thesis and the current approach of policy networks. This would assume that the public, the professions and the government mentioned above by Pattison (prologue in Iles and Sutherland, 2001:7) are the elements forming a type of network. A network has been broadly defined (Borzel 1997:1) as “*a set of relatively stable relationships ...linking a variety of actors who share common interests acknowledging that co-operation is the best way to achieve common goals*”.

1.3 The creation of NICE in the UK

In this thesis, the focus has been on the conditions and the criteria under which actors make decisions in health services with the resources allocated and the funding available in order to offer the best choices for citizens and for the state (Pearson and Rawlings, 2005).

The way that changes in health services have taken place arguably changes accordingly to the subject i.e. hospital care or mental health. In general, on the one hand, there have been

governments wanting to tackle inequalities in health and access to health care. On the other hand, there have been health professionals across the world wanting to give their patients the best possible care and learn or choose new treatments somehow from amongst all the available knowledge and information (Dean, 1999; Rawlings, 1999; Rawlins and Culyer, 2004; Maynard Bloor and Freemantle, 2004; Iles and Sutherland, 2001). In addition, patient organisations have been pressuring governments to become more involved since they have more knowledge, data and communication with other patients/networkers worldwide (Brown, Murray, Fisk *et al.*, 1996; Grobler *et al.*, 1996; Cardy, 1997; Hawkes, 2009).

Some of the largest issues have involved pharmaceuticals and prescribing costs, the variety of new treatments and technologies and how they can be used best (Birch and Gafni, 2003). The need for clinical evaluation and the setting of national guidance and standards have been discussed worldwide (Bloor and Maynard, 1999; Bloor *et al.*, 1995; Dalziel, 2000; Brown, Murray, Fisk *et al.*, 1996). Countries, such as Canada and Australia, have taken a series of actions and, in some cases; they have established organizations to promote clinical effectiveness.

In the UK, the problems of the high cost for healthcare services and inequalities such as postcode prescribing (Rawlings, 1999) led to the preparation of economic and clinical excellence reports and the setting up of a whole new network or sub-network (a smaller network within the one already existing, constituted by various public and private health organisations, institutions, the Department of Health, and others). The National Institute for Clinical Excellence (NICE) was established in 1999 to provide healthcare professionals in England and Wales with advice about securing the highest attainable standards of care for National Health Service patients, to promote the effective use of available resources in the health service in England and Wales and to help health professionals in the NHS give their

patients the best possible healthcare within the resources available (Rawlins,1999:1079). The organisations in Canada and Australia, similar to NICE, that were working on clinical evaluation of new treatments have contributed to the establishment of NICE and have influenced the Institute's profile, along with other authorities working on their own resources and on their own framework, together with the general request for societal changes (Birch and Gafni, 2003).

1.4 Analysing NICE: a policy network perspective

NICE's work has had an impact on health services and health policies (Maynard, Bloor and Freemantle, 2004). Pearson and Rawlings (2005:2618) argued that NICE was established in response to a big policy challenge arising in Britain and elsewhere. They discussed the *«interplay among quality of care, technological innovation, and cost control»* as those were the variables creating this policy challenge and the founding of NICE.

NICE could not work alone and so a number of organisations and other institutions were working around NICE on the appraisal of new technologies and treatments. In this thesis, the focus has been on the NICE Appraisal Committee (NICE AC) and its stakeholder groups which it is argued form a network in the way in which a network is defined in this thesis: a variety of actors who are linked to each other; they are interdependent and exchange resources and data; they share common interests.

Therefore, the network perspective has been considered to be applicable to NICE because NICE is thought to have the characteristics of a network, again assuming that a broad network definition includes cooperation and co-working between different actors and the exchange of information and data between different groups linking and promoting their own interests

(Kenis and Schneider, 1991:41-42). Details on NICE are discussed analytically in Chapter 2 but, with reference to the aims of this thesis, NICE as a network is discussed below.

NICE has been considered as a network, where a number of actors (e.g. politicians, health professionals, manufacturers, scientists and academics) were trying to deal with various issues such as appraising new available treatments and health technologies with regard to clinical and cost effectiveness data. The particular interest of this thesis was in the role and performance of the range of actors (including public, private and voluntary organisations and individuals) and their influence on the policy outcome.

Moreover, NICE was a response to the political and socio-economic context that was introducing new data and was demanding that more parameters to taken into consideration, such as cost effectiveness (Rivett 1998; Rawlings, 1999; Ham 1999, 2004; Raftery, 2001). Also, it could be argued that another network created NICE -the one existing before the establishment of NICE in the UK, which has been developed or updated in response to the interaction between actors and the policy challenges that formed the NICE network. Furthermore, the relationship between the networks existing prior to NICE and other networks in the UK or elsewhere, such as Canada, has changed and this change also had an impact on the new network formed and created by NICE (Birch and Gafni, 2003).

These “networks” have been formed because all the involved parts (participants/“actors”) were depending on each other due to data and information exchange and so they created similarly, weak or strong, relationships between them. Nevertheless, the requirements of the broader socio-economic and political environment have transformed and enriched the existed networks, whilst the exchange of data between actors has become more complex (Ferlie, Fitzgerald, McGivern, *et al.*, 2011, 2013; Williamson, 2008).

This thesis studied the network formed around NICE and how the network participants linked to each other. Further, it sought to examine the operation of that network; how the exchange of data was taking place and how the networkers were working in order to promote their own interest (Pearson and Rawlins, 2005) i.e. an outcome in terms of produced policies such as the funding of a particular treatment.

1.5 Rationale: why this research was needed

The analysis of policy has been a way of understanding why some policies fail whilst others succeed, and, in general, it has happened in order to improve the processes and to achieve better policies (Walt and Gilson, 1994; Giddens, 1984; Turner 1986; Ferlie, Fitzgerald, McGivern, *et al.*, 2011, 2013). The modern, western societies were fighting not only for the better allocation of limited resources but also were in a position to pursue quality in health services and elsewhere. There were data regarding technology, scientific information and expertise that a government should manage and apply at every possible level. It could be said that to the plethora of questions there was a corresponding plethora of answers. So this thesis' rationale linked to the analysis of policy making in health services and especially the policies on pharmaceuticals. The understanding of the policy process would provide an insight into the role of the actors and the improvement of this process assuming that the obtained information would bring further changes.

This thesis sought to examine the setting of the network around NICE, for evaluating clinical excellence and how this has been developing, and its operation. In broad terms, the focus aimed to be on how actors interacted with each other, and how they might have acted in promoting their own interests. Whether they were “seeing” beyond their own good or whether

they were, occasionally, moving back from their initial goals for others' welfare and how this influenced the final policy outcome.

Serious issues emerged and a series of assumptions were made in studying and analysing policy-making regarding humans, institutions, organisations and structures (Ferlie, Fitzgerald, McGivern, *et al.*, 2013; Pearson and Rawlins, 2005; Lamshal, 2012; Walt and Gilson, 1994). Moreover, it could be argued that there was a plethora of problems and discussions, and of doubts and dilemmas, regarding the choices made by actors between the different options within the healthcare services network and elsewhere, and about the motivation behind every choice that actors made and in respect of the network's operation. The answers were not easy to find and often there were parties or people held responsible for the problems such as politicians, health professionals and scientists but the findings did not constitute a theory that could be applied and provide some kind of solution or right answer regarding the way that health policy should be made.

1.6 Research aims

The research ran an analysis of the processes in terms of networks and actors and argued that a specific examination of the process questioned the role of the networkers and their motive behind their decisions or their choices. This questioning meant examining the decisions made and their impact on citizens through the provided services.

The NICE network was explored by examining the roles of the actors and their goals so as to answer the following questions:

- How did the actors' resources influence the outcome?
- Did the professional and personal status of the networkers influence their behaviour?
- Did the networks serve collective or personal interests of the networkers?

- How did health policies (outcomes) emerge?

1.7 Structure of the thesis

This introduction provides an overview of the aims and structure of the thesis.

The second chapter initially discusses NICE and its establishment in terms of networks. It shows how NICE could be linked to the policy network and how it influenced the healthcare policy making process with reference to the beta-interferon appraisal case study.

The third chapter explores policy networks in terms of which variables are used for formulating policy and examines the roles of actors within them. The chapter also reviews the literature on “policy networks” and it presents the Dialectical Relationships Model on “policy networks” and the two cases studies where the Model was applied.

Chapter 4 summarizes on the research questions, gives a brief introduction to qualitative research methods and presents the methodology in detail. It also examines the data collection process and the data analysis methods.

Chapter 5 presents the research findings collected from a series of in-depth interviews and document analysis and the results of the study. The findings are presented in themes and discussed in terms of health policy networks and using the case study as a means to explore the concept of the policy network approach and of the Dialectical Model.

The last part of the thesis concludes on the research findings in terms of policy networks as a tool for policy analysis. Finally, it discusses on the applicability and usability of the Dialectical Model in healthcare policy.

The thesis closes with four main issues/findings. The first one is that research questions made during the study regarding the network’s operation are verified.

The second finding of the thesis is that it seems to be very difficult or may be impossible-to develop a new policy-making process (Giddens, 1984, cited in Lamshal, 2012).

The third finding of the thesis refers to the significance that personal and professional characteristics have for actors and, hence, for the network's operation.

Finally, with regard to the application of the Dialectical Model, it is shown that the Model indeed provides a general framework for studying policy making process.

CHAPTER 2

REVIEW OF THE NICE APPRAISAL PROCESS

2.1 Introduction

This chapter discusses the policy network concept as a tool for policy analysis with reference to the National Institute for Clinical Excellence (NICE), as an Institution that contributes to creating policy and as a network member. This discussion aims to explain further and to support the rationale for the thesis in terms of studying the healthcare policy making process and in applying the policy network concept.

The chapter describes the founding of NICE as an important governmental decision and it explains why it is considered as part of a network, whilst explaining why the policy networks approach is applicable. It starts with a discussion regarding policy analysis in healthcare (Walt and Gilson, 1994) and draws on the analysis of the appraisal process in terms of networks which create policies. Further, it is argued that the network revolving around the NICE Appraisal Committee (NICE AC) influences the development and implementation of health policy while focusing on the question of how networks behave and how policies emerge, and what kind of interdependencies are developing between actors (Walt and Gilson, 1994:354). The chapter also reviews the beta interferon appraisal and presents a short of timeline of the actors' actions and interactions between them during the appraisal. This appraisal review aims to link the research to the case study and the concept of policy networks. It should be noted that the research was completed in 2005 and, therefore, some web pages have changed such that it is not possible to give an exact date or address for some web references.

2.2. The New Labour and the NHS

The New Labour government, elected in 1997, developed its own policies aimed at the modernization of the National Health Service (NHS). Priorities changed and the White Paper regarding the NHS requested a refocusing of health services onto a public health agenda, with an aim to reduce ill health and health inequalities for the whole population. It acknowledged that the NHS alone could not achieve this agenda; thus the Paper put considerable emphasis on inter-agency collaboration and joint working. The duty to build this partnership was placed on key stakeholders (EOHCST, 1999; Dalziel, 2000:703).

The UK government was shifting its focus away from efficiency towards integrated care for patients, as a reaction against the fragmentation of previous “market” policy and from a concern to promote continuity of care and collaboration between different agencies and staff. The evolution of health policy in the 1990s indicated the influence of learning in the policy process (Ham, 2004: 29). The state intervention led to re-examination of the nature of the relationship between the health service and society and the purposes served by health services as being additional to the role of the medical profession (Ham, 2004: 29). Furthermore, state involvement in the provision of health services in the United Kingdom was focusing on the importance of negotiation and bargaining in the policy community while seeking to understand and explain the detailed process of making health policy (Ham, 2004:29).

Many new central bodies and regulatory authorities were established with the rationale for some being the improvement of the quality of care. One such mechanism was NICE; its establishment was intended to reduce variations in the performance of the service by setting national service frameworks and reviewing the cost-effectiveness of healthcare technologies (EOHCST, 1999:8; Ham, 1999; 2004; Rivett, 1998). The concept of clinical freedom posed

peculiar difficulties for policy-makers seeking to change patterns of resource allocation, and raised questions about the power structure of the NHS (Ham, 2004:29).

2.3 The National Institute for Clinical Excellence (NICE)

In Britain and in every health care system in the world, people were working to find solutions that will provide the best possible treatment for every patient. Governments had a responsibility to look at health spending to see whether money was being spent effectively and that the maximum benefit for patients was being achieved (Lovatt, 1996: 180). The arguments around the increase in pharmaceutical expenditure and the cost-effective use of resources had led countries such as Australia to request the pharmaceutical industry prepare and submit economic analyses/evaluations, in an attempt to prove not only the clinical but also the cost effectiveness of their products (NHMRC, 1998).

In the late 1980s, pharmacoeconomic studies were increasingly being required as the market response had grown and companies were required to commission cost-effectiveness or cost-benefit analyses of their products (Ham 2004:29). Yet, in most countries, this responsibility was placed on the pharmaceutical companies and not the government.

In response to the need for control over pharmaceutical expenditure and cost-effectiveness, the 1997 White Paper on NHS reorganisation announced the creation of a National Institute of Clinical Excellence (NICE) with responsibility amongst other things for the development of clinical guidelines for the NHS in England and Wales (Hutton and Maynard, 2000:89).

NICE was committed to ensure that the deliberations, conclusions and reasons for its advice and guidance were as transparent as possible (NHS Plan, 2000) and it has set clear national standards to help improve the quality and consistency of NHS services throughout England and Wales. These standards formed an important part of improving the overall health of the

population and were intended to help to tackle inequalities in health and access to care (<http://www.nice.org.uk> [texts accessed in 2000]).

The UK government believed that high quality healthcare services should be available for all. Improving the quality and consistency of health services was an important part of improving everybody's health and of providing a genuinely National Health Service that would provide dependable, high standards of treatment everywhere. The development of national guidance, based on reliable evidence, the experience of professionals and managers and the values and wishes of patients, would be an essential part of achieving the targets set by the government for providing high quality healthcare services (<http://www.nice.org.uk>. [texts accessed in 2000]).

Also, whilst all health professionals across the world wanted to give their patients the best possible care, they were facing two particular difficulties: firstly, the pace of scientific and clinical discovery had become so fast that it was impossible for individual health professionals to remain at the forefront of knowledge across the wide range of conditions with which they had to deal; secondly, the demand for health care – partly due to past successes, partly because of the emergence of effective new technologies and partly because of the continuing use of less effective technologies – had exceeded the available financial and human resources (<http://www.nice.org.uk>. [texts accessed in 2000]).

When it was established the Institute was to provide guidance to the NHS on the use of selected new and established health technologies and to assess evidence of all the clinical benefits of an intervention in the broadest sense. In cases where an intervention had already been made for a condition, the Institute estimated the net impact on both costs and benefits of the new intervention (<http://www.nice.org.uk/guidance>[texts accessed in 2000]). Working with the NHS, the Institute completed systematic appraisals of health interventions in support

of everyone in the NHS, including doctors, nurses, and in general those who made the complex decisions about the treatment of patients. The resources available to the Institute arose from a combination of funding from the Department of Health (DoH) and the Welsh Assembly, which were the Institute's only sources of income (<http://www.nice.org.uk/resources>[texts accessed in 2000]).

NICE was generally welcomed on its inauguration. Previously, a lack of capacity at national level to appraise healthcare interventions before, or indeed after, their widespread diffusion had several adverse consequences: no guidance was available when important new drugs were first marketed, local policies varied and unproved interventions entered routine use. NICE aimed to fill this gap, giving guidance on interventions of uncertain value and providing clinical guidelines and clinical audit packages (Dent and Sadler, 2002:842).

2.4 Status/Accountability

The Institute was accountable through its chair to the Secretary of State for Health who was accountable to the Parliament and the Welsh Assembly for the financial resources, delivery of work programme and the guidance produced for the NHS. Rawlins (1999) wrote that NICE was also accountable to the Government for the way it handled its resources, delivered its work programme, provided guidance to the NHS and discussed its activities with the Institute's Partners' Council. Members of the Council were appointed by the Secretary of State for Health and were drawn from „key stakeholders“, including patients, the health professions, NHS interests and the healthcare industry(Rawlins, 1999:1081).

2.5 Functions of the Institute

The methods for developing the different guidance were underpinned by the key NICE principles of basic recommendations on the best available evidence and involvement of all stakeholders in a transparent and collaborative manner (NICE, 2004a:1-1). The Institute would issue the developed guidance, as shown in Figure 2.1, through clinical guidelines, technology appraisals and interventional work programmes.

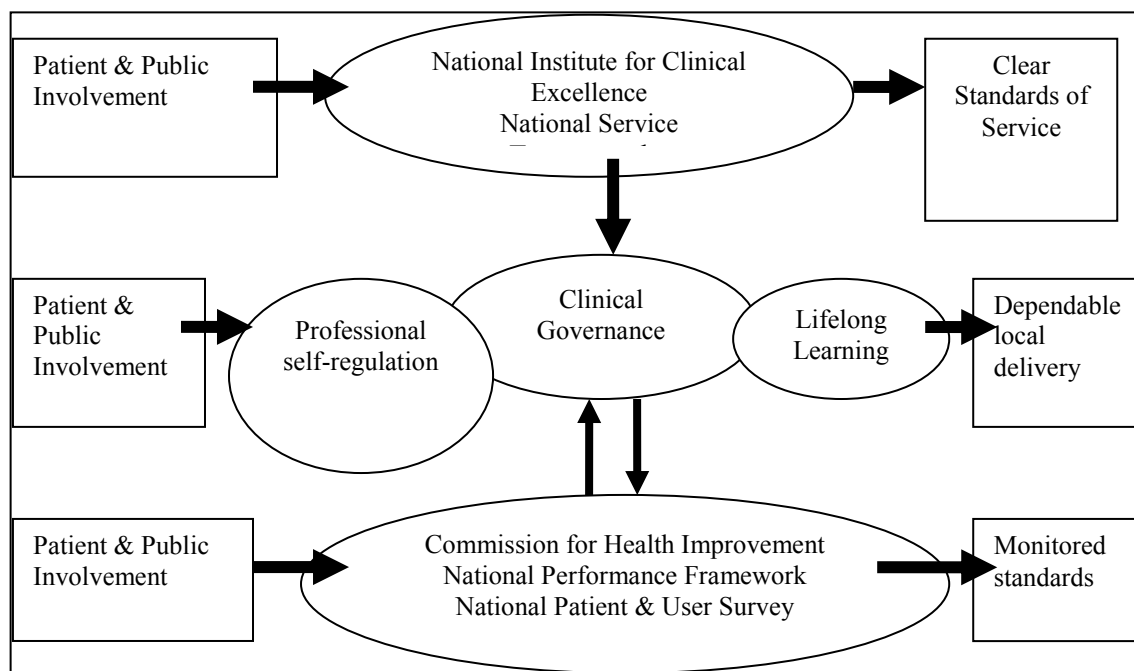


Figure 2.1 The NICE Appraisal Process. Source: www.nice.org.uk/nice/nic_q04.htm

The Institute would also try to develop and disseminate robust and authoritative clinical guidelines to help health professionals give their patients the best care the service could afford and, where appropriate, to produce guidelines for patients and their carers. The clinical audit process involved a quality improvement process that aimed to improve patient care and outcomes through a systematic review of care provided against explicit criteria and the implementation of change (NICE, 2004:23).

2.6 Structure of the Institute

It is important to review the structure of NICE and of the NICE AC since these structures link the research and the case study to the policy networks concept. It is argued within the thesis that the way that NICE was founded and the rationale behind it emphasised the existence of actors, their interdependence and their interrelationships and supported the application of the network concept in policy analysis.

NICE had been established as a special Health Authority, with a Board consisting of a chairman, seven non-executive members and four executives. The backgrounds of the non-executives were intended to reflect both the scope and geographical range of the Institute's activities, in England and Wales. The executives included a chief executive, a clinical Director, a director of communications and a part-time finance Director (<http://www.nice.org.uk>[texts accessed in 2000]). The introduction of limitations and rules on the background of the people working with or for NICE might provide the evidence for the need for changes and for a different decision or policy making process such that not only the powerful groups (e.g. clinicians) would be heard but also others, such as patient groups. This expressed need for change stemmed from various motives (Iles and Sutherland, 2001). The fact that there is more information available, more knowledge and more expertise makes people/patients fight for the best healthcare services that they can have by rights and for participation in the decision/policy making process. Their fighting leads to societal changes and the possibility of some kind of power redistribution i.e. the manufacturers of beta interferon supported MS patient groups, which permitted them to communicate their disappointment and organise their reaction to the NICE's guidance on Beta interferon treatment.

"The MS Society has handed 120,000 signatures to the government in protest of NICE's decision in beta interferon drug" (News report.)

“Alliances between actors strengthen one side against the other” (politician respondent).

More analytically, the structure of the Institute involved three sectors/bodies:

- **The NICE Board:** the Board reflected a range of expertise, including the clinical professions, patients and user groups, NHS managers and research bodies.
- **NICE Partners’ Council:** the Council was formed of representatives of key stakeholder groups. It reviewed NICE’s progress annually and reported and contributed to the development of the work programme commissioned by the DoH and the Welsh Office.
- **NICE Secretariat:** consisted of the staff that provided technical and administrative support.

The structure of NICE seemed inclusive rather than exclusive. It attempted to maintain independence from politicians who might prefer NICE to address new and politically sensitive issues.

- **Stakeholder Groups:**

To support its work, NICE has developed a network of relationships and, according to its framework document, the following levels of consultation occur:

- At a local level, NICE would work locally with NHS Trusts, other service providers and with patient representatives to ensure the dissemination of guidance was effective. It worked with Health Authorities, Primary Care Groups (Local Health Groups in Wales) and other service commissioners (<http://www.nice.org.uk> [texts accessed in 2000]).
- At a regional level, NICE was receiving feedback from Regional Health Authorities’ offices for performance monitoring, to address gaps in guidance and to support local implementation.
- At a national level, NICE had developed a work programme with the Department of Health and was working alongside Royal Colleges, professional associations, academic

units and health care industries, all of which have the specialist expertise required. This was to ensure that the information from the Commission for Health Improvement's systematic service reviews would feed into further clinical guidance or audit methodologies (<http://www.nice.org.uk> [texts accessed in 2000]).

The creation of the Institute occurred at a time of real and significant change in the approach to clinical practice in developed healthcare systems. It could be argued that the structure of the Institute and its function also reflected the need for more voices to be heard and to become involved in the healthcare policy process.

This change and the development of NICE was characterised by a shift towards the use of research based evidence as a means of securing improved outcomes and consistency of approach. NICE was established to help the NHS get value for money (Rawlins, 1999:1082) but it seemed to have been driven primarily by a desire to make real improvements to the quality of care. This development was also the product of a need to make the best use of the available resources in ways that could be seen to be fair and reasonable (<http://www.nice.org.uk> [texts accessed in 2000]).

2.7 The Appraisal Process

This thesis focuses on the appraisal process since the appraisal of new technologies was seen as NICE's main function (NHS Plan 2000; Rawlins, 1999; Horton, 1999) and therefore the case study involves a treatment appraised by NICE AC. The next section reviews in detail the different stages of the appraisal process to provide a view of how NICE AC and the particular network for the beta-interferon appraisal worked; the discussion refers to the structure and the context of the network, the relationships between actors, their resources and objectives.

2.8 How NICE worked

The DoH, in consultation with the Welsh Assembly, identified possible topics for referral to NICE and proposals were then considered in relation to the government's health priorities, their intrinsic significance to NHS patient services and the potential for NICE to „add value“ (HSC, 1999/176).

The main goal of an appraisal carried out by the Institute was to evaluate the clinical benefits and costs of interventions and consult its stakeholders over this methodology and over any future changes. It meant also that the Institute would assess the evidence of all the clinical benefits of an intervention in the broadest sense and develop a detailed methodology for its appraisals, consistent with guidance given by the Department of Health.

2.9 The stages of the NICE Appraisal Process

The steps taken at each stage in the appraisal process are described in Figure 2.2. The Institute followed a particular process for its appraisals, meaning that it was interacting and interrelating with the other actors, giving interested parties the opportunity to submit evidence to exchange data, to comment on draft conclusions and to appeal to a panel. This panel was independent of those involved in the original judgement and it sat in cases where the Institute was alleged to have failed to act fairly, exceeded its powers or acted perversely in the light of the evidence submitted (<http://www.nice.org.uk> [texts accessed in 2000]).

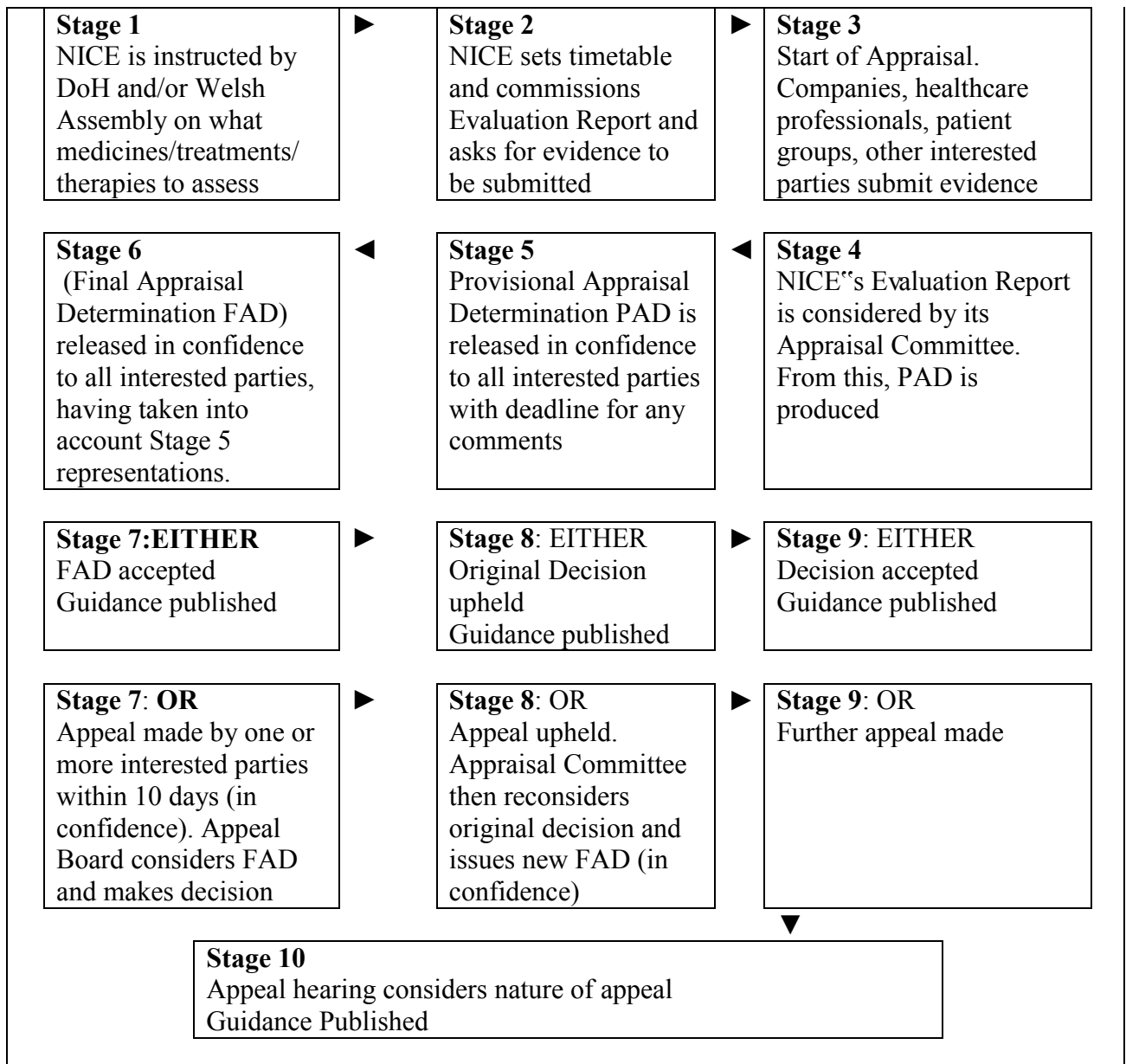


Figure 2.2 How NICE will work (Source: ABPI www.abpi.org.uk)

2.10 Review of NICE

The establishment of NICE was generally approved since NICE had all the prospects of being an important and valuable agent for change in the NHS (Horton, 1999: 1029).

Until that time the incapacity, at national level, for appraising healthcare interventions, either prior to or following extensive circulation, was creating a number of problems. These

included a lack of regulation rules for newly imported drugs, dissimilarity in local policies and routine use of non-proven interventions (Dent and Sadler, 2002: 842).

Nevertheless, the introduction of NICE was subject to criticism. Horton (1999:1028) characterised NICE as one of the most important developments in securing the quality of the NHS, since the launch of the Research and Development Strategy in April 1991. However, Horton also said that most of the major steps in NHS progress were not the result of wise planning and noted the coincidence that NICE had started its work after the Kennedy¹enquiry. In addition, it was said that an important step for NICE would have been gaining the early confidence of the health professions as well as the public and Parliament (Rawlins, 1999 quoted in Warden, 1999:416).

On the one hand, there was optimism about what NICE would do, and on the other there were concerns regarding who NICE would work with (Smith 2000; Freemantle 2002; 2004; Maynard and Sheldon, 2002; Kmietowicz 2000; Burke, 2002).

The first appraisal on Relenza treatment for flu was negative and it fired the debate on NICE. The most severe critique, however, seemed to have begun during the beta interferon appraisal. There were discussions on the role of NICE (Dillon, 1999, Horton, 1999, Rawlins, 1999) but before any critique, it was necessary to see the Institute in operation and give it some time. Moreover, the publicity and questioning of NICE had climaxed during the appraisal of interferon for MS as will be discussed in later in this chapter and in Chapter 3. During this appraisal period, most criticism of NICE was coming from patients, organisations lobbying for the pharmaceutical industry and the media.

¹An enquiry related to the Bristol scandal. A report published in 2001 of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-1995

“The Institute’s rejection of a second appeal on beta interferon and glatiramer signalled an end to a process which began in August 1999 and attracted an unparalleled amount of criticism of NICE” (<http://www.pharmafile.com/pharmafocus/news/story>, 2002).

The criticism was focusing mostly on those concerns brought up by the introduction of NICE and concerned, amongst others, the introduction of a new form of rationing, the transparency of the appraisal process, consequences for the pharmaceutical industry investments worldwide, implications for the national economy and NICE’s political independence. Parallel to the critique were suggestions on how NICE should be restructured (Freemantle 2002, 2004; Maynard and Sheldon, 2002).

2.10.1 The critique of NICE at the appraisal of beta interferon

The beta-interferon appraisal lasted for more than 2 years and during that time, NICE and the appraisal process were exposed to enormous publicity. Furthermore, it could be argued that the media attacked NICE in a very surprising manner. People have often used very negative language about NICE. It was surprising to hear network members such as pharmaceutical industry representatives or patient organisations’ representatives, expressing their opinions so forcefully i.e. threatening to hold the government responsible for financial consequences and losses (Smith, 2000, ABPI, 1/2002). But this element of actors having bad reactions when their interests are threatened highlights the discussion on the important role of the actors in policy analysis and on the way actors are acting or/and reacting as discussed by researchers such as Walt and Gilson (1994) and Giddens (1984).

Many questions surfaced (Rawlins, 1999; Birch and Gafni, 2003; Maynard, Bloor and Freemantle, 2004; Pearson and Rawlins, 2005) regarding the autonomy of NICE, as an Institute working on clinical excellence and what the role of the state should be. If there are

key-players who are holding most of the resources or reasons for performing technology appraisals, why should the appraisals be completed in that way, or be completed in the first place? NICE was said to rely heavily on unpaid input in the form of non-executive directors and members of its appraisal committee. It was considered to be a large organisation relying on a small office and a large network, centred on electronic communication, and contracting out specific tasks (Raftery, 2001: 1302). Beyond the bad publicity about NICE, there were other pressures for a review of NICE from the pharmaceutical industry and, more particularly, the Association of the British Pharmaceutical Industry (ABPI) as well as patient organisations.

A formal governmental review of NICE took place in 2001, an investigation on NICE by the House of Commons (parliamentary enquiry on NICE) in 2002 and a review of NICE by the World Health Organisation in 2003. Reviews raised concerns but also made suggestions regarding the operation of the Institute.

The review made by World Health Organisation (WHO) (Hill, *et al.*, 2003) stressed the important role of NICE and of the AC in the operation of the technology appraisal process and made a few key recommendations. Among these were the increase of data available because there was limited access to data due to confidentiality issues, so more information available was needed; the exchange of information and interaction between some of the participants; the reduction of unnecessary duplication of effort in the assessment phase; the collection of data from all relevant stakeholders and, most importantly, the including of pharmaceutical industry's membership in the Appraisal Committee.

The recommendations made by the WHO report were also addressed to organisations similar to NICE in other countries "*so as to deal with their difficulties and meet their expectations*" (Hill *et al.*, 2003:4).

Nevertheless NICE had also marked an innovation internationally. Other countries had similar bodies providing advice on the use of new technologies but NICE was the first national body issuing guidance covering all aspects of the health service and not only just new treatments or new technologies. Guidance from NICE applied to the NHS in the same way as guidance from other parts of the DoH; health authorities were required to take into account the guidance but not necessarily to follow it while general practitioners had greater discretion (Raftery, 2001:1300).

2.11 A new role for NICE

NICE has changed since its establishment; it was formed as a Special Health Authority a body funded by the Department of Health—and became a non-Departmental Public Body that would expand so that it would also produce quality standards for the social care sector. NICE's new role was set out in the 2004 White Paper “Choosing health: making healthier choices easier”. The government’s paper set out key principles for helping people make healthier and more informed choices about their health. NICE was supposed to bring together knowledge and guidance on ways of promoting good health and treating ill health.

NICE was working on a series of projects such as clinical guidelines, technology appraisals, public health guidance, medical technologies, and international activities which were having benefits outside of the individual countries ([online] available from: <https://www.nice.org.uk/about/who-we-are>[accessed 1/12/2014]).

NICE, as described and discussed above, has been a dynamic network member, an actor interacting with other actors, forming interdependencies and interrelationships. The way that NICE was set up by the government and the diversity of actors/groups involved to the appraisal process has shown the link between NICE and the policy network concept and the

case study thus proving the rationale for this research.

NICE was changed in 2013 into the National Institute for Health and Care Excellence. It became a Non Departmental Public Body (NDPB) and was placed “on a solid statutory footing” as set out in the Health and Social Care Act 2012. “Its role became to provide guidance and support to providers and commissioners and to help improve outcomes for people using the NHS, public health and social care services. NICE’s aim is to be the principal UK source of evidence to support health, public health and social care practice, commissioning and local decision making, including practical support to help put recommendations into practice. NICE does this by producing recommendations about effective and cost effective practice in a range of forms, together with services to support their implementation” [online] Available from: <https://www.nice.org.uk/about/who-we-are> accessed 01/12/2015]

As an NDPB, they are accountable to the Department of Health, their “sponsor department”, but, as stated by NICE, operationally they “are independent of government” ([online] available from: <https://www.nice.org.uk/about/who-we-are>[accessed 01/12/2014]).

The role of NICE has been reviewed recently (NICE Triennial Review of NICE, 2015) as have the roles of other NDBP. It is worth mentioning some of the comments made regarding the role of NICE and the challenges it faces as a link to the rationale and research questions of this thesis. The report discusses the “difficulties that the health care system is facing, the significant challenges, including demographics, constrained resources, public expectation and new technologies. Furthermore, it notifies the need for NICE to be committed in supporting the NHS, public health and social care, and organisations in the wider public and voluntary sector to respond to the challenges. NICE must make the best use of their resources by setting out the case for investment and disinvestment through their guidance programmes and other

advice. It must work in collaboration with the DoH, NHS England and Public Health England as well as with many other national partners on their plans for a clear and compelling long-term vision for the future of health and care services”. The report’s evaluation has been positive for NICE. The main conclusion of the review was that NICE performs necessary functions and should continue to operate as an executive non-departmental public body. The review report also contains recommendations for the improvement of NICE’s performance, governance and efficiency ([online] available from: <https://www.gov.uk/government/uploads/system/uploads/attachmentanddata/file/447317/NICETriennialReviewReport.pdf>.(accessed 01/12/2015)).

2.12 NICE and the appraisal of Beta Interferon

Beta Interferon treatment for Multiple Sclerosis (MS) had been an issue in the late 1990’s not only for the UK and NICE but also for other countries such as Canada and the USA; it has been widely discussed because of the nature of the MS disease and the lack of alternative treatments. Below, the appraisal of NICE for the beta interferon treatment for patients with Multiple Sclerosis is discussed in a chronological order, from an introduction to beta interferon to the publication of final guidance by NICE. It is being presented in this way, as a timeline, so as to link the case study to the policy networks approach and the earlier discussion on the establishment of NICE within a general framework for changes in the health service (Ham, 1999; Horton, 1999; Iles and Sutherland, 2001) and thus showing there was a network where actions between actors has brought about a new network in the form of NICE. The timeline focuses on a number of issues. One is to show how the/a „pre-NICE” policy network was interacting and how actors operated in promoting their interests. Moreover, it underlines how actors’ continuous interaction led to the structuring of a new network and the

establishment of NICE.

It is interesting to see how the new product beta interferon came into the UK market and how it had been handled by another network (the one before NICE) and until the NICE Final Appraisal Determination (FAD). This background information shows how conflicts of interest led to the formation of the NICE network. The presentation of the timeline provides a picture of how the network has transformed.

2.13 Multiple Sclerosis: information on the disease

Some information on Multiple Sclerosis (MS) is provided to aid understanding of the feelings aroused by it, not only for patients and their families but also for health professionals and the state. A disease without a cure such as MS is more difficult to manage in comparison with others; there is more tension and pressure.

It is an inflammatory disease of the central nervous system (CNS) which affects the CNS myelin. The cause and pathogenesis of MS are unknown, but the most common view is that MS is an autoimmune disease. MS can cause a series of different symptoms and a person's symptoms will depend on which signals are affected (Clegg *et al.*, 2000; Trentham, 1999:1).

MS has debilitating effects accompanied by neurological symptoms of differing severity, which, over many years, can lead to chronic disability (NCCCC, 2004). Some features are vertigo, nystagmus, double vision, pain, incontinence, cerebellar signs, paresthesiae in arms or legs, while less commonly occurring effects include facial palsy, epilepsy, aphasia, euphoria and dementia.

The UK prevalence of MS varies geographically. Surveys conducted in the UK between 1970 and 1996 suggested that MS is more prevalent in the north of the UK than the south. However, some of the differences observed may be attributable to different methodologies

used for diagnosis.

In 1999 in the UK, there were estimated to be 80,000 MS patients with around 60,000 in England and Wales, and approximately twice as many women as men affected. At any one time, it is estimated that around 40% of patients have secondary progressive MS and 45% have relapsing-remitting MS (including benign cases) (Clegg *et al.*, 2000; DEC Report no. 98, 1999:6).

2.13.1 Types of MS

For many years, MS has been classified according to the initial pattern at the onset of the disease (DEC, 1998). There is some overlap between these categories and many people progress through more than one of these:

- **Relapsing-remitting** (exacerbating-remitting) form whereby patients have discrete motor, sensory, cerebellar, or visual attacks that come on over a 1-2 week period and resolve over a 4-8 week period, with or without treatment.
- **Secondary progressive form.** Patients who previously had relapsing remitting disease experience gradually increasing disability with or without discrete relapses.
- **Primary progressive MS.** People with primary progressive MS do not have periods of remissions and relapse. Instead, from the start, they have steadily worsening symptoms and progressive disability. About 10% of people with MS have this form.
- **Benign, or stable MS.** People with benign MS have a few mild attacks and then recover completely. They do not get worse over time or have any permanent disability. A small proportion has this benign type with minimal disability after 10-15 years (DEC 1998:4).
- **Chronic progressive type** characterised by unrelenting advancement of the disease and maximum disability ensuing within months or over several years, often without loss or deterioration of their body functions.

2.13.2 Impact of MS on patients

Very important issues emerge when considering the impact that MS has on patients, their families and on society in general. The disease causes many problems for patients, their families and carers who have to deal with many practical and emotional difficulties. Patients and carers have founded organisations to help people with MS, such as the MS Society. These organisations act as patient representatives and aim to promote patients' interests i.e. to access available treatments (MS Society, 2000; Hughes 1997). The contribution of patients' organisations in general, such as the MS Society in the current case or other smaller local organisations and groups, is very important. They help patients and their families to deal with issues such as receiving new treatments. The MS Society and other patient groups had a significant role in the case of the beta interferon appraisal by NICE AC and that encouraged other patients groups.

2.13.3 Treatments for MS

Until the 1990s, there was no specific therapy for the treatment of MS. The goal of therapy in patients with MS is to prevent or reduce the number of relapses and to prevent or slow the progression of the disease.

Some approaches (sometimes combinations of approaches) to the treatment of MS included prevention of disease progression; treatment of acute exacerbations with steroids to reduce their severity; treatment of symptoms and disability with speech therapy, physiotherapy etc. or treatment of the emotional and social consequences of relapses and disability. Management of the disease consisted also of symptom control, physiotherapy, psychiatric and social support and disability aids (Tappenden *et al.*, 2001:7; DEC Report no 77, 1997).

Beta interferon and glatiramer acetate were the only options available at early 1990's and that

fact was important for the development of their appraisal since they were medicines prescribed with the aim of reducing the frequency and/or severity of relapses and/or slow the course of the disease. They seemed very expensive treatments compared with others but they had greater benefits according to published clinical trials studies (DEC Report no 77, 1997; DEC Report no 98, 1999; Forbes *et al.*, 1999; NYRDTC, 2000; Clegg *et al.*, 2000).

In Table 2.1, the annual costs of some of the treatments are presented.

Table 2.1: Annual cost of MS treatments

	Treatment	Annual Cost per patient
1	Azathioprine	£50 and £120
2	Intravenous immunoglobulin	£1600 and £10,000
5	Cladribine	£5800 and £8800
8	Methotrexate	£18-58
9	Mitoxantrone	£3600
10	Interferon beta-1b (IFNB-1b)	£10,000 and £20,000
11	Interferon beta-1a (IFNB-1a)	£10,000 and £20,000
12	Glatiramer	£10,000

Source: HTA, 2000:29

2.13.4 Beta -Interferon and Glatiramer Reviews

The introduction of interferon beta-1b in the UK was controversial. It was the first occasion when the NHS Executive had issued guidance about purchasing and prescribing due to the delay by NICE in issuing its final guidance. The delay was caused whilst waiting for more clinical data and more economic modeling work to be done (DEC Report no 77, 1997:3; (<http://www.nice.org.uk> [accessed 2000])).

While examining both treatments, it was argued (Clegg *et al.*, 2000:29) that both beta interferon and glatiramer acetate treatment have an effect on relapses, as well as on slowing the progression of disability. Clinical studies have shown that, on average, people with relapsing-remitting and secondary-progressive MS who are treated with beta interferon or glatiramer have fewer relapses than they would have if they had not taken the drug. In general, though, none of the studies was finding significantly better results compared with others treatments (IFNB MS Study Group and the University of Columbia MS/MRI Studying Group, 1993, 1995; Jacobs *et al.*, and the MSRCG, 1996; The OWIMS Study Group, 1999; PRISMS Study Group 1998).

2.14 Interferon treatment in the UK

A debate on the use of interferon-beta appears to have started in the early 1980s with the use of interferon as a multi-treatment product (Toine, 1998). The debate was „transferred“ to the UK with the introduction of interferon and its European licensing in 1995. The news coming from other countries and individual cases about the benefits gained from treatment with interferon beta started a debate between the MS Society, Health and Regional Authorities, patients“ carers groups, neurologists, clinical researchers, nurses, health economists and many others about the licensing and introduction of the treatment in the NHS. Following a controversial debate, interferon was licensed in the UK by early 1996 (Toine, 1998).

2.15 The development of beta interferon in the UK: Timeline:

The debate on interferon grew around issues not only of cost, clinical effectiveness and the introduction of guidelines but also around a number of questions such as who should get the (expensive) treatment, who would decide about it and what the criteria should be. This section

focuses on the progress and appraisal process of introducing beta-interferon treatment for patients with MS and emphasizes the interaction between the actors who are trying to achieve their goals, which is a very important parameter in the study of policy analysis and the analysis of the policy processes (Walt and Gibson, 1994).

The goal of the timeline is not only to explore and understand part of the decision-making process (through the NICE appraisal process) but also to confirm the presence of a rather large interactive network, in which actors try to defend and promote their own interests and influence the outcome. The writing of the timeline was based on a variety of sources: articles, editorials, letters, broadcast news, official documents (NICE announcements, Health Services Circular, parliamentary announcements records) and the internet (on-line debates records). It was also based on scientific work such as reports, clinical trials, case studies and clinical evaluation documents on beta-interferon, before it had been evaluated by NICE, during its evaluation and until final guidance was published. The timeline describes the facts during the appraisal and, in parallel, emphasizes facts such as actors' reactions when interacting with each other i.e. patients groups and the DoH, and on how their interaction was aimed at promoting their interests or boycotting unbeneficial outcomes.

The timeline refers to three periods: the first one is the development and the debate on beta-interferon as an MS treatment before its licensing in the UK and before the establishment of NICE and the NICE appraisal, namely 1992 until February 1999. It has to be noted that some key arguments are highlighted which form part of the debate on Beta interferon in the UK so as to provide evidence and give emphasis to the research approach; it presents the discussions the different actions and reactions of the involved parts i.e. patients, physicians, professionals and justifies the framework of the research. The second period: 1999- July 2000 begins with the establishment of NICE - since the appraisal of beta-interferon was one of the first granted

to NICE - and includes the progress of the appraisal as it was communicated by NICE as well as the discussions and actions following the appraisal. The third period September 2000-2002, refers to the consideration of the appeals and the process to the final guidance in 2002.

2.15.1 First period: 1992- February 1999

The debate on interferon was „transferred“ to the UK with the introduction of interferon and its European licensing in 1995. Important issues about the use and prescription of interferon beta were debated regarding the clinical and cost effectiveness of the treatment. Different professional groups, organisations and patients/carer groups were involved in this discussion trying to promote and defend their own interests. This was a non-set debate; the views of the participants were expressed in a written form, via articles in newspapers and scientific magazines, official announcements from various organisations, letters and on-line discussions (Rous *et al.*, 1996; Toine, 1998:1233).

In the meantime, reports were published discussing cost-effectiveness and cost-utility analyses of beta interferon treatment in types of MS. The studies were concluding that the “*quantifiable benefits*” were very small in terms of disability progression, noticing also that clinical benefits were still unproven (DEC Report no 77, 1997; DEC Report no 98, 1999).

The questions put by the researchers (Parkin *et al.*, HTA Report 1998) were focusing on the patients and clinicians considering the true extent of the gains from the use of interferon and also on Health Authorities and their consideration of whether the extra investment required was worthwhile compared with the gains that health care produces for people with other conditions, “*bearing in mind both efficiency, as indicated by the cost-utility figures, and also equity*” (Parkin *et al.*, 1998: iv).

While the discussion on the role of health authorities (HA) continued, the Stockport HA had decided to prescribe the (interferon) medicine to their patients in 1995, when it was not even

licensed in the UK *“as it was really hard to resist giving patients a promising treatment”* (Rous *et al.*, 1996:1195). The authority had the support of one manufacturer, who was also offering a “free nurse” to support the package of care for MS patients (as discussed by Rous *et al.*, 1996).

Different groups were expressing different opinions since there were neurologists who suggested that widespread prescription of the drug could not yet be justified (Losseff, Kingsley, McDonald *et al.*, 1996; Rous *et al.*, 1996:1196) and others who did not wish to prescribe the drug on the basis of current evidence and thought that any additional resources should be directed to more supportive care for patients with MS. Emphasis was placed on the fact that there was no other treatment for MS and that was giving the relationship between patients and doctors a different perspective since providing a treatment was not going to cure the disease:

“Purchasers fear that if the guidelines are not tight enough to limit prescribing within available resources or neurologists find themselves unable to stick to them because of patient pressure, then resources would be sucked from elsewhere in the NHS to fund this drug” (Rous *et al.*, 1996:1196).

Health professionals, who studied the results proving that interferon beta has no significant effect on the development of disability in MS, stated their opposition to the use of the drug but there were other health professionals that believed that, despite the fact that the results had not been very encouraging, they were promising and the new treatment should be given a chance (Harvey, 1996: 297; McKee, 1998).

Participants from patient organisations and health professionals also referred to the needs and wishes of MS patients which should be taken into account and to the call that treatments, which give important symptomatic relief in other conditions such as cancer, should not be

withheld on the grounds that they will not produce long term benefits or cure.

„The disease has an adverse and often highly debilitating impact on the quality of life of people with MS and their families. ... Weakness, chronic fatigue, unsteady gait, speech problems and incontinence can leave people with MS feeling isolated and depressed. Substantial burdens are imposed on primary/informal carers, who are often patients' partners. In the management of MS, emphasis is often placed on the problems of long-term disability. However, the emotional impact of relapse on patients and carers is also considerable.“(NICE technology appraisal guidance, 2002).

Although there were financial costs involved with prescribing interferon, patients' organisations compared these with the additional hospital admission costs that a relapse has for patients and their families, highlighting two points: firstly, that it is an abstraction to suggest that a reduction in the progression of disability is more relevant than a reduction in attacks and secondly, that there is lack of compassion and humanity in this calculation: *“Relapses deserve treatment, and it is sad to see so much ingenuity spent on maintaining the tradition that MS is untreatable”*(Cardy, 1997:600a).

Patients' organisations have also referred to their attempts to ensure access to authoritative information and criticized the DoH additionally for the time until the introduction of interferon beta treatment, a year after its licensing and the great disparities in its purchasing across Britain (Richards, 1996; Holmes, 1997; Cardy, 1997).

The status of clinical trials in general has been questioned and doubts have been expressed about the validity and trustworthiness of a clinical trial, such as to imply that, in the case of beta interferon, the data were “manipulated” (Taubes, 1995)

“In achieving a key position in the distribution of research resources and materials needed to set up such trials, the pharmaceutical industry increasingly dictated development and clinical use of interferon. It was the industry itself that profited most from the very

dialectical nature of the “enterprise” of the randomised controlled trial” (Pieters, 1998:1233).

Table 2.2 presents the history of interferon beta, from its licensing in the US until its launch in the UK.

Table 2.2: Beta –interferon licensing

1992	US product license application for permission to promote beta-interferon for ambulant patients with RRMS
June 1993	Marketing approval was granted in the USA
October 1993	Treatment was launched in the USA
May 1994	In Europe, a license was filed and Betaferon was launched for the treatment of RRMS in December 1995
December 1995	The first license for beta interferon use outside a trial was granted to Schering Healthcare for Betaferon.
1995-1996	Licence: Interferon beta was licensed in the UK in 1996.
April 1997	Biogen’s Anovex (beta interferon treatment) was licensed
May 1998	Ares-Serrano’s Rebif (beta interferon treatment) was licensed.
May (and June) 1998:	Application to the European health authorities and in June to the US health authorities for approval to promote use of Betaferon in SPMS
January 1999	The European health authorities granted approval to promote use of Betaferon in SPMS
February 1999	Betaferon was licensed for secondary progressive MS.

2.15.2 Second Period: August 1999 - July 2000

This period, as it is briefly presented in Table 2.3, begins with the establishment of NICE

and includes the progress of the appraisal, as communicated by NICE, as well as the discussions and actions following the appraisal.

Table 2.3: Beta-interferon appraisal progress

August 1999	Appraisal ordered by the DoH and Welsh Assembly WA
February 2000	Evidence on the drug is submitted to NICE
May 2000	First meeting of the AC: publication of the PAD
June 2000	Glatimer acetate is licensed for people with RRMS by the UK Licensing Authority (but not launched by company until December 2000)
July 2000	Second meeting of the AC: publication of the FAD
July 2000	Appeals made before the final guidance is published

On the 1st April 1999, the National Institute for Clinical Excellence (NICE) was established (NICE, 2000). Interferon and glatimer (a type of interferon) were two of the first technologies that the DoH and the Welsh Assembly were planning to assess and so they asked NICE to appraise beta interferon and glatimer acetate use for clinical and cost effectiveness when treating multiple sclerosis (Rawlins, 1999).

Clinical trials published on interferon had shown that, in some cases, it could reduce disease activity; in other cases, the data confirmed an MRI benefit of interferon in MS but highlighted the limited clinical effect (Li *et al.*, and the UBC MS/MRI Analysis Group and the PRISMS Study Group, 1999; The OWIMS Study Group, 1999).

Regarding the high cost of the drug, the MS Society expressed the belief that, while the financial cost of beta interferon will always be high, the health gain it provides to patients is worth the expenditure. Nonetheless, the society also believed that the manufacturers of beta

interferon should reduce their prices in line with some other European and North American countries (MS Society, 2000:23-4).

In February 2000, NICE received submissions from the manufacturers, patient/carers groups and the professional bodies involved (the consultees).

At the first meeting of the Appraisal Committee, there were signs of alteration to the process due to pressure, from all parties, and the many discussions on beta interferon in relation to other appraisals, in the media, at that time. So, in addition to the written submissions which were considered, several experts participated and talked to the NICE AC meetings to represent one patient/carer organisation (the MS Research Trust) and health professionals with experience in this area.

The organisations that represent pharmaceutical and medical device manufacturers had, earlier, informed the Institute that a Provisional Appraisal Determination (PAD) could have a significant impact on their share price and on patients' confidence and asked that PAD and the remaining appraisal documentation be treated as confidential material (minutes from the meeting, (<http://www.nice.org.uk/> [accessed in 2000])).

In the meantime, the Appraisal Committee's preliminary decision that beta interferon should not be made available to new patients was leaked to the BBC and broadcasted on the 9 o'clock news and the "Newsnight" programme, causing a strong reaction from patients' organisations and manufacturers (NICE, 2000).

2.15.3 Third period: September 2000 – February 2002

This third period entailed the consideration of the appeals and the process to the final guidance in 2002. An independent Panel considered the appeals that NICE had received against the draft guidance for beta interferon. Patients also organised their own actions against NICE guidance. What was notable was the publication of personal appeals by MS sufferers

and their carers who stated the benefits received from the use of beta-interferon and were asking the Secretary of Health not to withhold the treatment from patients (Boseley, 2001).

NICE asked the AC to reconsider the original evidence in light of the Appeal Panel's decision about the beta interferon treatment with particular reference to evidence showing the long term benefits of beta interferon; new data which had become available since the start of the process; MRI data which demonstrated the impact of beta interferon on the underlying course of the disease; and the issue of inequality. NICE also asked the Committee to look at a new economic model submitted by manufacturer Schering, as commercial in confidence material at the appeal hearing (MS Society, 2000).

At the first meeting of the NICE Appraisal Committee and after the appeals hearing on beta interferon, a number of concerns arose regarding the economic models applied to the medicine on methodological grounds and casting doubts on the reasoning behind the assumptions used. Given the importance of the advice which the Committee was being asked to provide, it was suggested that these models be adhered to and in cases in which they could be rectified, the Committee should do so (MS Society, 2000).

In the meantime, the MS Research Trust sent out a questionnaire to supporters asking for information on their experience of MS and their quality of life. More than 2500 responses were received. The MS Research Trust submitted these responses (the largest piece of research in this area until then) and requested that to be included in the model. It also documented its concerns (MS Society, 2000).

In light of the evidence, some health authorities suspended prescription of drug therapies whilst NICE was deciding. Moreover, because of ensuing pressure from the MS Research Trust, the DoH reminded NHS trusts that existing guidance on drug treatments remained in place pending publication of a decision (DoH: EL (95)/97; HSC 1999/176).

At the AC meeting regarding the new economic modeling, the Provisional Appraisal

Determination (PAD) was produced. The PAD identified that *“on the balance of their clinical and cost effectiveness neither beta- interferon nor glatimer-acetate are recommended for the treatment of Multiple sclerosis in the NHS in England and Wales”*(NICE PAD, 2001:2).

Nevertheless, NICE recognised the impact that this might have on patients and suggested to patients and their consultants that treatment be continued until they considered it appropriate to stop, having regard for the criteria established for withdrawal from treatment in the guidelines of the Association of British Neurologists (ABN) (NICE MS PAD, 2001:2/). The PAD was also sent to consultees, including patient /carer organisations, professional bodies and manufacturers.

Once again and despite being subject to confidentiality, the result was leaked to the Reuters and Financial Times” websites but NICE dismissed the coverage as speculative.

The Institute issued the Final Appraisal Determination (FAD) to consultees so they could consider if they wished to appeal and NICE announced that it had received a number of appeals. Having considered the oral and written submission made by the appellants, the Appeal Panel concluded that neither the Appraisal Committee nor the Institute had acted unfairly, perversely or illegally with respect to any of the matters that had been put to it by appellants. The Appeal Panel dismissed the appeal accordingly on all grounds (Decision of the Appeal Panel, 2001: 45).

The Institute announced that the appeals against the guidance had not been upheld. As stated in the Institute”s guidance for appellants, *“the Board may amend the guidance to the NHS in the light of the appeal panel’s advice”* (NICE Press Release, 2001).

On 4th February 2002, NICE issued its guidance to the NHS in England and Wales. The guidance stated that:

“On the balance of their clinical and cost effectiveness neither beta-interferon nor glatimer acetate is recommended for the treatment of MS in the NHS in England and Wales. Because people with MS currently receiving these drugs could suffer loss of well-being if treatment

was stopped at a time they did not anticipate, they should continue treatment until they and their consultant decide it is appropriate to stop” (NICE FAD2001:1).

The guidance concluded that the DoH and the WA along with the manufacturers should consider ways to obtain these medicines for the NHS in a manner which was cost effective (NICE, 2002).

Table 2.4 summarises the progress of interferon appraisal, from NICE’s final guidance through to the launch of the risk-sharing scheme and NICE’s final guidance.

Table 2.4: Beta –interferon appraisal

September 2000	Consideration of the appeals by an appeal panel
November 2000	The appeal panel announces its decision
December 2000	The AC meets for the first time after the appeal to organize its further actions, including more economic modeling work
July 2001	The AC meets again and produces PAD
October 2001	The AC Publishes FAD
November 2001	The received appeals (against FAD) are examined
January 2002	NICE announces that the appeals against its guidance had not been upheld
February 2002	NICE issues its guidance and the decision for a risk sharing scheme between the DoH, the WA and the manufacturers is agreed

2.15.4 Final Guidance

As a direct result of NICE guidance, the DoH, Welsh Assembly, Scottish Executive and Northern Ireland Department of Health, Social Services and Public Safety reached an

agreement with manufacturers on a risk-sharing scheme for the supply of these medicines on the NHS (NICE, 11/ 2003).

This scheme meant that the cost of the drugs to the NHS would be reduced significantly and that the information collected would help to determine the real benefit of these drugs to people with MS(NICE, 11/ 2003).

Under the new scheme, eligible patients would be contacted by a specialist neurologist and assessed. Only patients' neurologists would be able to prescribe the appropriate medication. The treatment would be funded by the NHS until it was deemed to be no longer effective. Under the scheme, the cost of drugs per patient was cut from between £7000 and £12000 to between £6000 and £9000 a year per patient. The expected yearly NHS bill was estimated at £50 million (NICE, 11/2003).

Groups of patients would be monitored over the lifetime of the scheme and costs to the NHS would be adjusted according to whether expected benefits were realised. The price would drop further if expected clinical improvement targets were not met.

It was calculated that up to 20,000-30,000 patients of the estimated 60,000-80,000 people with MS would be assessed and about 10,000 of them were expected to be eligible (MS Society, 2002). The drug manufacturers had to provide some specialist nurses to assist in the assessment process, which might take up to 18 months. The scheme had to produce data on this cohort of patients for further information and research into the efficacy of this treatment (Little, 2002).

2.16 Summary

This chapter introduced NICE and its establishment and reviewed the way that NICE works with reference to the concept of policy networks. The aim was to explain the rationale behind the research with NICE whilst discussing healthcare policy analysis and the application of the

policy network concept. Other sections of the chapter discussed how policy making could be analyzed in terms of networks, how NICE and the appraisal process are pictured as a network and how the policy networks concept was applied. The „timeline“ section provided a review of the beta interferon treatment in detail so as to emphasize the interaction and interrelationships between actors and the context in which they operated, how they were influenced and were influencing others in order to succeed in their aims. Each of them was working for their own good but none of them worked alone since the interaction between them and their interdependence created complex relationships. The next chapter is about policy networks which will introduce and discuss the relationships between the actors in terms of interdependencies and interaction between them and to link the concept to health care policy.

CHAPTER 3

A DIALECTICAL MODEL ON POLICY NETWORKS

3.1 Introduction

This chapter discusses the theoretical development of policy networks in detail. The rationale of this chapter is to introduce and discuss the relationships between the actors in terms of interdependencies and interactions between them. Additionally, it will discuss how networks are formed because of these independencies and interactions and to link them to the policy networks approach and the case study.

3.2 The development of the Policy Network metaphor

The development of the policy network is discussed in parallel with other concepts which describe analogous phenomena such as the policy sector, the policy domain, the policy (actor) system, the policy community, the policy game and policy arena; (Benson, 1982; Laumann and Knoke, 1987; Sabatier, 1987; Jordan and Richardson, 1983; all quoted in Kenis and Schneider, 1991:32).

Nevertheless, the network concept and all other policy concepts are alternatives of one core issue: *“the idea of public policies which are not explained by the intentions of one or two central actors but which are generated within multiple actors sets in which the individual actors are interrelated in a more or less systematic way”* (Kenis and Schneider, 1991:32-33).

The policy network metaphor did not come about by coincidence but it is related to at least three more general transformations: -

1. Transformations in the political reality, or in other words in the reality of policy

making. The need for changes in the “political governance of modern democracies” was expressed through the development of theoretical trends to analyze policy making process, such as the emergence of organised society and “the increase in the importance of organised collectivities in social and political life” (Kenis and Schneider, 1991:34). Societal differentiation and policy growth lead to political overload and pressure for governments, which were unable to arrange significant policy resources within their own domain and, hence, they become dependent upon the cooperation of policy actors outside their hierarchical control. Policy networks should therefore be understood as the relatively stable and ongoing relationships which activate dispersed resources so that parallel action by various actors can be coordinated toward the solution of a common policy problem.

2. Transformations in conceptual and theoretical developments in the political sciences and in policy analysis in particular. Apparent changes in the political structures lead political scientists to adjusting their theoretical viewing. “Policy research had to expand its narrow focus from public policies to societal governance” (Kenis and Schneider, 1991:38). Liberal policy analysts have observed a change from a central form of governing view of political and social process to a different one, less state-centred. Policy analysis thus needed to broaden its analytical focus and include whole societal domains and dimensions of policy making.

3. The third transformation within policy analysis is the development of a “methodological apparatus” (Kenis and Schneider, 1991:39); of a set of functional processes by means of which a systematized activity such as structural analysis is carried out ([online] available from: <http://www.merriam-webster.com/dictionary/apparatus> [accessed 1/12/2015]). The development of “methodological” tools refers to the development of concepts and approaches such “resources and power dependency” or the “interorganisational relations:” and in parallel the application of mathematics and statistical procedures by social scientists.

Those methods, concepts and techniques enabled the studying of complex structures in the policy making process and the development of a methodological framework for structural analysis (Kenis and Schneider, 1991:39).

There are many discussions on policy networks and their utility or applicability in studying policy making and governance especially in Europe. According to Borzel (1997:1) there is „a Babylonian“ variety of policy network concepts and applications to be found in the literature. Whilst there is general agreement that policy networks exist and are more than an analytical tool for studying policy making (Borzel, 1997; Kickert, Klijn and Koppenjan, 1998; Marin and Mayntz (eds.), 1991), there is neither a common understanding of them nor has it been agreed whether they constitute a metaphor or a method or a theory (Borzel, 1997:1). So while policy networks exist and are operating as links between actors within a particular policy domain, it seems that there is much less agreement as to the explanatory utility of the concept or the broader significance of the growth of networks (Marsh and Smith, 2000:4).

The policy network metaphor has been defined and used in different ways. Kenis and Schneider (1991: 25, 34) argue that the term network has become the „new paradigm for the architecture of complexity“ and trace the discussion on policy networks metaphor to the end of the 1970s, when it became the metaphor for discussing the “critical changes in the political governance of modern democracies”.

All approaches to policy networks and within the different disciplines vary; but according to Borzel (1997:2), they all share a “common understanding”: of being a “set of relatively stable relationships which are of a non-hierarchical and interdependent nature linking a variety of actors, who share common interests with regard to a policy and who exchange resources to pursue these shared interests acknowledging that co-operation is the best way to achieve common goals”.

Borzel (1997:253) identifies two “schools” of policy networks in the field of public policy. The „interest intermediation school“, where the English/American literature mainly focuses, interprets policy networks as a generic term for different forms of relationships between different interest groups and the state. The basic assumption is that the existence of policy networks, which reflect the relative status of power of particular interests in a policy area, influences (though it does not determine) policy outcomes. In this approach, the term „policy network“ emphasizes: regular contacts between individuals within interest groups, bureaucratic agencies and government, which provide the basis of a sub-government and concentrates upon, especially in the American literature, the micro-level, dealing with personal rather than structural relations between institutions (Marsh and Rhodes, 1992; Marsh, 1998).

On the other hand there is the „governance school“, where the German literature focuses. It conceives policy networks as a specific form of governance, as a mechanism to mobilise political resources in situations where these resources are widely dispersed between public and private actors (Borzel, 1997:253). Policy networks are an emerging form of governance because neither hierarchy nor markets are appropriate forms of governance. In this approach, networks, as a mode of governance, are contrasted with hierarchy and markets.

Hierarchy as a mode of governance is characterized by a very close structural coupling between public-private organisations and central co-ordination, and thus control. On the contrary, markets as a form of governance involve no structural coupling and outcomes result from the market driven interplay between a plurality of autonomous agents drawn from the public and the private spheres; there is no central co-ordination (Borzel, 1997).

The policy network model offers a more realistic and indeed democratic alternative (Kickert, Klijn and Koppenjan, 1998:9-10). The government is no longer seen as a superior, directive

element, but as one actor among many with roughly equal power. Policy networks are involved in a loose structural coupling; interaction within networks and between autonomous actors produces a negotiated consensus, which provides the basis for co-ordination. The key to effective governance is the effective management of the network (Marsh, 1998:8).

In Britain the discussion on policy networks, according to Marsh and Smith (2000), emphasises the structural aspects of networks and the role that policy networks play in the development and implementation of policy. The approaches to policy networks vary in the British literature as well. However, there is also a “common ground; that all authors see policy networks as a key feature of modern policies” (Marsh, 1998:10; Daugberjerg and Marsh, 1998).

3.3 Background of policy networks

“The policy network approach builds on earlier theoretical concepts in policy science using insights from other social sciences” (Kickert, Klijn and Koppenjan, 1999:14). Interorganisational theory and the literature on the concepts of subsystems and policy communities have been mostly important to researchers and scientists. Policy networks form the context and the framework, in which the policy process takes place; they thus represent an attempt within policy science to analyze the relationship between context and process in policy making.

3.4 Types and dimensions

Kenis and Schneider (1991: 41-42) in their discussion about types and dimension of policy networks strongly argue in favour of networks as “new forms of political governance which reflect a changed relationship between state and society”. The researchers see the emergence

of networks as being “the result of the dominance of organised actors in policy making, the overcrowded participation, the fragmentation of the state, the blurring of the boundaries between the public and the private”.

The arguments of Kenis and Schneider (1991:41-42) on policy networks are referring to the significant amount of expertise and resources as a precondition for policy problems being solved as they involve “complex political, economic and technical task and resource interdependencies”, and therefore presuppose a significant amount of expertise and other specialized and dispersed policy resources. “The integrative logic on policy networks cannot be reduced to any single logic such as bureaucracy, market, community, or corporatist association”, because as an approach “it is characterized by the capacity for mixing different combinations of other developments. It is the mixture and not the individual logic per se which accounts for its functioning” (Kenis and Schneider (1991: 41-42).

A policy network is described by its actors, their linkages and by its boundary. It includes a relatively stable set of mainly public and private corporate actors.

Some dimensions of policy networks, discussed in the literature, in order to make the concept fruitful as a tool for comparative analysis are outlined by Van Waarden, (1992: 32).

1. **Actors:** Actors in policy networks are individuals, but as these are mostly representatives of the organisation, the network actors can also be considered as organisations. Relevant properties of the actors are their needs and interests, which form the basis of the interdependencies and give rise to the network structure in the first place (Van Waarden, 1992:33).
2. **Functions:** Networks are communication channels, which may perform various functions alone or simultaneously. Their functions depend on the needs, intentions, resources and strategies of the actors involved (Van Waarden, 1992:33).

3. **Structure:** The structure of policy networks refers to the pattern of relations between the actors in the network (Van Waarden, 1992:34).
4. **Institutionalization:** It refers to the formal character of the network structure and its stability i.e. the norms and accepted behaviours over time (Van Waarden, 1992:35).
5. **Rules of contact:** “Networks are characterized by conventions of interaction or „rules of the game“, which govern the exchanges within the network. The rules stem from the role perceptions, attitudes, interests, social and intellectual-educational background of the participating actors and are likely to influence these in turn. Indirectly, such conventions will derive from the more general political and administrative culture” (Van Waarden, 1992:35).
6. **Power relations:** Policy networks usually represent power relationships, and are hence characterized by the distribution of resources and needs amongst the actors and of their mutual organisational structures, when these are organisations (Van Waarden, 1992:36).
7. **Actor strategies:** Actors follow strategies both vis-a-vis networks, and within networks themselves.

The various dimensions of the “network” are interrelated and certain configurations of characteristics together can form a typology (Van Waarden, 1992:32).

Additionally, there are a number of viewpoints regarding the role of policy networks in the explanation of policy outcomes; actors’ presence, number, and attitude are discussed by many authors as some of the most important dimensions of the network (Van Waarden, 1992; Marsh, 1992, Smith, 1993, Borzel 1997, Marsh and Smith, 2000).

3.4.1 Why the policy networks concept has been applied

This diversity of opinion on policy networks and the different theoretical developments,

pointing in various directions, made the decision to utilise policy networks as a framework for the researcher very difficult. To apply this concept was a challenge but also a big risk. The researcher's inexperience turns into a kind of creativity and one might take risks that others would consider as unnecessary or pointless.

One could disagree on many aspects with the researchers and their theories on policy networks. However it could be considered and could be supported as a very strong approach for the policy analysis area because it could be argued to entail this element of "mixing the different combinations of the various developments or approaches" as Kenis and Schneider argue (1991:42). Policy networks are applicable to the NICE AC case study because of the type of questions the research is trying to answer. Other theoretical developments and approaches were considered and are acknowledged by the researcher such as Dowding's (1994) rational approach; policy communities and issue networks (Rhodes, 1997); state power and interest groups behaviour (Richardson, 2000) or the advocacy coalition framework of Sabatier (1988).

Every approach has advantages and disadvantages and researchers often strongly criticize one another. The policy network approach was selected as the best to be applied in the current study. The policy network concept or metaphor or approach is argued to have elements of all the other approaches because on the one hand, it involves membership, interaction between actors and state power and at the same time it cannot constitute a theory that can be applied in a particular method or for example has a mathematical form. Networks and policy networks are thought to describe best the modern complex societies that we are living and, therefore, they were chosen for this study i.e. they could set boundaries, from the point of view that they could describe the many different and complex relationships between actors and they are "open" to include more actors.

3.5 Policy networks in Britain

In this section, particular reference is made to the way that the policy networks metaphor has been theoretically developed in Britain. The reasons for this discussion are simple; the case study involves a British organisation, and the applied theoretical Model was introduced and developed by researchers who consider their approach as located within the British and American literature (Marsh and Smith, 2000:4).

3.6 Network typologies

In the British literature the development of policy networks is drawn upon literature on interorganisational theory (Rhodes, 1999:45) and is used to explore and discuss the shift from government to governance.

A typology on networks could be argued to be the development of specific types and characteristics of networks into a framework that researchers apply in studying state/central relationships. British researchers have developed certain typologies of policy network.

Typologies of network found in the literature “share a common understanding of policy networks as power dependency relationships between the government and interested groups” whereas resources are exchanged. Yet they differ from each other “according to the dimensions based on which the different types of networks are distinguished” (Borzel, 1997:256).

3.6.1 The Rhodes typology

Rhodes (1981 quoted in Rhodes, 1999:36) developed his typology for the study of British central-local relations. His framework was based on a theory of power-dependence which contains five propositions:

- (a) Any organisation is dependent upon other organisations for resources.
- (b) In order to achieve their goals, the organisations have to exchange resources.
- (c) Although decision-making within the organisations is constrained by other organisations, the dominant coalition retains some discretion. The appreciative system of the dominant coalition influences which relationships are seen as a problem and which resources will be sought.
- (d) The dominant coalition employs strategies within known rules of the game to regulate the process of exchange
- (e) Variation in the degree of discretion is a product of the goals and the relative power potential of interactive organisations. This relative power potential is the product of the resources of each organisation, of the rules of the game and of the process of exchange between organisations (Rhodes, 1981:98 quoted in Rhodes, 1999:36).

Rhodes, because of the intrinsic weakness of the corporatism literature and its imprecise use, revised his model (Rhodes, 1986a; 1986b in Rhodes 1999:37 Marsh and Rhodes, 1992a; Rhodes and Marsh, 1994, Marsh and Smith, 1995 quoted in Rhodes, 1999:45), so in his later work, he distinguishes the three level of analysis. “The macro-level of analysis of intergovernmental relations requires the involvement of an account of the changing characteristics of British government during the post-war period. The meso-level of analysis puts an emphasis on the variety of linkages between the centre and the range of sub-central political and governmental organisations. The concept of policy networks is apt for this level of analysis. The micro-level of analysis stresses the behaviour of particular actors, be it individuals or organisations”.

Nevertheless, networks involve the exchange of resources. Therefore, the distribution of

resources between actors in a specific network remains fundamental to any explanation of the distribution of power in that network. Similarly, the different pattern both of resources and their distribution between the several actors, in networks explains partly the differences between networks. The macro-level of analysis complements power-dependence by focusing for example, on the origins of the rules of a game between actors and why some actors control more resources than others. Possibly, the main “significant weakness of the power dependence model is its failure to distinguish clearly between micro-, meso-, and macro-levels of analysis; so the links between them is adequately explored” (March, 1983:1 quoted in Rhodes, 1999:37).

3.6. 2 The Wilks and Wright typology

Wilks and Wright (1987 in Rhodes 1999:40) adopt a societal-centred approach and emphasise interpersonal, rather than structural relations. “There are three major ways in which their typology differs from Rhodes. First, it emphasises the disaggregated nature of policy networks in the industrial policy sector, and indeed, suggests that such desegregation exists in all policy sectors”. Second, Wilks and Wright (1987:298) placed considerable emphasis on interpersonal relations as a key aspect of all policy networks; and third major difference between the two models is that is not amenable to empirical investigation and presents more problems.

Wilks and Wright use an idiosyncratic distinction between policy universe, policy communities and policy networks not used elsewhere. “The *policy universe* consists of the large population of actors and potential actors sharing a common interest in industrial policy, and may contribute to the policy process on a regular basis. The term *policy community* is reserved for a more disaggregated system involving those actors, who potentially share an

interest in a particular industry and who interact with one another, exchanging resources in order to balance and optimize their mutual relationships. The *policy network*, to Wilks and Wright becomes a linking process, the outcome of those exchanges within a policy community or between a number of policy communities” (Wright 1988a/: 606; Wilks and Wright 1987:299 quoted in Rhodes 1999:41).

Wilks and Wright argue that their new approach has several advantages over other models which distinguish between networks and communities according to the closeness of the relationships involved. In particular, they argue that it allows them both to recognize that not all the same policy issues in the same policy sub-sector are handled in the same network; and that the members of a same policy network may be drawn from different policy communities within the same policy area, or even from different policy areas (Wilks and Wright 1987:306-307).

3.6.3 The Marsh and Rhodes Typology

Rhodes (1988:77-8 quoted in Rhodes, 1999:43) identified four dimensions along which networks vary – interests, membership, interdependence (vertical and horizontal) and resources. Marsh and Rhodes “typology builds on these points, treating, policy communities, policy networks and issue networks as types of relationships between interest groups and government. They are meso-level concepts which leave whole variety of important questions open as matters for empirical analysis. Their typology treats networks as a generic term”.

3.7 Network Approaches

Besides the typologies, various approaches have been developed by British researchers regarding policy networks. In essence, the argument is about the relative importance of

structures and agents in affecting policy outcomes. Some authors, for example Marsh and Rhodes, stress the structural aspect of networks while others, like Dowding, emphasize intentional explanation (Marsh and Smith, 2000:4). However, all the approaches imply, at the very least, that policy networks affect policy outcomes.

- Laumann and Knoke (1987 cited in Thompson, 1991:175-176) formal network analysis argues that it is the position and roles performed by the actors which are crucial and the relationship between these roles, not the individuals who occupy them, which define the network.

- The Dowding Approach: Dowding (1994) claims that the concept of policy networks, as used by most of its proponents, has no theoretical basis and, thus, no explanatory power. In his view, the concept has been used merely as a heuristic device, as a metaphor. Network structures, per se, have no influence on policy outcomes. Rather, networks reflect patterns of interaction and resource exchanges between agents and it is those resource exchanges, which determine outcomes: “the explanation lies in the characteristics of the actors” (Dowding 1995:142). Network approaches fail because the driving forces of the explanation, the independent variables, are not the network characteristics per se but rather characteristics of components within the networks. These components explain both the nature of the network and the nature of the policy process (Dowding, 1994:69).

- McPherson and Raab’s (1988) anthropological approach sees networks as based on personal relationships between known and trusted individuals who share beliefs and a common culture.

- Marsh and Smith /The Dialectical Relationships Model: In Marsh and Smith (2000), a dialectical relationship is an interactive relationship between two variables in which each one affects the other in a continuing interactive process meaning that almost all

the relationships are interactive or dialectical. The Model highlighted (Marsh and Smith, 2000) the three dialectical relations and acknowledged that:

- The broader structural context affects both the network structure and the resources that actors have to utilize within the network.
- The skill that an actor has to utilize in bargaining is a product of their innate skill and the learning process which they have to follow.
- The network interaction and bargaining reflects a combination of the actor's resources, the actor's skill, the network structure and the policy interaction.
- The network structure is a reflection of the structural context, the actor's resources, the network interaction and the policy outcome.
- The policy outcome reflects the interaction between the network structure and network interaction.

The overall view of the authors, Marsh and Smith,(2000) was that, “while each approach has considerable strength, all fail to recognize that any attempt to use policy networks as an explanatory variable involves three dialectical relationships between: structure and agency; network and context; and network and outcome” (Marsh and Smith, 2000:5).

“All other approaches privilege either structure or agency. Structures matter, but agents interpret these structures and take decisions; so the role of the agents matters as well. What is needed is a model which recognizes the interrelated role of both: structures and agents” (Daugbejerg and Marsh, 1998:70in Marsh and Smith, 2000).

Usually, the utility and the limitations of network analysis need to be acknowledged. Policy outcomes cannot be explained simply by reference to the structures of the network or the behaviour of the agents. “Important questions remain why the networks take the form they do, how they relate to the broader political system, and how network structures and actors

behaviour affect outcomes and restructure networks” (Daugbejerg and Marsh, 1998:70).

3.8 Case study on policy networks.

An example of a case study (Toke and Marsh, 2003) that has applied the Dialectical Relationships Model on policy networks is presented, and aims to explore the approach in more detail and to understand the concept and its possible applications better. The concept has not been widely applied in the healthcare services, and, hence, the presentation of the example is in support of the thesis methodology.

3.8.1 Policy networks and the GM crops issue: assessing the utility of a dialectical model of policy networks (Toke and Marsh, 2003)

The study involved the deployment of the Dialectical Model of policy networks to analyse policy change in the area of GM crops in the UK. The model analyses the interaction between agents and structure, network and context, and network and outcomes to understand and explain the evolution of GM crops policy changes and comment on the utility of the dialectical model. The analysis was expanded on broader policy networks, literature and empirical quantitative data drawn from interviews.

The model allowed a sophisticated analysis of how a GM policy network was dominated by biotechnology and how farming interests had been transformed, through the interactive relationships between network structure and agents, network and context and network and outcomes, into a GM policy networks which included concerns of the more established wildlife protection groups. The study demonstrated the utility of the Dialectical Model of policy networks (Toke and Marsh, 2003:249).

A key advantage of the model according to Toke and Marsh (2003:250) was “that it increases understanding of network transformation, explanation of which has been an assumed weakness of the policy network approach”. However, regarding the application of the Model, they have also emphasized that “the model is not the only method to provide an explanation of policy change but rather one that facilitates the development of such an explanation”.

The case study also identified some shortcomings referring to the weakness of the Model to distinguish between individuals and groups as agents; to the exaggeration of the influence of the „insider“ groups at the expense of the „outsiders“ and also the focusing of the model on policy outcomes emanating from the policy networks (Toke and Marsh, 2003:250).

3.9 The Dialectical Relationships Model

The different approaches to policy networks, each of them with different strengths and weaknesses, can all be used in the development of a more efficient explanatory framework which Marsh and Smith(2000:4) have named the dialectical approach relationships. Yet again, researchers expressed their doubts about and critiqued (Dowding, 2001, Raab, 2001; Evans 2001) the Model and its applicability. The Model seems to have been applied in two case studies (Toke and Marsh, 2003; Greer, 2002) before this research was conducted. A recent bibliographical research on various databases showed that there were no other applications apart from those two studies. This might be because it has not been further developed with reference to the theoretical grounds and the difficulties in verifying any results.

Toke and Marsh (2003:232) have argued that the approach of Marsh and Smith (2000) is sufficient to see the relationships as dialectical, as they involve a strategic learning process. Action is taken by an actor within a structured context and the actor brings strategic knowledge to the structured context and both the knowledge and the context help shape the

agent's action. Nevertheless, the process involves constant iterations, since the action affects both the actor and the context, which then, in turn, shape, but do not determine, the agent's future action (Marsh and Smith, 2000:5).

3.9.1 Beyond structure versus agency

Networks as agents

Marsh and Smith (2000:5) highlight that networks are structures, types of relationships, which constrain and facilitate agents; and that the culture of a network could act either as a constraint or opportunity or both for the network members.

In this thesis, the terms „agent“ or „actor“ refer to a person who acts for, or manages the affairs of other people in business, politics, organisations, or institutions. Actors in policy networks are individuals literally, but as these are mostly members in the role of organisation-representative, organisations are in a metaphorical way considered as actors i.e. NICE or the industry are mentioned as actors but they are organisations/companies institutions where individuals are working. One of the research questions was to observe how individuals influence their work or how their working status influences their behaviour. Policy networks are political but not static structures. The relationships within the networks are considered structural because they define the roles that actors play within networks; set the issues that are discussed and how they could be dealt with; have distinct sets of rules; and contain organisational imperatives, so that, at least, there is a major pressure to maintain the network (Toke and Marsh, 2003:232).

Networks, in this thesis, are considered as a form of governance. They can also involve institutionalization, which, in a political sense, means the creation or organisation of governmental institutions or particular bodies responsible for overseeing or implementing

policy, for example in welfare or development, of beliefs, values, cultures and particular forms of behaviour. They shape attitudes and behaviour and affect policy outcomes in a complex way. “Networks reflect the structuration, whereby structuration is defined as the structuring of social relations across time and space, in virtue of the duality of structure of past conflicts and present organisational power” (Giddens and Pierson, 1998:76/77 cited in Wienges, 2010:69). Examining networks refers to investigating the institutionalization of power relations both within the network and within the broader socio-economic and political context.

The form of the network also affects the range of problems and solutions that are considered, which means that the network plays an agenda setting-role. Rules of the game within the network constrain who is included in the network and how participants act. Defining the sort of behaviour which is acceptable implies a preference for certain alternative outcomes. Actors who do not accept the rules set within the network are to be excluded (Van Waarden, 1992; Marsh and Rhodes, 1992).

The role of Agents

Agents matter and are those who interpret and negotiate constraints or opportunities. Agents are located within a structured context that both the network and the broader political and socio-structural context provide within which the network operates and whose contexts define the resources of an actor. It is apparent that the agents do not control either aspect of that structured context. At the same time, agents do interpret that context; and it is via their interpretation that the structural context affects the strategic calculations of actors (Toke and Marsh, 2003). The role of agents is discussed further by many other researchers (Giddens, 2001; Walt and Gilson, 1994; Ferlie, Fitzgerald and McGivern *et al.*, 2011, 2013; Evans, 2001) and how individuals’ behaviour “leads” into different decisions and pressures within a

network and, furthermore, their role in the formation and implementation of policies. It could be said that assuming there is a “black box” in policy making process; it would involve the role of the agents/individuals.

Outcomes cannot be explained by referring only to the structure of the network; they are the result of the actions of strategically calculating subjects. Three significant points in relation to the role of the agents are made by Marsh and Smith (2000:6). The first refers to the interests or preferences of members of a network that may not be defined merely or perhaps even mainly in terms of that membership. Secondly the constraints on, or opportunities for, an agent’s action do not happen automatically but derive from network structures and depend on the agent’s ability and flexibility to utilize those constraints or opportunities (Toke and Marsh, 2003:232). Thirdly, network members’ skills are connected to their capacity to use opportunities or negotiate constraints. Conclusively, whilst networks are both structural and causal, the essence is to understand how actors interpret these structures and that the relationships between actors are directed in both ways.

Agents Change Structures

It is important to acknowledge that network structures, and the recourse dependencies between the actors (who need each other in order to operate/exist perform) which they entail, are not fixed. There is a constant moving as agents discuss policy options, bargain, argue and breakup networks. Actors can and do negotiate and renegotiate network structures (Toke and Marsh, 2003:233). Therefore, any explanation of change should focus on the role of agents and, in parallel, on acknowledging that the broader context within which the network operates influences the interests and actions of network members.

3.9.2 Network and Context

The existing literature, in providing an explanation regarding network changes, and subsequent policy change, underlines either endogenous or exogenous factors. Moreover, the differences between exogenous and endogenous factors are difficult to maintain (Marsh and Smith, 2000:4). Realizing how networks affect outcomes creates an ability to identify and accept the dialectical relationship between the network and the broader context within which it is located. There are two different, but related issues here: first policy networks reflect exogenous structures; for example, class and gender structures, and, hence, the structure of networks is likely to reflect the broader pattern of structured inequality within the society (Toke and Marsh, 2003).

At the same time, actors are located in various structural positions and, while membership of a policy network may give them structural privilege, other exogenous structural positions, such as class or ethnicity, might be more important and so they are reflected in their network membership. Secondly, network structure, network change and the policy outcome may be partially explained by reference to factors exogenous to the network, but these contextual factors are dialectically related to network structure and network interaction. Certainly, if it is argued that networks affect policy outcomes and, hence, these changes in networks can result in policy change, then what leads to network change also has to be addressed (Marsh and Smith, 2000:7; Toke and Marsh 2003).

A specific change is normally explained in terms of factors exogenous to the network; as the external environment changes, it may affect the resources and interests of actors within a network. Yet, the extent and speed of change is clearly influenced by the network's capacity to mediate, and often minimize, the effect of such changes. Networks are often faced by very strong external uncertainties and that does affect the network structure, network interactions

and policy outcomes (Marsh and Smith, 2000:8).

In a complex policy, the relationship between networks is obviously crucial for all participants. Furthermore, there are at least two allied problems. In the first instance, the context within which networks operate is composed, partly, of other networks and, because of this aspect, the context has a significant impact on the operation of the network, upon change in the network and upon policy outcomes. Secondly, the issue of the relationship between sectoral and sub-sectoral networks is particularly important (Marsh and Smith, 2000:8). Sectoral networks provide a crucial aspect of the context within which sub-sectoral networks operate (Smith, 1993; Jansen 1991). Broadly, exogenous changes can affect the resources, interests and relationships of the actors within networks. Changes in these factors can produce tensions and conflicts that lead to either a breakdown in the network or the development of new policies (Marsh and Smith, 2000:8).

Nonetheless, the effect of changes is connected to the effect of the structure and interactions within the network. In addition, exogenous change is mediated through the understanding of agents and interpreted in the context of the structures, rules/norms and interpersonal relationships within the network (Marsh and Smith (2000:8).

3.9.3 Networks and Outcomes

Marsh and Smith (2000:9) are critical of the emphasis upon the question of whether, and, if so, to what extent, networks affect policy outcomes as Dowding, (1994) argues. The lack of recognition that policy outcomes also affect the shape of the policy network directly, as well as having an effect on the structural position of certain interests in civil society and the strategic learning of actors in the network, have been considered in addition to the argument that relationships between networks and outcomes are not unidirectional but dialectical.

Outcomes may influence, and are influenced by, networks in at least three ways. Firstly, a particular policy outcome may lead to a change in the membership of the network or to the balance of resources within it; for example, the changing of the UK governmental policy on health, while it clearly did not lead to the exclusion of the doctors from any networks, nevertheless it weakened their bargaining position within those networks by introducing the appraisal of clinical excellence of medicines and health technologies (Toke and Marsh, 2003; Hay, 1995, quoted in Marsh and Smith, 2000).

Secondly, policy outcomes may have an effect on the broader social structure, which weakens the position of a particular interest in relation to a given network. (Marsh and Smith, 2000:9).

Thirdly, policy outcomes can affect agents and actors can learn by experience, and as Hay (1995, quoted in Marsh and Smith, 2000:9) emphasizes strategic learning is obviously an important feature of political activity (Freeman cited in Moran, Rein, Goodin, 2008; Hall 1993, Sabatier 1988). When specific actions within a network are failing to produce a favourable - to an actor and the organisation she/he represents - outcome within the network, or more broadly for the entire network, then that actor is likely to employ further strategies and actions. For example, one of the companies producing interferon beta “provided” nurses for free to a particular authority so their product would be sold or patients groups becameorganised with other patient groups and journalists to promote the matter of prescribing interferon and put pressure on the DoH to reevaluate the situation and pay more attention to the matter.

3.10 Critique of the Dialectical Model

Evans (2001) argues that a significant difficulty with the Dialectical Model involves the use of the term „dialectic“ by the two authors. While Marsh and Smith (2000) clarify their usage

of „dialectical“ relationship as „an interactive relationship between two variables in which each one affects the other in a continuing iterative process“, the insufficiency in the use of the term which “leaves the definition open to misinterpretation” is underlined by Evans (2001:543). The word „dialectic“ is a controversial and meaningful word with a wide range of definitions from Plato to Marx. Furthermore, Evans (2001:544) acknowledges the potential development of the approach and states that Marsh and Smith have been “*too conservative in their formulation of the term dialectic, and also that they have failed to map out the contours of a truly dialectical approach to the study of policy networks*”.

Another question regarding the development of the Dialectical Model comes from Raab (2001:552), who is concerned about “the extent to which the Model can take us further, or clearly, towards reorienting the substance and reconsidering the methodology of policy making studies”. Raab (2001:552) argues additionally that Marsh and Smith (2000) “are not taking an unprecedented step” and, that moreover, they are failing to realise it may be because, to some extent, “*they misperceive the McPherson/Raab's „approach“ by seeing it only, or mainly, as a simple focus on interpersonal relations amongst agents who share a common culture*”.

Dowding (2001) refers to the Model and argues not only about the lack of the specific definition of the term „dialectical“ but also the definition provided by Marsh and Smith (2000) regarding the terms „interactive relationship“ and „iterative process“. Dowding (2001:99) argues against the “pointless theorizing” of Marsh and Smith and believes that the way forward is via more empirical work which could be done with some types of networks; these may be modeled in terms of agents“ characteristics and structural characteristics to produce descriptive and causal inferences.

In the next section, the application of the Dialectical Model Relationships Model in this thesis

and the case study are discussed.

3.11 Dialectical Model: its application in the present study

The various theoretical approaches considered above posed a dilemma for empirical researchers regarding which approach to pursue as an organising framework. Given the context of the present study, all approaches had potential value. However, the proposition of Marsh (1998) towards a more dialectic relationship, and the later development of the Dialectical Model by Marsh and Smith (2000) were seen as being the most convincing, along with the reporting on similar case studies (including the one presented above).

It was considered that policy network analysis would be the best approach to apply in the study of the policy process and exploration of this process with reference to the question of how health policies emerge. Actors and their resources; the structure and context of a network; the professional and personal status of the networkers and their behaviour were the variables chosen to be studied in the exploration of how healthcare policies emerge.

Furthermore, while studying the literature on policy networks, the element of it “being a dialectical model” was crucial in selecting it since it felt that this would place the research in a less biased position. The argument of Jansen (1991) that the policy networks concept begins from a neutral point and furthermore, the broad framework of analysis that the Dialectical model could support that argument. Also, the research could be designed to minimise bias with respect to the role of the actors or the nature of the relationships between them, assuming that there has always been discussion on who or what defines policy i.e. politics, money dependencies, professional expertise, and any bias brought in by the researchers because of the different cultural background and the different views.

3.12 Case study: setting the boundaries

In order to explore the process for the establishment of a new policy for MS patients treated with beta-interferon, the Dialectical Relationships Model on policy networks was applied (Toke and Marsh, 2003). The Model had been applied in only two cases at that time (Toke and Marsh, 2003; Greer, 2002). The Model uses an analysis of the interaction between agents and structure, network and context and network and outcomes in order to understand and explain, firstly, how policy change has occurred. A second purpose has been to assess the utility of the policy networks concept and of the Dialectical model itself.

The MS Treatments issue has generated significant debate in the past, and is an interesting issue for a variety of reasons. Initially, it offers an example of a conflict between the powerful interests of the pharmaceutical industry, the government, health professionals, clinicians, academics and patient groups; secondly, this is an issue where public opinion and „patient power“ appear to have played a significant role, while the topic has also received extensive publicity in the media. There were press releases, editorials and letters (see appendix G list of analysed documents). Third, the role of „scientific experts“ and their “professional autonomy” has, on many occasions, been questioned (Burke, 2002; Cardy, 1997; Black, 2001; Beggs, 2003) not only with respect to the role of the health economists, or researchers performing clinical trials but also regarding the validity of the results of the trials (Pieters, 1998; McDonald, 2000; McKee, 1998).

This case study of MS treatments involves network interaction between various groups such as patients groups, pharmaceutical industry, clinicians and the government. A further concern has been to assess the extent to which the dialectical model can provide an understanding of the processes of network operation, the role of the actors, and the relationship between policy networks and policy outcomes. Thus, within the aims of this thesis as outlined in Section 1.6,

the research endeavoured to offer an explanation on how policy changes on MS treatment emerged and to comment on the utility of the Marsh and Smith (2000) framework and of the policy networks concept.

3.13 Case study questions

The dialectical model generates questions in connection with the three relationships. Here these questions are outlined in order to link the research questions of the thesis, as outlined in chapter 1, with the particular case study and the applied Model thus providing the rationale for applying the policy network concept and the Dialectical Model.

i) The first relationship (**Beyond Structure versus Agency**) refers to a number of questions generated by the discussion of the dialectical relationship between structure and agency. These questions are linked to the research questions and hypotheses regarding the existence a network revolving around NICE and the identification of the actors within it. There is an additional link with the actors' resources, their usage and their impact on the interactions between the actors and on the final outcome.

- **Who is in the network:** it is difficult to decide who is in and who is out within a network because it depends on many issues, such as the nature of the research and the research questions. Answering this question "who is in the network" sometimes seems to be an objective exercise, setting a reference point i.e. the network is the actors revolved around the NICE AC. However, while progressing the research, the answer to this question would be different. Every actor's position and own resources change analogously to other actors with similar or conflicting interests. In the current case study, the focus was around the National Institute for Clinical Excellence (NICE). It involves the verification of a network revolved around NICE and of the actors within it. Further, it seeks to study other variables such as the

professional background of participants with a particular interest in the individual characteristics of the participants i.e. health professionals, patients, patient groups, academics and others; all those who, presumably, could comprise “the NICE policy network”. Focusing on that network would help when contrasting with other networks and actors and how they interact.

- **What resources do these network members have:** The resources that network members have define their position in the network and they build interdependencies between them. The context of the relationships in the network is discussed in three levels, political, economic and social. The resources that the members have could be divided in analogous types but are also the result of their social status i.e. clinicians have the power of resourcing for their profession and the expertise. Politicians have positional power and patient groups have the power of being a pressure group. Otherwise, resources could be political power, economic, social, and expertise. The resources are varied and given that networks are dynamic, their validity varies accordingly.

- **To what extent do these resources reflect the structural position of the interests these members represent and/or the skills and abilities of the individuals who represent these interests in the network:**

The control of resources is reflected in the structural position of the network members to a great degree, and additionally in the skills and abilities of individuals who represent these interests in the network.

- **Have these individuals changed the structure of the network in an attempt to forward their interests:**

The personal characteristics of those who represent these groups or organisations play an important role and have a great influence in the process, and often „battles“ between actors reflect personal matters. On the one hand, one would wish that it should be taken personally

so one can do their best. On the other, there is always the risk of pursuing individual rather than group benefits.

- **Has the network structure altered the perceived interests of the network participants:**

It could be argued here that any restructuring or change in the network probably means an alteration in the interests and aims of the participants and an adjustment to the different conditions/circumstances. The extent of this alteration would not always be observable but, in all probability, it will be happening and could be seen whilst comparing actors using different methods such as observation or collecting and analyzing data. Some of the actors have advantages compared with others, i.e. some actors are gaining more resources, others have losses or they cannot achieve their goals.

ii) The second part (**Beyond Network Versus Context**) refers to the relationship between the structure and the context of the network. This part links to the research questions and analytical discussion on actors' interaction and relationships within the network structure and context. Also in this section reference has been made to the role of individuals within the network and how the professional and personal status of the networkers influences their behaviour and their strategies;

Changes in the context in which the network operates do have an effect on the structure of the network (Marsh, 1998:197) and the interactions within it. These changes could involve changes to the rules, the norms, and the interpersonal relationships within the network and are mediated through the understanding of agents and interpreted in the context of the structures. This discussion suggests a number of questions:

- **How has the network changed over time:** The network reflects the social changes and responds to the actors' needs. The structure of the system has changed over the years and so has, it is assumed, the structure of the network; for example there have been new actors

entering the network with other actors in a supporting role. However, changes to the network such as new and possibly stricter rules, force other actors to leave the network.

- **How has the political, ideological, economic and knowledge-based context within which the network operates changed over time:** The network context is the result of a political, ideological, economic and knowledge-based framework of a society, and it reflects on how it “operates”. The evaluation and feedback of this performance influences and creates that framework. In this case, the establishment of NICE and other bodies aiming to improve the standards of the health services provided, as well as the request for better quality services, was a reflection or a reaction to that context. This has been a two way relationship: NICE changed the way that the societal network operates, and NICE has had to respond and adjust to this change.

- **How has the relationship between the network and other related networks changed over time:** As argued in Marsh (1998), there are no networks that operate individually. The changes, within the network, influence the relationship between the network and other related networks as links are created or interrupted. The societal (political, economic, etc.) changes may cause changes to the distribution of resources so some networks might become more or less powerful and, consequently, more or less dependent on others. Additionally, the existence of a network means the development of sub-networks that operate within the main one. The time period that a policy formulation lasts for reflects on how it has influenced further changes the complex process of policy change (Sabatier, 1988:130). The time period for every change could depend on a number of variables; yet Heclo (1974, quoted in Sabatier 1988:130) considers two as most important; firstly, large scale social, economic and political changes and secondly, strategic interaction of people within a policy community or of those that get involved. Nowadays, it could be said that things are changing rapidly. There is more economic pressure and this brings in more social and political pressure. How Heclo’s and

Sabatier's analyses about time frame apply during this period and these circumstances are to be discovered. In the case of NICE AC and the beta interferon appraisal and the development of the network, a number of changes took place, such as the introduction of the final guidance and the Risk Sharing Scheme.

- **How members of the network have interpreted any changes in the broader political and social context within which the network operates:** Every member of the network is likely to interpret changes in relation to their own interests. For example, the problems of the high costs of pharmaceuticals and in prescribing them led to the preparation of economic and clinical excellence reports and the setting up of a whole new network, for evaluating different treatments. This network would serve governmental interests of reducing costs. Within it, industries would try to serve their own interest by finding away to sell their products and patients would try to serve their own interest by receiving the treatment that they have chosen. Possibly those network members who won less than they expected would learn lessons and get ready for next/future goal.

- **How have the exogenous/ contextual factors and the endogenous/network factors interacted:** As stressed previously, networks do not operate individually; they are influenced by exogenous factors such as the withdrawal of a network member or other networks. Exogenous factors might be difficult to control for the actors within the network, since they can disturb the operation of the network. On the other hand, the network itself could cause the intervention of exogenous factors that will lead to a „necessary“ restructuring of it. Actors interpret changes in line with their interests; hence, they also interact in accordance with their interests unless the network itself is under threat. Interaction is a „dialectical“ process, and, sometimes, it is difficult to categorise factors as either exogenous or endogenous since they could be both.

iii) This third part (Beyond Network versus Outcomes) discusses the third relationship

between networks and outcomes. It links to a concluding discussion on how all the previous “variables (networks, actors, resources, relationships, personal characteristics and actions) have interacted and produced an outcome and furthermore, how this outcome (i.e. in here a health policy) emerged.

The existing literature pointed in several directions to either simple or complicated questions or approaches in policy analysis. The behavioural approach was concentrating on one simple question: “why do people behave in the way they do?” (Sanders, 2002 in Stoker and Marsh (eds.), 2002:45). The rational choice theory asked “when faced with several courses of action, people usually do what they believe is likely to have the best overall outcome” (Elster, 1989a quoted by Ward, 2002 in Stoker and Marsh (eds.), 2002:65). There were other approaches and theories discussed in literature such as institutionalism, interpretive theory, Marxism and normative theory. Marsh (1998) argued that all literature concentrated upon the question as to what extent networks affect policy outcomes and why. This discussion suggested three questions:

- **Have previous policy outcomes affected the structure of the network:** Every policy outcome has an impact on the network and its structure. The impact can cause minor or major changes since it is also linked to the shaping of policy agenda, as argued by Parsons (1999). This section should also discuss the role of issue networks as part of the policy networks approach. Issue networks are defined “as a shared knowledge group having to do with some aspect (or as defined by the network some problem) of public policy” (Heclo, 1978:103). Usually, issue networks push for a change in policy within the government bureaucracy. An issue network is a type of policy network, and is “characterized by a large and/or wide range of affected interests, fluctuations in contacts, access, and level of agreement, unequal resource distribution combined with varying abilities to deliver member

support, and unequal power distribution among the group members” (Bleiklie, 2013 in Hawkesworth and Kogan,2013:376). According to this definition, and with reference to what has been discussed previously about NICE and the “pre-NICE” network, the presence of issue networks could be assumed in this case.

- **Have previous policy outcomes affected the broader political and socio-economic context within which the network operates:** A network reflects the broader political and socio-economic context within which the network operates (Marsh, 1998).The expressed need for clinical evaluation and cost effectiveness as well as the debates and argument on the role of clinicians, of the pharmaceutical industry and of patients have led to the founding of NICE. Furthermore, the work of NICE meant the development of a network trying to apply a new, and more trustworthy, decision making process to health care so that the broader political and socio-economic environment feels “content”. The various debates led to NICE and when NICE started with the technologies appraisals a new series of arguments emerged on the role of NICE and of the technology appraisals (Wailoo *et al.*, 2004; Hutton and Maynard, 2000, Abbasi, 1998; Davies 2002).

- **Have the strategy/tactics pursued by members of the network changed as a result of their prior experience in the network:** Some of the characteristics of the network are its dynamism as well as the actors’ „flexibility“. When a strategy has been successful, it can be repeated and improved; vice versa, unsuccessful strategies and tactics would not be used a second time.

3.14 Summary

This chapter described different approaches to the study of the policy process, and provided an initial link from public policy to the policy network concept and subsequently to the policy

making process. It developed the policy networks approach further, by reviewing the development of the approach in Britain and exploring the dialectical relationship model. It also discussed the British approaches in policy network, exploring the concept in depth and presented case studies which underlined the theoretical perspective of networks and supported the methodology followed in the thesis. Also, the Dialectical Relationships Model on policy networks was introduced, in relation to case studies where the Model has been applied for the better understanding of the concept and its applications.

CHAPTER 4

RESEARCH METHODOLOGY

4.1 Introduction

This chapter provides a discussion of the particular methods used in this study (interviews and documentation analysis, within a case study). The chapter includes detail on the data collection processes in both the pilot and main studies; offers an overview and rationale of the sampling and data collection instruments as well as the analytical process followed, from selecting interviewees to structuring the questions and collecting the data.

4.2 Qualitative research methodology

This section discusses in detail the methodology applied to the study and, in parallel, introduces qualitative research methods. The findings of the pilot and main studies, along with the findings of the documentation analysis, are presented in the following chapter.

The research questions, as specified in chapter 3, section 3.13, informed the choice of data collection and analysis. Strauss and Corbin (1998:41) argued that the questions in a study set the tone for the research project and help the researcher to stay focused.

The following table presents some of the research questions briefly, as they were adjusted to the Dialectical Relationships Model and the methods applied in this study:

Table 4.1: Research questions and Data collecting methods

Research components	Methods used
Verify the existence of a policy network on healthcare policy and identification of its actors (who is the network?)	In-depth interviews and document Analysis
What are the relationships between the actors within the network? How do they interact? What resources do they have?	In-depth interviews and Document Analysis
How does individuals' behaviour influence the process?	In-depth interviews and Document Analysis
What factors influence the network's structure and context within which it operates?	In-depth interviews and Document Analysis
How has the relationship between the network and other networks changed?	In-depth interviews and Document Analysis
How policies emerge? How does the network affect outcomes?	Application of the Model and case study
How the Dialectical Relationships Model on policy networks applies to the current research	In-depth interviews and data analysis policy networks

Mason (1998:11-13) argued that, initially, a researcher should ask themselves two important questions and introduced the concepts of ontology and epistemology. The first difficult questions a researcher should ask are what is "their research about, in a fundamental way, and what is the nature of the phenomena or entities, or social „reality“ to be investigated"? It

involves asking what a researcher “sees as the very nature and essence of things in the social world or, in other words what is (the researcher’s) *ontological* position or perspective”?

Secondly, a critical question for a researcher refers to what is regarded as knowledge or evidence of things in the social world - epistemological questions that are designed to explore the nature of evidence and knowledge “generated” from data (Mason, 1998:13). Epistemology is a theory of knowledge and concerns the principles and rules by which a researcher decides whether and how social phenomena can be known and how knowledge can be demonstrated. As Mason discussed (1998:13), “epistemological questions should direct a researcher to a consideration of philosophical issues involved in working out exactly what would be counted as evidence or knowledge of social things”. Answers to both these epistemological and ontological questions should be consistent.

Qualitative methods were appropriate in this research, given the exploratory setting of the study in accordance with the researcher’s personal interests and the nature of the applied Dialectical Model on policy networks considered above. Qualitative research is largely an investigative process that intends to understand a particular situation, event, role or interaction (Creswell, 2003:181). It can be distinguished from quantitative methodology by numerous unique characteristics that are inherent in the design. A synthesis of those characteristics is presented by Creswell (2003:186-187) illustrated by the work of various researchers, some of which is presented here. To summarize briefly, qualitative research occurs in natural settings and typically does not establish a priori hypotheses; instead, the focus is on participants’ perceptions and experiences and the way they make sense of their lives (Creswell 2003:199). It is based on the collection of narrative data which are not quantifiable in the traditional sense of the word.

In qualitative analysis, the reference point is not the quantification of the data - although this can happen at some point - but rather a non-mathematical process of interpretation carried out with the purpose of discovering concepts and relationships in raw data and then organising these into a theoretical explanatory scheme (Strauss and Corbin, 1998:10-11).

Qualitative methods can be used to explore substantive areas about which little is known or about which much is known to gain novel understandings (Stern, 1980; cited in Strauss and Corbin, 1998:11).

There have been many attempts to define qualitative research in the social sciences; Mason (1998: 3) stated that such research does not represent a unified set of techniques and philosophies, and indeed has grown out of a wide range of intellectual and disciplinary traditions. Denzin and Lincoln (2000:3) characterised qualitative research as a situated activity that locates the observer in the world. It consists of a set of interpretive, material practices that make the world visible and, in doing so, transform it. Qualitative research deploys a wide range of interconnected interpretive practices, hoping always to get a better understanding of the subject matter at hand. Strauss and Corbin (1998:11-12) identified three major components in qualitative research. Firstly, there are the data, which can come from various sources; interviews, documents, records. Secondly, there are the procedures that researchers can use to interpret and organize the data. These usually consist of conceptualizing and reducing data, elaborating categories in terms of their properties and dimensions and relating these through a series of prepositional statements. Conceptualizing, reducing, elaborating and relating are often referred to as coding. Other procedures are part of the analytical process. These include non-statistical sampling, the writing of memos and diagramming. Lastly, there are written and verbal reports (Strauss and Corbin, 1998:11-12).

For Denzin and Lincoln (2000:18), the researcher's personal characteristics and background are important to the setting of the research, its progress and development and the data analysis as well as to the final outcomes. It has an impact on the way that the research is conducted: she or he speaks from a particular class, gender, racial, cultural and ethnic community perspective and approaches the world with a certain set of ideas. Those characteristics have an impact on the way the results would be analysed and understood.

The fundamentals of interviews and interviewing as a feature of qualitative research constitute the methods of maintaining and generating conversations with people on a specific topic or range of topics and the interpretations which social researchers make of the resultant data (May, 2003:120). In a qualitative research interview, the aim is to discover the interviewee's own framework of meanings and the research task is to avoid imposing the researcher's structures and assumptions as far as possible. Furthermore, a researcher needs to remain open to the possibility that the concepts which emerge may be very different from those that might have been predicted (Britten, 1995:252).

Creswell (2003: 186-187) outlined the advantages and limitations of interviews as a data collection method (Table 4.2).

Table 4.2: Data Collection types: Interviews

Option within types	Advantages of the type	Limitations of the type
<ul style="list-style-type: none">▪Face to face: one on one, in person interview▪Telephone: researcher interviews by phone▪Group: researcher interviews participants in a group	<ul style="list-style-type: none">▪Useful when participants cannot be observed directly▪ Participants can provide historical information▪Allows researcher “control” over the line of questioning	<ul style="list-style-type: none">▪Provides “indirect” information filtered through the views of interviewees▪Provides information in a designed “place” rather than the natural field setting▪Researcher’s presence may bias responses▪People are not equally articulate and perspective

Source: Creswell, 2003:186-187

Many types of interviews are used in social research. While there are characteristics that appear to demarcate one method strictly from another, a research project may apply a mixture of two or more of the following (May, 2003: 120-121).

- Structured interviews refer to the collection of data through surveys. In structured interviewing, the interviewer asks all respondents the same series of pre-established questions with a limited set of response categories. There is generally little room for variation in responses (Fontana and Frey, 2000:649).
- Unstructured interviewing (in-depth interviews) can provide a greater breadth of data than any other type, given its qualitative nature. The respondent does not employ a specific set of questions but discusses with the interviewer ideas and meanings attached to a topic. Moreover, it is a dialogue between a skilled interviewer and an interviewee. Its goal is to elicit

rich, detailed material that can be used in analysis (Lofland, 1971; quoted by Fontana and Frey, 2000: 652)

- Semi-structured interviews are conducted on the basis of a loose structure consisting of open ended questions that define the area to be explored, at least initially, and from which the interviewer or interviewee may diverge in order to pursue an idea in more detail (May, 2003:123).

- Group interviews constitute a valuable tool of investigation, allowing researchers to explore group norms and dynamics around issues and topics which they wish to investigate. The extent of control of the group discussion will determine the nature of the data produced by this method. One method within this category that has become more widely known is focus groups. Group interviews and focus groups differ mainly because, in the latter, participants are explicitly encouraged to talk to one another, as opposed to answering questions of each person in turn (Kitzinger and Barbour, 1999 quoted by May, 2003:125).

Interviews have been used in an attempt to access interpretations, such as what people think about the world they live in, how they evaluate their experiences within it and why they behave as they do. Put simply, the choice to use interviews to collect data can be interpreted as “If you want to understand what people do, believe and think, ask them” (Murphy *et al.*, 1998:112). However, they cannot be treated as providing unproblematic access to information and must always be analysed in relation to the circumstances of their production (Murphy *et al.*, 1998:123). At this point, other methods of collecting data, such as observation, could be discussed. Mason (1998: 69) argued that researchers should ask themselves the same questions no matter which method they are going to use to collect their data; interviews or observation, documents or visual data. Every method has its pros and cons and relates not only to the research questions but also to issues such as the researcher’s experience, the time

limits and the available resources. Observation (for example, being present at meetings and hearings of the NICE AC in this case) might have been a very interesting way to collect data. Mason (1998) argued that observation is time and resource consuming. However, there were practical issues since it was not permissible for the public to participate in meeting of the NICE AC due to issues of confidentiality and this was confirmed by the poor turnout of interviewees for this research. Moreover there was no funding to cover any expenses and the researcher did not have the experience. It could be argued though that the researcher's ontological and epistemological questions and preference was interviewing via face to face communication.

Asking questions and getting answers is a much harder task than it might seem at first. The spoken or written word always has a residue of ambiguity, no matter how carefully the questions are worded and how carefully the answer is reported or coded (Fontana and Frey in Denzin and Lincoln, 2000:645). Yet interviewing is one of the most common and powerful ways in which researchers try to understand fellow human beings.

A document analysis was performed for a second time after the interviews to deal with the issue of very low response rates in the interviews. The documents were qualitatively analysed, using the method of content analysis, in order to enrich and enlarge the quantity of the collected data and in support of the thesis.

4.2.1 Qualitative research studies in health care

In the past decades, qualitative methods have become more commonplace in areas such as health services research and health technology assessment and there has been a corresponding rise in the reporting of qualitative research studies (Mays and Pope, 2000:50-52). The complexity of the issues that health professionals have to address and increasing recognition

by policy makers, academics and practitioners of the value of case studies in evaluating health service interventions, suggest that the use of such studies is likely to increase in the future.

In policy research, qualitative methods can be used within a case study to address many practical and policy questions, particularly where those questions are concerned with how or why events or initiatives take a particular course (Keen and Packwood, 1995 cited in Mays and Pope, 2000:51).

4.3 Research setting: the case study methodology

The data collection initially involved conducting a case study in order to approach the network and study its operation. The choice of a case study approach instead of others was believed to be more appropriate because it permitted to look at NICE in depth on paper first and then to try to tease out the characteristics of the network used in the AC. NICE as a network to be studied had, arguably, great advantages considering some of the characteristics and dimensions of the network (Kenis and Schneider, 1991). Network boundaries are set, there are interactions and interrelationships between a variety of actors, and all these interactions were observable, to some degree. In each NICE appraisal, different actors were involved i.e. pharmaceutical industry was always involved but in each appraisal, different companies were participating. The selection of the beta interferon study was the first NICE appraisal that NICE said “no” to a treatment for an incurable disease such as MS. It became the one where there was a reaction from the actors and there was much more tension between them, probably because of the nature of the disease. The analysis of documents regarding the network and the publicity of the beta-interferon appraisal for the treatment of MS attracted attention. Moreover, it seemed from actors’ reactions that this appraisal would be critical to the network’s operation and, therefore, provided the chance to explore a more fascinating,

multifaceted side of the network and the interaction between actors and how it actually influenced health policies (Walt and Gilson 1994). The appraisals made by NICE until then were all approved and there was no criticism. So as a researcher, it was considered that earlier appraisals would not provide as interesting an insight into the operation of networks as the one for beta-interferon. This appraisal and its characteristics were closer to the ontological and epistemological questions of the researcher. Keen and Packwood (1995 cited in Mays and Pope 2000:51) argued that case studies are valuable where policy change is occurring in complex real world settings and where “complex questions have to be addressed in complex circumstances”. In health policy, difficult and complex questions need to be addressed and to be answered. It is important to understand why such interventions succeed or fail, given that there are certain outputs and outcomes that need to be justified by their inputs and processes (Keen and Packwood, 1995:444-446). The case study on the appraisal of beta-interferon treatment for patients with MS was expected to offer an insight into processes of NICE which constituted part of the broader decision/policy-making process; furthermore, it would support and contribute to the exploration and understanding of the healthcare policy-making process. Appleton (2002:88) argued that case studies have become one of the most common ways to do qualitative enquiry, but they are neither new nor essentially qualitative. In healthcare research, case studies are recommended as a valuable strategy and their adoption as a research approach appears to be increasing in popularity.

According to Yin (2003 cited in Baxter and Jackson, 2008:545[online] available from: <http://www.nova.edu/ssss/QR/QR13-4/baxter.pdf> [accessed 30/12/2014]), “case study design should be considered when: (a) the focus of the study is to answer “how” and “why” questions; (b) you cannot manipulate the behaviour of those involved in the study; (c) you want to cover contextual conditions because you believe they are relevant to the phenomenon

under study; or (d) the boundaries are not clear between the phenomenon and context”. Yin (2003) categorized case studies as explanatory, exploratory or descriptive and also differentiated between single, holistic case studies and multiple-case studies, as explained below:

- Explanatory: This type of case study would be used if you were seeking to answer a question that sought to explain the presumed causal links in real-life interventions that are too complex for survey or experimental strategies. In evaluation language, the explanations would link program implementation with program effects (Yin, 2003).
- Exploratory: This type of case study is used to explore those situations in which the intervention being evaluated has no clear, single set of outcomes (Yin, 2003).
- Descriptive: This type of case study is used to describe an intervention or phenomenon and the real-life context in which it occurred (Yin, 2003).
- Multiple case studies: A multiple case study enables the researcher to explore differences within and between cases. The goal is to replicate findings across cases. Because comparisons will be drawn, it is imperative that the cases are chosen carefully so that the researcher can predict similar results across cases or predict contrasting results based on a theory (Yin, 2003).
- Collective case study: Collective case studies are similar in nature and description to multiple case studies (Yin, 2003).

Perhaps the most unique aspect of a case study in social sciences and human services is the selection of a case to study. (Baxter and Jackson, 2008:556) argued “that case study research is more than simply conducting research on a single individual or situation”. It has the potential to deal with situations from simple through to complex because it allows the researcher to answer “how” and “why” type questions, while taking into consideration how a

phenomenon is influenced by the context within which it is situated. A case study gives the researcher the opportunity to gather data from a variety of sources and to illuminate the case.

4.3.1 Sample selection

In qualitative methods, sample sizes are not determined by hard and fast rules but by factors such as the depth and duration of the interview and what would be feasible for a single interviewer (Britten, 1995:251). In this case, the sampling was directed by the theoretical framework of policy networks and actors. Since the study discussed networks and actors, it seemed appropriate and reasonable to draw a sample from those actors. Identifying the network actors should be done in the least biased way; moreover, because the network was already illustrated, it was decided that candidates would be identified through that network. Official documentation on the appraisal (reports, press releases etc.) published by NICE and other stakeholder groups were used as a sample frame, and as the basis for the creation of the network map (discussed in Section 4.8 below).

The next step was to identify the actors and the people to be interviewed. The nature of the process and the network recommended contacting people such as leaders or persons very high up in the hierarchy, and those who were acting as representatives of their organisations. The appraisal of beta interferon has received publicity and this was maybe creating a lot of pressure on people involved to the appraisal to give interviews and to talk about this appraisal and also, there was a matter of professional deontology (since the University of Birmingham was cooperating with the NICE AC) and people might get suspicious regarding the nature of this research. The conducting of research meant following a protocol, non-formal, on who should be contacted, how and how the retrieved data should be evaluated.

4.3.2 Data collection

Qualitative research uses multiple methods that are interactive and humanistic (Creswell, 2003:185). The methods of data collection are growing and increasingly involve active contribution by participants and sensitivity to the candidates of the study. In addition, there are steps in data collection which include setting the boundaries for the study, collecting information through unstructured or semi structured interviews, observations, documents and visual materials as well as establishing the protocol for recording information.

In this study, it was decided that the setting would be the network revolving around the NICE Appraisal Committee (AC) and was dealing with, amongst other areas, the cost and clinical effectiveness of new technologies. It could be argued that the NICE and the NICE AC formed a link, a meeting point where actors met or networked and interacted to produce outcomes that define health policies.

Data collection was via semi-structured interviews and documents, discussed in detail in Section 4.5 below. The decision was informed by the explanatory nature of the study and the intention to explore network actors' perceptions of their relationships with other actors. Standard ethical clearance procedures were followed; all necessary permissions/ethics approval was obtained from the South West Multi-centre Research Ethics Committee (MREC/03/6/34). The Committee also approved the research protocol, a research information sheet and a consent form. Documents were collated to provide insights into the setting and/or group of people that could not be observed or noted in another way.

As the interviews were semi-structured, the research protocol (see a copy in Appendix F) identified the purpose and reasoning for the candidates' invitation to the interview and explained the interview procedure, tape recording of data and its safe handling. The inclusion

criteria for documents was that they ought to have been published during the time of the appraisal; refer to the beta-interferon appraisal; and been produced by one of a variety of authors-actors (NICE, the Industry, patients etc.).

4.3.3 Document analysis

In order to strengthen the study and provide some triangulation of data, the interviews were supplemented by a document analysis, in keeping with the study's explorative nature and to provide a better insight into the behaviour of the actors. Documents, as previously discussed, were used at two different points and times. Prior to conducting the interviews, the documents were used in order to identify the network, its actors, structure and context, and to collect information on the network and draw the map handed to the interviewees regarding the network participants. In the second instance, due to dealing with the issue of very low response rates in the interviews, a document analysis was performed. The documents were qualitatively analysed, using the method of content analysis, in order to enrich and enlarge the quantity of the collected data and in support of the thesis.

A document is defined as "any written or recorded material" not prepared for the purposes of the evaluation or the request of the enquirer (Lincoln and Cuba 1985; cited in Denzin and Lincoln, 2000:703). The analysis of documentary sources is a major method of social research and one which many qualitative researchers see as meaningful and appropriate in the context of their research strategy (Mason, 1998:71).

Table 4.3: Data collection types: Documents

Options within type	Advantages of the type	Limitations of the type
Public documents such as minutes of meetings, and newspapers	Enables the researcher to obtain the language and words of participants	May be protected information unavailable to public or private access
Private documents such as journals, diaries and emails	Can be assessed at a time convenient to the researcher – an unobtrusive source of information	Requires the researcher to search out the information in hard-to-find places
E-comments, webpages comments, letters, discussions	Represents data that are thoughtful, in that participants have given attention their compilation As written evidence, it saves a researcher the time and expense of transcribing	Requires transcribing or optically scanning for computer entry Materials may be incomplete The documents may not be authentic or accurate

Source: Creswell (2003:187)

Additionally, Silverman (2001:119) added that the use of textual data offers some important advantages such as: richness, since a close analysis of written texts reveals presentational subtleties and skills; relevance and effect given that texts influence how individuals see the world, the people in it and how individuals act; they are naturally occurring texts that document what participants are actually doing in the world without being dependent on being asked by researchers; and, finally, availability because texts are usually readily accessible and

not always dependent on access of ethical constraints; moreover because they can be gathered quickly, their analysis could begin earlier.

4.3.4 Qualitative data analysis

“Unquestionably data analysis in qualitative research is the most complex and mysterious of all the phases of a qualitative project” (Thorne, 2000:68).

It has been argued (Berkowitz, 1997:1¹) that qualitative methods in data analysis allow the researcher to discern, examine, compare, contrast and interpret meaningful patterns or themes. Meaningfulness and authenticity are determined by the particular goals and objectives of the particular project: the same data can be analysed and synthesized from multiple angles depending on the particular research or evaluation questions being addressed. The various approaches - including discourse and textual analysis - correspond to different types of data, disciplinary traditions, objectives and philosophical orientations.

4.3.5 Data from interviews

The way that researchers set their research questions will define the way in which the researched data will be examined. It also sets a specific perspective and the use of certain data-gathering techniques and modes of data analysis (Strauss and Corbin, 1998:52).

The transcripts of the interviews were read repeatedly, line by line, so as to identify the themes responding to the questions of the Model, which were then coded under several themes. For example, on the question regarding network memberships, themes answering the question were identified initially i.e. academic and health professional members. Categories were then formed, in relation to the Model, and others also emerged because the interviewees

¹ This is an on-line version of the book and there are no page numbers, it is the first page in chapter 4

made further comments. On occasion, categories were formed by the researcher's observations during the interview, i.e. when mentioning a specific fact or actor; most respondents seemed to find this provoking because they thought that, with this attitude, the process was somehow manipulated in favour of those specific actors and that this led to an underestimation of the rest of the participants.

There are so many different approaches to analysing qualitative data (Mason, 1998; Silverman, 2001); which one should be chosen in each case depends on the researcher's characteristics i.e. cultural background. The way in which the research questions originate and are expressed together with the linking between ontological and epistemological questions and answers are some of the issues to be considered when analysing data. Ryan and Russell Bernard (2000:767 in Denzin and Lincoln (eds.) 2000) argued that "*qualitative data*" means texts and discussion about linguistic tradition whereas analysis treats texts as objects of analysis within themselves. Sociological tradition analysis treats texts "as a window into human experience" Ryan and Russell Bernard (2000:767 in Denzin and Lincoln (eds.) 2000).

It has been said that "There are a number of different theoretical perspectives on in-depth interviewing, and different types of interviews. But the features which are broadly consistent across research models are their flexible and interactive nature, their ability to achieve depth, the generative nature of the data and the fact that it is captured in its natural form" (Legard, Keegan and Ward, 2003:168 in Ritchie and Lewis (eds.) 2003).

Creswell (2003:183) mentioned that there are unusual data which go beyond the typical methods; the researcher might use them to capture useful information that a typical methodology might miss. It could be argued here that the analysis of that kind of data is somehow connected to the analysis of narrative structures where researchers treat texts as creating their own "realities" (Silverman, 2001:158).

Silverman (2001:158) suggested four methods/approaches for analysing textual (documentary) data:

- Content analysis: it involves establishing categories and then counting the number of instances when those categories are used in a particular item of text, for instance a newspaper report. The crucial element is that the categories are sufficiently precise to enable different coders to arrive at the same results when the same body of material is examined. It is used in qualitative studies for the analysis of texts and documents.
- Analysis of narrative structures: researchers treat texts as creating their own “realities”. Silverman (2001:158) discussed texts and the “transforming power of language”. Qualitative data take the form of a narrative which means the “organisation of stories meaningful or coherent in a form appropriate to a particular context. When analysing how a text works one should not forget that texts have their own narrative structure designed to persuade the reader that, confronted with any given textual fragment, we can see „that a favoured“ reading is applied” (Silverman, 2001:166, 403).
- Ethnography: it involves the study of written accounts and the way in which documents exemplify certain features of societal settings (Hammersley and Atkinson, 1983; cited in Silverman, 2001:158).
- Ethnomethodology: it locates these methods and the skills through which people are trying to develop an understanding of each other and of social situations. (Sacks, 1974; cited in Silverman, 2001:151).

In addition, and with reference to qualitative research methods in health care, Pope, Ziebland and Mays (2000) linked content analysis with the quantification of qualitative data while also noting that, in the distinction between qualitative and quantitative methods, it is preferable to

use the term “indexing” data in qualitative research instead of “coding”, which mostly refers to numbers.

Apart from being a lengthy process, indexing qualitative data requires reading the material collected again and again to identify themes and categories – these may centre on particular phrases, incidents or types of behaviour (Pope, Ziebland and Mays, 2000:114-115). Sometimes the unfamiliar or interesting terms used by respondents can form analytical categories. Furthermore, many categories might be created initially which then need to be related so that categories are not repeated and related themes also might be put together.

Different forms of analysis may be identified (May 2003; Creswell 2003; Mason 1998; Ryan and Bernard in Denzin and Lincoln, 2000). Of course all approaches share common characteristics, such as the nature of content analysis, and they all have a common base of making sense of the text (Creswell, 2003:190) but, in each of them, there is a different detail or concept. In this thesis, content analysis was applied to both interview transcripts and documents. The established categories were in reference to the Model questions and new categories were added. The fact that there were questions asked also shaped the way in which the data were analysed. So for every question there were analogous answers. For example, in the question of “who is the network?” all the answers of the interviewees and texts documents were analysed in categories and were coded; similarly for the second question and so on. The interviews and documents analysis drew on the three relationships and the questions provided by the applied Dialectical Model. The relationships and questions of the Model were analysed in chapter 3 (also see a copy of the questions in Appendix D), therefore texts were analysed using the same model.

4.3.6 Document (textual) data

May (2003) argued that documents and interviews are ultimately the same, as interviews are transcribed and analysed as texts, in a similar way to documents. Sparks (1992; quoted in May 2003:183) claimed that documents are now viewed as media through which social power is expressed. They are approached in terms of the cultural context in which they were written and may be viewed as attempts of persuasion. Moreover, Acker (1991:7 in May, 2003:183) argued that approaching a document in this way “tells us a great deal about the societies in which writers write and readers read”.

The method of content analysis was applied for the analysis of text documents. Apart from the identified themes linked with the answers to the questions of the Model, more categories were formed with additional data provided through the way in which the text was written. Moreover, there was sub-text which could be gleaned from examining the way words were used, rather than just the words. For example, a document in a press release by NICE did not use the negative, somewhat threatening and disturbing, language used in a press release by one of the MS Society’s branches. The pilot and main study research details are presented next together with information on the document analysis.

4.4 Pilot study: procedures

A pilot study was conducted initially in an attempt to test the nature and structure of the questions and as a way to assess the application of the policy networks concept and of the Dialectical Model. The policy networks concept had not been used widely in healthcare services research when this research was taking place. Personal communication of the researcher with authors/researchers who were working on policy networks showed that there was not research conducted in this area. Also searches of various databases, such as Google,

Medline and libraries' databases, returned very few results on similar research. Keywords that were used were "policy networks in health care", or "healthcare networks", or "health policy networks". There were references to policy networks in other areas but not in health care policy. The results of this pilot study were later added to the main study in order to validate the main study's limited findings the details of the main study are discussed below in Section 4.5 but, in relation to the pilot study, it is mentioned here that few candidates responded because it had been decided by members of the NICE Appraisal Committee to have only one person participate and be interviewed.

Conducting a pilot study might involve extra resources for the research but the result was important for the future of the project, since it would enable the methodology to be refined and to provide some reassurance on the suitability of the approach. There was the risk of a negative result but this would not have stopped the research; instead, it would have led in a different direction or changed the methodology; a positive outcome would be encouraging.

4.4.1 Sampling

The sampling for the pilot study was drawn from the Health Services Management Centre (HSMC) staff directory and mainly from personal contacts of the researcher and supervisor of the thesis. An important criterion was that the candidate interviewees had, where possible, to represent different organisations or come from different backgrounds, in order to capture a variety of perspectives as would happen within a policy network. Some of these people had already completed some work for NICE AC so it could be said that they were familiar with the NICE policy network. Indeed, the selected interviewees all had different backgrounds: from the five people that participated in the study, 3 were men and 2 women. In terms of profession, they were a health economist (working as an academic), a pharmaceutical industry

representative, a health professional/physiotherapist, a member of the public and an academic member of NICE AC.

4.4.2 Contacting interviewees

Interviewees were contacted by email, and asked to respond within 3 weeks from the day that they received the email in order to confirm whether they were interested and willing to participate. The information provided in the email was about the topic of the thesis, the aim of the study and the structure and details of the interview process. Candidates were asked to suggest dates, times and places convenient to their schedules.

4.4.3 Data collection: structure of the interview questions

Data collection was based on qualitative semi-structured interviews using the Dialectical Relationship Model (see Appendix D for the analytical questions list and the map handed to the interviewees at the beginning of the interview by the researcher, or sent to them on the occasions when the interviewee was contacted by telephone). The Model suggests that, in order to understand the process, three different relationships needed to be explored within the network: the actors and the structure, the context, and the network and outcome. Every relationship prompted analogous questions which were adjusted to the case study of NICE and the appraisal of beta-interferon for the treatment of multiple sclerosis. Hence, the structure of the interview was divided into three parts and each part discussed a single relationship. The process of identifying the network actors in existing official and unofficial documentation on the appraisal (reports, press releases etc.) published by NICE, stakeholder groups, the media and others, allowed them to be fitted into the framework set when the researcher was designing the research. A diagram of the actors emerged (see Appendix C) and

illustrated the network and the actors' links. The diagrammatic representation of the network made it visible, and proved helpful for interviewees in clarifying the term „policy network“ through visualising the area under study.

The map was used as stimulus material in the interviews; instead of asking “who is the network?”, the interviewees were handed the map and asked to comment on the actors and relationships. Handing out the map had pros and cons. The pros had to do with explaining the research question and the terms policy network, actors and interaction. The explaining power of map and the provided information would help the interviewer and the interviewee to communicate better. The cons are mainly that the map may have influenced the interviewee's judgement on policy networks and influenced the way that they will evaluate the network metaphor, or maybe the role between the actors (Creswell, 2003). The first part related to networks as structures that constrain and facilitate agents (Marsh and Smith, 2000; Toke and Marsh, 2003:231-232). Questions were generated from this discussion on the dialectical relationship between structure and agency, which were then analysed and adjusted to the pilot case study part; for example “who is in the network?” or “what relationships do the network members have?”.

In the second part of the interview, the questions ask the interviewees if they think that changes in policy and different outcomes (i.e. such as the involvement of patient groups and local authorities in the appraisal of health technologies), resulted from changes in the network. Therefore, understanding how networks affect outcomes means recognising that there is a dialectical relationship between the network and the broader context within which it is located (Marsh and Smith, 2000; Toke and Marsh, 2003: 233). Questions were generated from this discussion on the dialectical relationship between structure and agency, i.e. “How has the

network changed over time? How has the relationship between the network and other related networks on a national level changed over time?”.

The third part of the interview referred to the relationship between networks and outcomes and the way in which outcomes may affect networks. Firstly, a particular policy outcome may lead to a change in the membership of the network or to the balance of resources within it (Marsh and Smith, 2000; Toke and Marsh, 2003: 234). Secondly, policy outcomes may have an effect on the broader social structure that weakens the position of a particular interest in relation to a given network. Thirdly, policy outcomes can affect agents. However, while agents learn by experience they might repeat mistakes as, primarily, they defend and protect their own interests. This situation makes for extremely interesting research. If certain actions within the network fail to produce an outcome beneficial to an actor within the network and the organisation they represent, or more broadly to the network as a whole, then that actor is likely to pursue other strategies and actions (Toke and Marsh, 2003: 234). Questions were generated from this discussion of the dialectical relationship between structure and agency, such as “Have previous policy outcomes affected the structure of the network?”; “Have the strategy/tactics pursued by members of the network changed as a result of their prior experience in the network?”.

4.4.4 Interviews processing and data analysis

Interviews were conducted and tape recorded by the researcher and additional notes were also kept. The transcription of the interviews was completed by the researcher and it proved quite a difficult process as English was not the researcher’s first language. Approximately eight hours were required to transcribe one hour’s worth of recorded interview. In some cases, an English friend’s help was “employed”, especially in cases where people used idiomatic

expressions. The interviewees were notified regarding the dispatch of a copy of the transcript so they could confirm their views but none of them wanted to receive, check and, if necessary, return a copy of the transcript because they had signed consent forms so they possibly felt the transcripts would be accurate.

There were techniques and software packages for analysing qualitative data which could be applied for either the transcription or the analysis of the data. However, at that point, none could be accessed because the research was self-funded and paying an expert for the audio transcribing was not affordable. In addition, the quantity of data was not sufficient to conduct an analysis with one of the better known, at that time, computer packages such as NVivo or Atlas.

The analytic process requires three forms of activity: **data management** in which the raw data are reviewed, labelled, sorted and synthesized; **descriptive accounts** in which the analyst makes use of the ordered data to identify key dimensions, map the range and diversity of each phenomenon and develop classifications and typologies; and **explanatory accounts** in which the analyst builds explanations as to why the data take the forms that are found and presented (Spenser, Ritchie and O'Connor, 2003:209 in Ritchie and Lewis (eds.) 2003).

Every method has advantages and disadvantages and there is no single method which would be considered as the most appropriate since the role of the researcher/analyst is very important.

The method of analysing the transcripts involved careful and repeated examination of the data, their indexing/coding into categories, wide or narrow. Themes were identified in relation to the Model's questions and to other general issues brought up by the interviewees. Due to the positive feedback received regarding the nature of the study, the reduced quantity of data and in support of the main research because of the small number of the interviewees, it was

decided to add in the data from the pilot study. They were analysed with the main study's transcripts and were included in the study's findings. It has been argued (Spenser, Ritchie and O'Connor, 2003:209 in Ritchie and Lewis (eds.) 2003) that "in order to carry out a robust analysis that allows all the different levels of investigation to be achieved, researchers need certain aids and tools at their disposal. When data have been properly collected, they will be rich in descriptive detail and full of explanatory evidence. But, almost inevitably, the data will be unmanageable and tangled in its raw form. The analyst therefore needs certain facilities not only to do full justice to the evidence collected but also to make the task one that is manageable within the resources and time scales that will be available".

Data analysis involves managing the amount of collected data and producing descriptive accounts and explanatory accounts. There are many available tools and techniques for a researcher to choose and, as it has been argued that there is no ideal method (Ryan and Russell Bernard, 2000 in Denzin and Lincoln, 2000), the same data can be analysed in many different ways. This could also be argued to be an advantage in analysing data because, once they are transcribed, they become available to others or the public to analyse them with different ways and produce their own results and explanations. The disadvantage in this method is the difficulty in managing a usually large amount of data and the fact that the researchers analyse data according to their own views and research questions (Silverman 2001; Mason 1998).

4.4.5 Feedback

At the end of the pilot studies, interviewees were handed an Evaluation/ Feedback Form (see a copy on Appendix H) for comments on developing further and designing the main study along with a pre-stamped envelope for return. The interviewees were asked to evaluate the content and structure of the interview and the interviewer's style, and furthermore to make

any suggestions for improving the interviews. All respondents completed their forms and submitted them to the interviewer immediately while also encouraging the researcher to develop the topic further and publish the results of the study.

Comments on the content and structure of the interview were mainly positive. Some minor changes were made following feedback; in particular, the sequence of the questions and some repetition that existing in the questions referring to change in actors' relationships and changes in network structures. The format of the map was altered slightly to correct a printing error (although the interviewees had been informed about the error at the beginning of each interview) which suggested that some of the actors belonged to different types of frames thus looking as if they were separated. Overall, the changes applied involved the restructuring and rephrasing of some questions, while only one question, relating to human resources, was removed altogether. One of the interviewees commented that the Model and the three relationships are "absolutely right" and "give the academic spin". Comments were also very positive and encouraging with respect to the researcher's style; the only observation was that the researcher should perhaps speak louder.

4.5 Main Study: procedures

The main study required only minor changes from the pilot study feedback; data from the pilot could be reported within and in support of the main study.

4.5.1 Contacting interviewees

A letter was sent to candidate interviewees asking them whether they would be willing to participate in the study. The letter introduced the researcher and the thesis topic. It then explained the aim of the study, the content and structure of the questions. Candidates were

given information about the duration of the interview and were requested to suggest dates, times and places when they were available. At the end of the letter, the interviewees were assured about the anonymity and confidentiality of the process and data. The letter was followed by an email sent to the interviewees two days after the letter was sent by post to their working addresses. The email enclosed the same information and it was sent in case the letter did not reach the candidate and as a reminder to reply to the invitation.

4.5.2 Sampling and data collection

The data collection involved qualitative semi-structured interviews. Since the study addressed networks and actors, it seemed appropriate and reasonable to draw a sample from those actors within the network. Official documentation on the appraisal (reports, press releases etc.) published by NICE and other stakeholder group was used to identify people who could be interviewed. There were not many reasons given for non-participation apart from an email informing that it has been decided that one specific person, a member of the NICE AC, would do the interview on behalf of all the NICE AC members who were invited. There were some who initially accepted but, after the reply that the NICE AC person would do it, they didn't want to participate. In a few cases where stakeholders had a spokesperson for the specific appraisal, that person was contacted while a few people were also invited from the NICE AC; apart from the executives, there were members of the technical and other support teams who were asked to participate.

The number of people invited to participate in the research was defined by the number of participants in the appraisal and the participants added to the map (by the respondents); the ratio was, therefore, one person for every actor. A list of candidates and their profile was made, since it was important for the research to have people with different professional backgrounds. After presenting the candidates' list to the supervisors, a list of 35 people was

made in total, in order to deal with the issue of non-response rates. Initially, twenty-five people were invited to participate in the study. Nine people responded positively (apart from the pilot study interviewees), of whom eight were available for interview: one person cancelled due to sickness. The respondents were two members of the NICE AC committee, one person representing the DoH, one person representing a patient organisation, three academics, a member of the academic review teams working with NICE and a health professional-neurologist.

The explanation for the poor response is that the NICE AC leadership would allow only one person to be interviewed because of the issue being in the press and the strong reactions by involved parties. There was also no reply from the pharmaceutical industry, and most people simply emailed the researcher back stating that the NICE AC person would be the only person interviewed regarding the issue. However, of the two people from the AC who were interviewed eventually, one later resigned from the Committee. The critical press comments regarding NICE may well have influenced people who were reluctant to talk about the beta-interferon appraisal. It is worth mentioning here Mason's warning (1998) that the qualitative researcher is often seen as a journalist and people get suspicious of what might come out. At the time of the interviews, the appraisal of beta interferon had been completed but there was still tension, which made people more cautious. Respondents' views were, probably, different from what they would have been if the decision had not been finalised. Although during the interviews, respondents were positive about the process of economic and clinical evaluation, they expressed disappointment and, in some cases, bitterness regarding the way in which their work was overturned by politicians. There was general disappointment regarding the intervention of politicians the decision was based on evidence, and the loss of credibility of

the process itself and of the role of NICE. The case of beta-interferon appraisal by NICE had influenced the entire network according to the data.

During the interview with the NICE AC member, who had notified others initially that he would do the interview on behalf of all AC members, there was a change. Questions were asked about the rationale and approach of the research regarding the role of NICE as well as its progress. The low response rate was also discussed and there was an offer of help to identify more people to interview. The NICE AC interviewee suggested one more person, the DoH representative another person and the patient organisation respondent recommended three more people. Therefore, five more people were contacted. In total, eight people were contacted the second time and were invited to be interviewed; apart from the suggested five, three more people were contacted: one member of the press, one patient organisation rep and one academic. But unfortunately they did not agree to participate to the research. From those that replied, one of the candidates had been on maternity leave and another had gone abroad, whilst there was no reply from the other six candidates contacted.

In the meantime, nobody from the group of manufacturers or the Association of the British Pharmaceutical Industries had agreed to be interviewed. In one case, the pharmaceutical industry representative interviewed during the pilot study expressed their desire to help and contacted some of the manufacturers' representatives regarding the interview but the answer remained negative. The four pharmaceutical companies and the ABPI also gave a negative response. Three of the companies were sent the questions first and then declined to participate. It should also be noted that the completion of the appraisal and its negative publicity influenced the attempt to get more interviewees and additional data. In the following table, the numerical data regarding the interviews are summarised.

Table 4.4: Interviewees: arithmetical data

Categories/ Invitations	Candidates Invited	Responded positively	Responded negatively	Did not reply	Final number of interviewees
1 st	25	9	14	2	8
2 nd	8	2 ²	-	6	0
Total	33	11	14	8	8

Of the eight interviewees, two were women and six men. The intervention of NICE caused great difficulties in obtaining a more substantial number of interviewees. However, this development and also the fact that pharmaceutical industry respondents were not willing to complete the interview were indications of the study's sensitivity. Other methods to collect data were discussed such as observations i.e. attend the NICE AC meetings, but this was not allowed and there was no funding to cover travel expenses. However, the minutes from the meetings of the NICE AC were available on the NICE website.

Before inviting the candidates to interview, the necessary permission/ ethics approval (MREC/03/6/34) was received by the South West Multi-centre Research Ethics Committee. The interviewees and the researcher all signed a consent form confirming the confidentiality of the interview whilst interviewees were also handed a copy of the research protocol.

4.5.3 Data collection: structure of questions

The Model suggested the investigation of the three different relationships within the network; the actors and the structure, the context, and the network and outcome so as to get a picture of the decision making process. Questions were adjusted according to this order; actors and the structure, the context and the network and the outcome, so they were divided into three parts.

²The two respondents expressed willingness to do the interview but could not actually make it.

There was an introductory part where the participants were assured about confidentiality, and the concept and scope of the research and the terms “policy networks”, “actors”, and “actors” relationships” were explained. It could be argued that the respondents were in some way influenced when they were given all this information but that it was also introducing them to the rationale of the research. A map was handed to the interviewees during the first question picturing the network and actors” links and relationships, and the interviewees were asked for their thoughts and comments.

The questions to the first part (Marsh and Smith, 2000; Toke and Marsh, 2003) stressed that policy networks are structures that constrain and facilitate agents. In the second part, the questions referred to the fact that policy change often results from changes in the network.

The third part had three questions. Outcomes may affect networks in at least three ways as it was previously mentioned.

4.5.4 Interviews processing and data analysis

Conducted interviews during the main study were tape-recorded with permission from the interviewees. Each interview lasted at least one hour and 30 minutes while, in two cases, they lasted almost two hours. Six of them were face to face and two were conducted over the phone due to changes in the interviewees” schedules. The researcher kept notes only occasionally as this distracted attention from the discussion. The transcription of the interviews was completed by the researcher. The method of analysing the transcribed text was described above. The answers to every question were gathered and categorised analogously.

4.6 Documentation analysis procedures

A document analysis was carried out in order to provide more data regarding the policy-making process and the appraisal of beta-interferon treatment for MS. As previously identified, the documents were used in two phases: the first was related to the beta-interferon review, the pre-NICE era (chapter 2 section 2.12) and the identification of actors within the network; the second referred to the case study and was performed in order to support the interview data.

Data collection was based on an internet search of various databases such as the Medline and search engines (such as Google and the BMJ database) and the NICE webpage. The search terms included keywords such as “beta interferon for MS, clinical evaluation, MS Society and beta interferon appraisal, NICE and beta interferon appraisal”. Approximately 120 documents were retrieved including articles, on-line written news, reports, editorials and letters. The following areas were used to assess which documents should be included in the research - the case study and the appraisal of beta interferon for MS; clinical evaluation information of the treatment; involved NICE; came from actors who were involved in a direct way i.e. as members of the NICE AC; or they were involved but non-officially i.e. MS patients but non-members of the MS Society. In the end, 73 documents were analysed and those were the documents published during the appraisal of beta interferon by NICE (see Appendix G for a list of titles). Details on the types of documents analysed are provided in Table 4.5.

Table 4.5: Documents analysed

Articles, Editorials, Letters	Reports	Online Printed news	Press Releases	Total
49	1	15	8	73

During the introduction and licensing of beta-interferon in the UK, there was a discussion regarding the product and its benefits. Various actors were debating the advantages and disadvantages of the treatment and the clinical and cost parameters. The dialogue was mediated via published material such as articles, editorial letters, printed interviews and news, and on-line discussions.

The debate continued during the beta interferon appraisal involving the outcome of the appraisal process, as well as the process itself. It could be said that issues brought forward during this discussion such as the cost and clinical effectiveness of the treatment, or the actual reliability and validity of the clinical trial on interferon became reasons for the establishment of NICE itself, as an institute that evaluates new technologies; and for beta-interferon to be among the first products appraised by NICE.

The documents were arranged chronologically starting from the beginning of the beta interferon appraisal in 1999. For the analysis of texts and transcripts, the method of content analysis was used. The next chapter discusses the results in accordance with the model of the three dialectical relationships.

4.7 Validating the accuracy of findings

“There are many issues surrounding the values and uses of conclusion drawing and verification in qualitative analysis... and on the how to judge the validity and quality of qualitative research” (Berkowitz, 1997 cited in Frechtling *et al.* (eds.), 1997: ([online]

available from: <http://www.ehr.nsf.gov/EHR/REC/pubs/NSF97-153/START .HTM> [accessed 18/07/2005]). Silverman (2000:9) referred to two main problems, the reliability of data and the validity of data since many researchers used them to support the ideas that “quantified data and *“statistical analysis” are the bedrock of research*”.

Creswell (2003:4) argued that validation of findings in qualitative research occurs throughout the process. Validity, generalizability (external validity of applying results to new settings, people or samples) and reliability (examining stability or consistency of responses) are mentioned as some of the requisites in qualitative research (Silverman, 2000; Mason, 1998).

The issue of generalisation (or generalizability) of data possibly became the most important for judging qualitative research. The term refers to whether the findings of a study which was based on a sample or on a case study, could be generalised and general conclusions be drawn for a population beyond the particular sample or case study (Lewis and Ritchie, 2003: 264). There is diversity between authors regarding the meaning of generalisation such as there is about qualitative research and there is not a clear and agreed set of ground rules under which qualitative research findings can be generalised or agreement on what the process involves.

Generalisation can be seen as involving three linked but separate concepts: representational generalisation, whether what is found in a research sample can be generalised to, or held to be equally true of , the parent population from which the sample is drawn; inferential generalisation, whether the findings from a particular study can be generalised, or inferred, to other settings or contexts beyond the sampled one; and theoretical generalisation, whether theoretical propositions, principles or statements can be drawn from the findings of a study for wider application.

The validity and reliability of data have an important bearing on whether wider inference can be drawn from a single study since, in different ways, they are concerned with the robustness and „credibility“ of the original research evidence.

There are strategies which could be applied in order to check the accuracy of the data such as the triangulation of the data and the clarification of bias that the researcher brings into the study.

Strategies applied to the study include sending interviewees transcripts of their interviews to check for accuracy (member-checking strategy), and researcher reflexivity i.e. stating those things that could influence the study. Moreover, it could be argued that the way the data collection developed offered some form of triangulation of the data, since the data from the document analysis mostly confirmed the interviews“ findings.

4.8 Summary

In this chapter, the methodology and research design of the thesis were discussed analytically while the theoretical framework of qualitative research methods applied was reviewed in parallel. All phases of the study were described so as to present an understanding not only of why this particular framework was applied but also of the research questions and the general concept under which this thesis was developed. The findings of the study are presented and discussed in the next chapter.

CHAPTER 5

RESULTS AND DISCUSSION

5.1 Introduction: Interviews and Documents findings

This chapter presents the research findings in conjunction with the three Dialectical Model relationships. The Dialectical Model has been employed to explore policy change in the area of MS Treatment in the UK. The model focuses on the interaction between network agents and its structure, the network and its context, and the network and its outcomes with the aim of understanding and explaining how policy change has occurred. The findings of the research are presented in relation to the case study questions discussed in chapter 3. The findings are discussed in depth in chapter 6; they are presented in this format so as to show the different approaches of the respondents as actors within the described network and the connections or antitheses in their responses as they represent different or conflicting actors within the same network.

5. 2 Beyond Structure versus Agency (actors of the network)

According to the Dialectical Model, the first relationship refers to a number of questions generated by the discussion of the dialectical relationship between structure and agency and the first question posed to the respondents: “**Who is in the network?**”. The presentation of the results begins with the respondents’ observation of a formal network map prepared by the researcher with a view to discussing it with the respondents and eliciting their comments on included and excluded actors (agents). Figure 5.1 illustrates the network participants (actors) and the relationships between them. The actors shown in black boxes, linked to one another

with black lines, were part of the initial map of the network, prepared by the researcher. The lines illustrate the relationships between actors as members of the NICE AC; such relationships are indicative only, meaning they show the existence of a relationship and no other characteristic, for example closer relationships. The orange actors were added by the interviewees as integral parts missing from the initial network map. The participant listed as “other actors” refer to actors that exist and have an influence on the network but not a direct relationship, such as members of institutions equivalent to NICE in other countries, or other patient groups. The participant “public” refers to the people who might have heard and read about the beta interferon case or the NICE AC and have an opinion, positive or negative. Their opinion, expressed through the media or as public opinion, can have some impact.

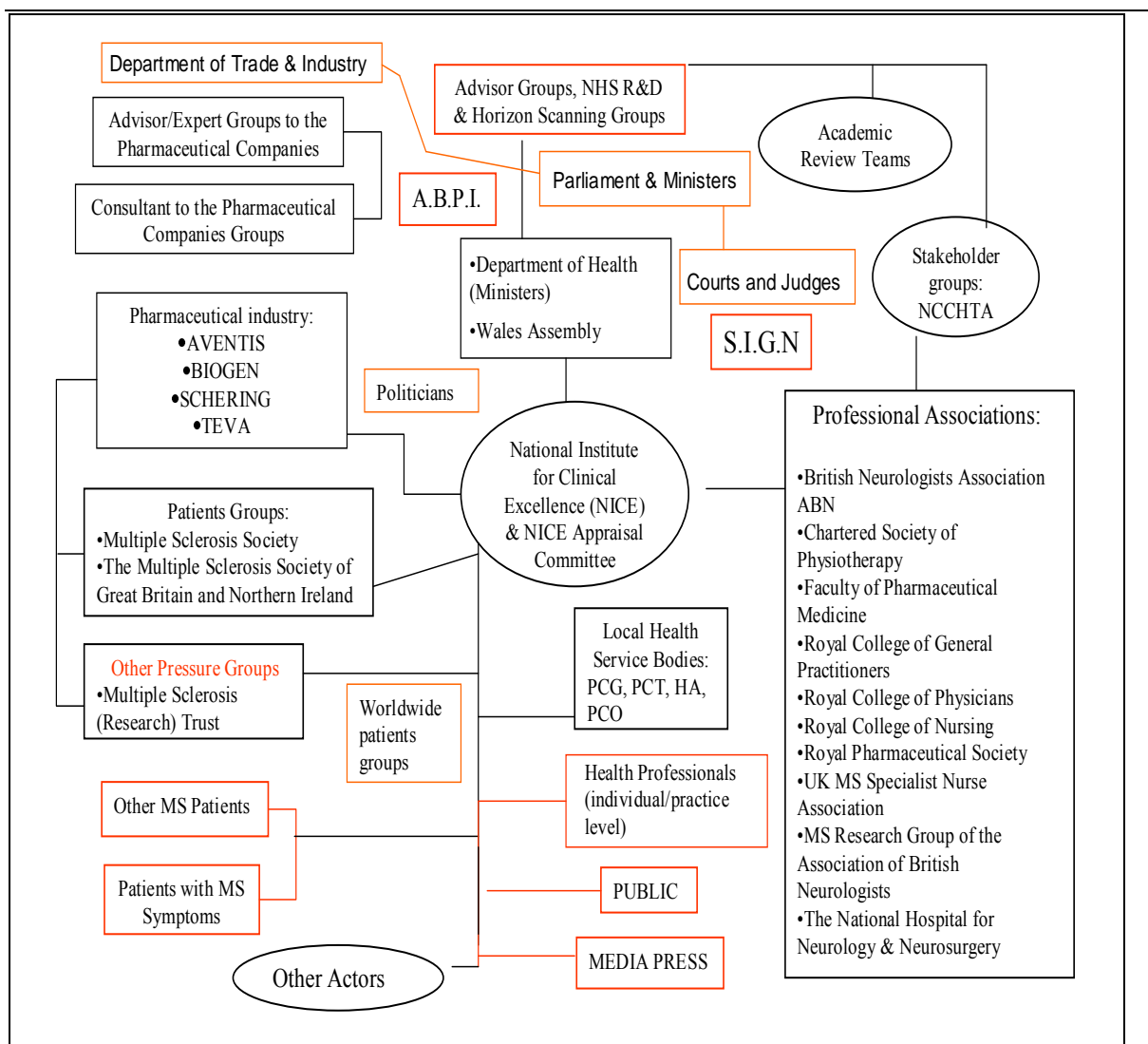


Figure 5.1: The network actors

The data analysis showed the existence of four overlapping networks:

- 1) The formal network is the one drawn by the researcher on the basis of the document analysis, the study of the literature on policy networks and the case study. This map was presented to the respondents for comment.
- 2) The formal network as it emerged after the research, with all the actors added and removed by the interviewees.
- 3) A “non-formal” network in support of the “formal network” that exists and has been

influencing the whole decision making process in the case of the appraisal of beta-interferon treatment.

4) A sub-network that includes some of the actors within the existing network, which is said to have had a greater influence.

“NICE, DoH, WA, manufacturers, the ABN, the MS Society, the MS Research Trust...these are the real actors, the rest have membership but no influence” (academic respondent).

Three main points are highlighted with reference to the first question: additional actors need to be inserted into the network; some actors are excluded from the network; and the actors’ positions and role in the network map require some adjustment as discussed in sections 5.2.1 and 5.2.2.

With regard to the first research question of the thesis of whether there is a kind of network, there was positive response. The existence of a healthcare policy network has been verified by the respondents and the actors were identified.

5.2.1 Actors added to the formal network

There were respondents who added actors to the network. These added actors were influenced the decision making process formally when they began participating in the process through their professional status. The following table (Table 5.1) presents a list of respondents and the actors/agents they added to the formal network. There were actors added to the network by those actors cooperating with them, for example a physiotherapist added non-registered MS patients and, the DoH interviewee added the MPs;

TABLE 5.1: Actors added to network (map)

Who added to the network	Who was added
Health professional physiotherapist	MS patients: not registered to any organisation
Health professional physiotherapist	Future MS patients: presenting initial symptoms; not ill yet
A member of the public	Patient organisations from around the world
A health economist	Health professionals on an individual level
A health economist	The public
A member of the public	Bodies equivalent to NICE in Scotland and N. Ireland
A pharmaceutical respondent	The ABPI had a supervising role for other companies
A pharmaceutical respondent	The groups advising the DoH about what should be appraised.
Academic review teams	NHS RD Centre, and the Horizon Scanning Centre
Academic review teams	The Parliament in a role supervising for the DoH
DoH, interviewee	The MPs (politicians)
DoH, interviewee	Courts and Judges
DoH, interviewee	The Department of Trade and Industry which has an interest in what is happening to the industry, and is probably in contact with the Department of Health, ABPI and NICE
Patient's organisation respondent	Politicians, the House of Commons, and Parliament

Patient's organisation respondent	Medicines Control Agency
Patient's organisation respondent	Opposition party Politicians, in England and Wales
Document analysis	MS Charities
Document analysis	Individual Patients

5.2.2 Actors excluded from the network

Actors, who were excluded by the respondents from the network, are presented in Table 5.2. They were excluded because they were either seen as not really participating in the process of decision making or because they were seen as lacking enough resources to influence the process and generally not having a substantial role in the process.

"Health Authorities...They have no resources and no participation but they are asked to implement" (the NICE AC decision).

"There are those who have no resources and have no friends" (academic respondent).

TABLE 5.2: Actors "excluded" from the network

Who has "excluded an actor":	Who has been excluded
NICE AC member	Bodies Equivalent to NICE -for Scotland and N. Ireland
NICE AC member	Advisors to the industry companies
NICE AC member	Local Authorities
Academic	Local Authorities

A member of the NICE AC, with the main responsibility for the process, has excluded these three actors as they were not participating in the process; and they had no direct involvement or contribution. The local authorities were excluded because they had no contribution to the process and were said to belong to another network; the one that should implement the final outcome of the NICE AC.

5.3 Network boundaries and actors' membership

During the discussion of how the boundaries of a network can be set and who were the actors participating in the network with the power to influence the decision making process, the responses seemed to depend upon how each person/actor within the network saw or appreciated the relationships within the network thus setting the network boundaries accordingly. The points made by the actors covered the following areas: actors' influence, actors' resources, personal beliefs/issues and political authority.

The first point regarding the setting of the network boundaries was that there were within the network very influential actors, others with less influence but also those with no influence. The boundaries were differentiated because there were simple actors and key players. The research has shown that interviewees placed actors on the map according to how influential they have been on smaller or wider networks and therefore the networks have different boundaries.

The second point made regarding the membership and network boundaries was that how "much" influence an actor has is defined by the amount and the kind of resources they hold. Every actor uses their own resources, even if these seem very few, to seek allies so as to influence the network jointly. Therefore, there are interdependencies among the actors; every actor has, in a way, something unique to offer.

“Alliances between actors depend on the motivation to get a positive outcome” (Health Professional respondent).

Nevertheless, it is not only the resources of actors that define network membership; a third point made by respondents was that boundaries and network membership were defined by authority and the presence of groups formed in order to defend, promote and support the rights of their members, such as patients’ organisations. The government with its political authority, and the wider political and societal context within which the network operated, managed the network. Some of the relationships are imposed by the government due to this political authority. Past conflicts and the organisational power reflected onto the actors’ relationships also influenced network membership and the inclusion or exclusion of actors.

The research has shown that there are different inclusion and exclusion criteria for actors to be seen as part of the network or not. Those who fulfill the criteria can join the network. The criteria are set by the actors themselves, the government, the existing social, economic and political situation. The criteria of inclusion and exclusion adjust as part of the interaction between actors in the network.

The set criteria can be seen as defining the formal and informal rules within the network. According to the respondents, rules define which actors can be included and so the other actors who cannot fulfill them are excluded. For example, a condition for an actor to participate in the network is to have resources of the right kind and of the right quantity, which could be defined in terms of money or in terms of special knowledge or skills.

Equally, the actors excluded from the network all have common characteristics: either they do not possess the right kind of resources to be of value to other key actors within the particular network or they do possess resources and power but their power might threaten other actors’ interests. Yet, an actor without any resources might still be part of the network, as was

previously mentioned. In some cases they hold a kind of membership, but have no influence i.e. the equivalent to NICE institute of Scotland. Nevertheless, there actors excluded who wish and try to stay within the network and resist the very powerful actors who might want them excluded because they are trying to impose their interests and controlling membership. They are excluded for these reasons, and there is very limited or no interaction between the “excluded” and other actors.

Another important point raised related to actors’ personal beliefs. There are individuals who might exclude themselves because they do not agree with the position of their organisation and these reasons, such as personal interests or ethical dilemmas, may lead them to leave the network. In cases where those who decide to leave are known professionals or individuals with strong influence, then their leaving would have a critical impact since the network’s composition is influenced by the role of individuals within their group/organisation and it shapes other actors’ behaviour and, therefore, the network in terms of boundaries and actors’ membership

“It tends to be the people rather than the organizations. So if M Rawlings moved I suspect that that would change slightly, but whatever organization he went into, you track him (...) because he would take some authority and power with him....” (pharmaceutical industry respondent).

5.3.1 Position of the actors in the network

The positions of the added actors changed the image of the network map. The changes mainly involved the placing of certain actors in the centre of the network because of their more influential role. This observation is further supported by the document analysis, which demonstrated that the media is said to have had a substantial role in the evaluation process

because they were circulating information about the appraisal and the evaluation of beta-interferon as the only treatment available. It also promoted patients' rights to a treatment, putting pressure onto the committee to produce what could be seen as a fair ending.

"All (of it) happened because of the media" (NICE AC member).

The research revealed further issues regarding network members and their position in the network. Some interviewees talked about an "over-presence" of health professionals and academic associations in the network, implying that every profession is favouring their interests, further suggesting that they (the professionals) looked more important than they actually were.

- **Autonomous actors**

Some of the actors were also considered to be more autonomous from the point of view that they were considered to be more independent and that they were not "forced" to line-up as others did. The public, and health professionals on an individual level, emerged as a new actor and they were placed on the map with reference to the equivalent professional associations.

"There is authority coming from being a recognized expert on a clinical or an economic field" (health economist respondent).

- **"Divided" actors**

One other aspect the research revealed has been that, although some actors appeared as one group/body, they have been divided by the respondents into two different parts. The interviewees have said that NICE consists of two bodies, the Appraisal Committee and the Secretariat and that the first one works for the latter while they have a very strong and complex relationship. An academic respondent also said that the DoH is working as two bodies: the Ministers, who make the decisions, and the civil servants, who are doing the work. If the divided groups did not have a good relationship with each other, this would influence

everybody involved.

“NICE Secretariat handles the NICE AC reports; it can span a decision of the AC, or can completely ignore a report, or present it in a different way” (academic respondent.)

5.4 The relationships between actors in the network

For most actors, relationships within the network were evolving constantly. The changes consisted of shifts of influence and resources while some actions of the involved actors may not have been relationships *per se*. For some actors, relationships developed into hard working alliances, while other actors’ alliances strengthened, broke down or remained the same. Interviewees spoke mostly about the relationship of their organisation to other actors in the network and how that had been influenced by the media and the differing actions of others.

Figure 5.3 presents the network map with an additional aspect. It illustrates the relationships of the actors of the network as they emerged during the research.

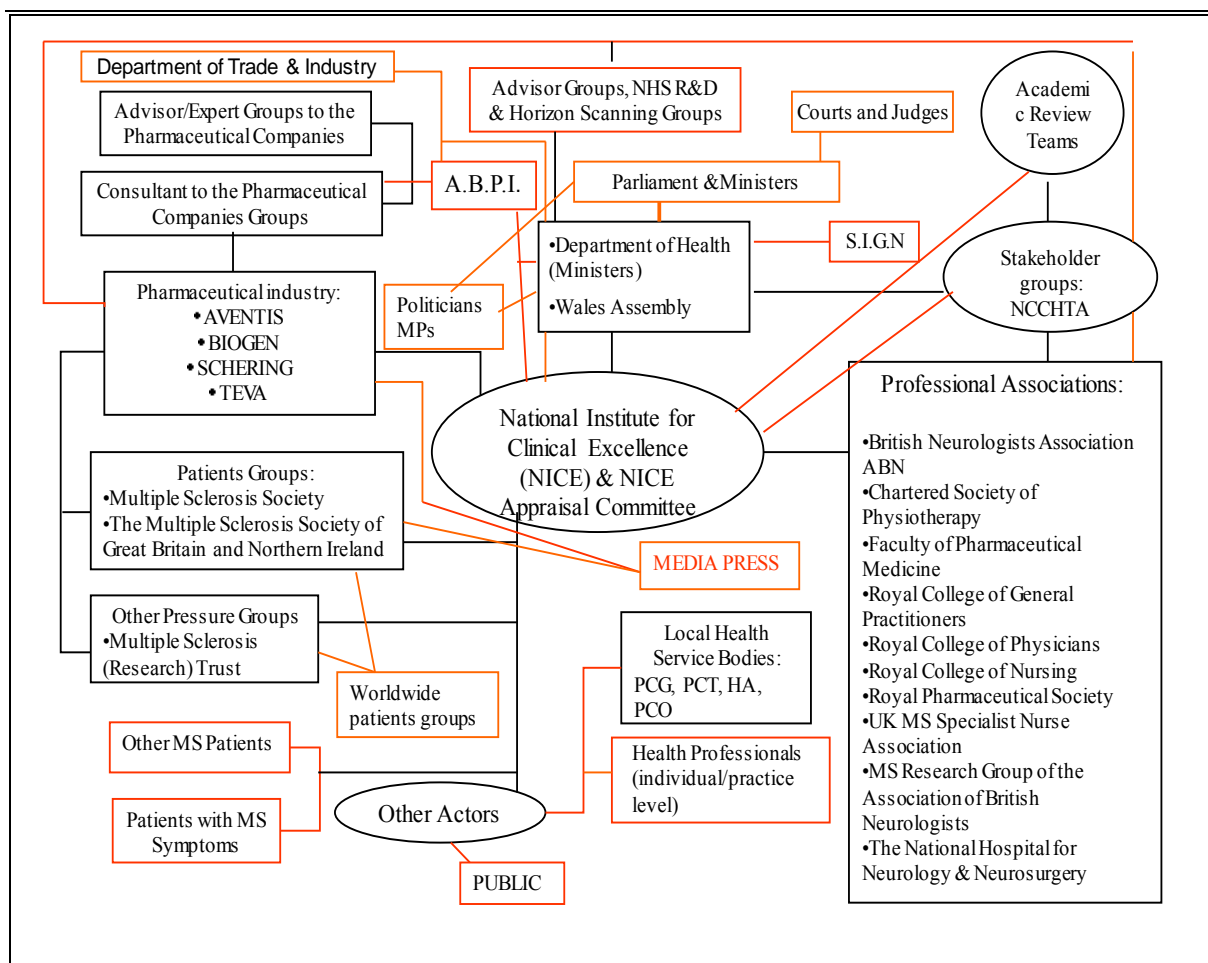


Figure 5.2: Map of the relationships between the actors within the network

The relationship between the actors was initially illustrated on the map is indicated in black colour, while the relationships added are in orange, which is also the colour used for the added actors.

5.4.1 Actors form sub-networks

Another important issue that surfaced during the empirical data collection was the existence of sub-networks, smaller networks within the network formed by some of the participant actors. The respondents identified a sub-network within the main network as shown in Figure 5.2.

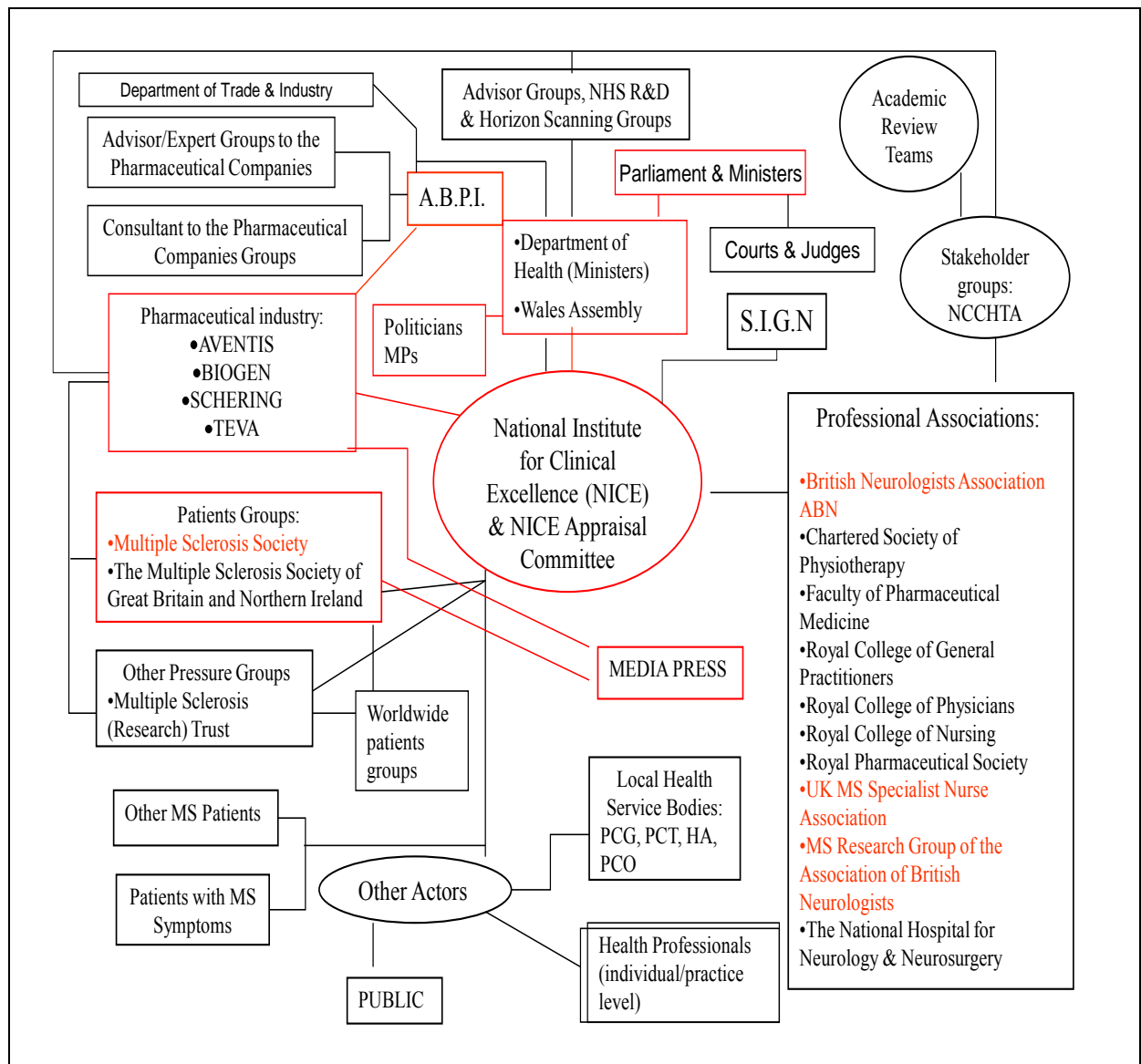


Figure 5.3: a sub-network within the network

Respondents identified so called active actors, who are actors with power and passive actors, who are actors present in the network but without real influential power. The most powerful actors are those who formed smaller and tighter networks. Figure 5.2 presents the actors who form the suggested sub-network (in red frames and in red letters) and their relationships.

When actors feel threatened they ally with others or form lobbies, thus establishing a subnetwork within the network in order to defend themselves and gain more power.

5.4.2 Alliances between the actors

Usually, the strengthening of alliances means a shift of resources from those in power either towards actors with no resources or between them. Actors' behaviour in the network often characterizes their future attitude towards each other and shapes other actors' behaviour towards them.

The formation of alliances depends upon the amount of pressure that actors have to endure at a particular moment and their potential need for particular resources to deal with various exogenous variables, such as the length of an appraisal or pressure from the media.

Past actions affect the formation of alliances between actors and play a significant role in the structure of the network i.e. introducing or excluding old or new actors from groups of existing ones. Actors are excluded either because they lack resources and power or because they have enough resources to succeed and threaten others' interests.

Findings from the study have shown that the most important alliance has been among the manufacturers of the treatment and the two patient groups: the MS Society and MS Research Trust.

“So we (the MS Society) show ourselves as the (twining axes) ... The other important axes for us were the pharmaceutical companies, the ABN, and the Multiple Sclerosis Research Trust” (patient organization representative)

Patients' organisations were allied to MS patients from around the world and other patient groups in general. These groups were stating their support and sympathy towards MS patients while also criticising NICE and the government for denying patients the only available treatment. Relationships among actors are determined by the exchange of information and different resources.

The relationships of the actors are also influenced by the fact that individuals participate in

more than one group. This not only influences the process itself but also raises ethical questions regarding conflicting interests. On the one hand, there is the question of how they can work and whether they can be independent. On the other hand, there is a question of how substantial the interaction among actors might be.

“I think eventually there is a conflict of interests you know, if you are making representations to NICE on behalf of professional bodies then you know, if you have an association with the industry or indeed the patient support group then that is a potential conflict of interest because that might bias your opinion on the intervention that’s being assessed” (health professional respondent).

Nevertheless, there is pressure coming from relationships to other actors within different networks; the relationships formed in a specific context are difficult to change. The work of actors is not always appreciated and properly evaluated by other actors within the network, or internally by members of the same organisation.

5.4.3 The role of other (external) networks/ other issues

During the discussion on the network memberships, other issues were brought forward regarding the network, its shape and membership. The respondents discussed the formation of the network map and commented on a variety of issues such as the influence of external networks to the one studied and networks external to a national UK network.

There were other networks influencing the studied network, i.e. institutions and organisations from around the world working on clinical evaluation, like NICE that were trying to, or were, influencing the network. This was happening because a decision by NICE would also have an impact on them and other networks.

“The decision gave other countries the opportunity to say „no” (health economist respondent)

“If NICE is not doing it why should we?”(NICE AC member respondent)

Also MS patients and patients’ organisations from all over the world were organizing communication campaigns to express their support and alliance to the UK patient groups. These bodies may not have had a direct involvement in the process but they were part of that network as collaborating institutions.

“If you can do this to me, to the difficult British Public, then you can certainly do it to the much more compliant Danish or Swedish or Canadian public”(Patient organisationrespondent).

The network membership reflects upon the past and on the social, political and economic environment not only at a national level but also at international level as seen with the MS patient groups and their continuous communication and support. In general terms, it seems that policy processes, such as the making of health policy, are becoming more complex and complicated. Even though there is more expertise, advances and knowledge in science (e.g. availability of medicines), there are still issues such as the allocation of resources.

The discussion regarding the network’s membership also reflects on the existing polyphony which is seen as another reason for the increasing complexity of the process: inclusion of even more groups and organisationswho bring their expertise and their views into the process. Furthermore, the network membership should reflect fairness from the point of view that all involved, in the NICE evaluation process, have a role in the process. Some respondents talked about the development of a "fairer" network, where all actors would be included and would have an influence from the beginning of the process. However, an increased number of participants would not necessarily lead to a "fairer" process. The network’s membership

should respond to rules of deontology and ethics. In general, respondents believed that all participants' views should be taken into consideration and especially those of the patients.

"So, there is this movement to try and get that into a more humanly meaning ways, so we're learning. The whole thing is an evolution, so I think that was one thing that beta-interferon definitely contributed to that" (DoH respondent).

5.5 Resources and power

The resources network members have define their position in the network and the interdependencies between them and other actors.

Initially it was stressed, by the respondents, that the word „resources" most often meant "financial resources". What the meaning of resources is and how one defines resources determines how powerful or not one sees the other actors in the network. Actors' broad interests and resources shape the restructuring and relationships between actors within the network; if resources are money then the most important/ powerful actors are those who have the most money. For example, in terms of money, the most powerful actor is pharmaceutical industry which seems to exceed all the others.

"The Industry has a lot of resources (they have) money but that in other words is "control of information"(academic respondent).

5. 5.1 Defining the resources of the actors

Resources have different meanings for each actor, and actors' perspectives and motivation are also different regarding which are the most important resources that an actor can hold.

Resources could be divided into "quantifiable" such as money or data and "non-quantifiable" such as expertise or political authority.

The data analysis has shown that resources could be financial, intellectual, access to data; political power and political authority, information, knowledge and certainty of own products; personnel and good skills mix, expertise, determination, motivation, ethical values and communication (mass media).

- **The role of the media**

The analysis of documents has emphasized the power that the media had. The respondents recognized the media as an actor and emphasized on their critical role in the beta-interferon appraisal. Therefore, the media were placed at the centre of the network map (figure 5.2). They held the resource of “mass communication”. For example, broadcast news report about the NICE AC intention to “reject” beta interferon caused a series of announcements and reactions from patients aimed towards the NICE AC and the DoH, putting pressure not only on the DoH and NICE AC but most of the actors.

“The decision sparked outrage among patient and support groups across the UK” (BBC broadcast news)

5.5.2 Resources and the structural position of actors within the network

The control of resources is reflected in the structural position of the network members to a great degree, and additionally in the skills and abilities of individuals who represent these interests in the network.

The research has also shown that the way actors interpret themselves and others within the network indicates their position in the network and shows how they perceive other actors’ resources. Actors’ behaviour towards each other is dictated by the way that they value the exchanged information/resources and how trustworthy were those passing the information around.

Furthermore, when an actor is providing resources to other actors in the network, this shows

an intention to ally with them not only regarding the output but also their input into the process. For example, the pharmaceutical industry sponsored MS patients' groups' campaigns against the NICE AC, on the beta interferon. The changing of the process and the continuous restructuring also influenced who was considered as the most powerful actor.

Some actors are said to have no power or resources such as the health authorities. Having "friends" or not within the network is significant since those who have allies are more successful and they achieve more of their targets.

"There was a constant kind of push and pull between the MS Society and the MS Research Trust and again as with the companies it wasn't clear until very late at the process that we all point in the same direction and actually going to work in concert rather than working separately" (patients representative respondent).

The research has shown there are different attitudes between common interests and, moreover, that there is competition among actors who, although they are sharing the same interests, are fighting or are not collaborating to obtain resources, unless there is an "emergency" situation that they might have to deal such as the beta interferon appraisal. Otherwise, they seem to prefer preserving or protecting their position and status within the network. This argument also links with the discussion next on the role of individuals.

"The ABPI, the role of the ABPI was I think probably more than anything to keep the peace between the pharmaceutical companies and try to get them to work a little more together, which is something they seem to be fundamentally incapable of doing" (patients representative respondent).

5.5.3 Resources and the role of individuals:

Individual's skills constitute not only an important resource but also add power to an actor.

Skills matter and are reflected in the process, not only in terms of leadership but also on other levels. Different types of people, with different attitudes and backgrounds, constitute the network and all these people are expected to come to a common decision. Those with stronger personalities tend to be more influential. Individuals' personalities, therefore, play an important role in the agenda setting process.

“Dynamic and forceful people, strong personalities, promote the agenda they feel right or proper” (health professional respondent).

The personal characteristics of those who represent these groups or organisations play an important role and have a great influence in the process, and often „battles“ between actors reflect personal matters. Two very significant points have been indicated; the first relates to the ethical dilemmas that people face when deciding whether they should express themselves as individuals or as group members i.e. members of the NICE AC. Their individual side usually means a more ethical viewing of issues/ matters. The second was that there is indeed an "individualistic" side of the network and this means that, in some cases, people see other people rather than organisations, making interactions more personal.

5.5.4 Resources and external networks

The resources that actors are holding are further connected to other networks and applications. The network affects other networks significantly. For example, making health policy affects the broader socio-economic-political environment within which the network operates as the decision on beta interferon case did. However, this is a two way connection since the network is also influenced by other networks and the broader socio-economic and political environment and the NICE AC guidance on beta interferon provided an example of this.

Additionally, it seems that there is an issue regarding not only who is holding the most

resources but also on how the information and resources are being directed in the network and how that influences the outcome. Another issue brought forward has been people's ethics in obtaining resources. There are questions on how an actor is getting hold of resources and in what ways, or how ethical it is for some actors to hold a large amount of resources while others cannot.

5.6 Network Structure and Context

The second relationship of the Dialectical Model asks how the network has changed over time. Changes in the context in which the network operates do have an effect on the structure of the network and the interactions within it.

The respondents have verified that there are changes in the structure of the network. The changes are expected from the point of view that changes happen everywhere and so they are happening within the current network. There are changes in the structure of the network which are mainly expressed through the interaction among actors; changes refer to the shifting of resources and the distribution of power among actors.

The research has shown that during the beta-interferon appraisal and, regarding the changes in the structure of the network and actors' relationships, there were changes within the network with a further impact on its relationship to other networks.

5.6.1 Changes in the structure referring to the shifting of resources

Members of the network have interpreted any changes in the broader political and social context within which the network operates in a different way and in combination with the resources available to each actor. Therefore, changes in the structure and context are linked to the shifting of resources, as discussed previously. Shifting of resources enabled non-powerful

groups, to improve their position in the network and to alter the network's structure. In the current case study, it was seen that the appraisal of beta interferon made a difference and has affected the validity and reliability of the other studies that were appraised by NICE at that time. Actors used their resources and have caused changes; i.e. the MS Society had not enough resources to defend the funding of beta interferon treatment, but the companies supplying the treatment sponsored their battle against the NICE guidance and promoted the issue to the media.

"MS Society had very deep pockets to use" (patient organisation respondent)

The MS Society had obtained resources and power that put pressure to the DoH and may have weakened the position of other actors such as neurologists who believed that the treatment should be funded by the NHS.

"The MS Society has handed 120,000 signatures to the government in protest of NICE's decision in beta interferon drug" (News report)

The shifting of resources involves not only giving them to strengthen the recipients but also the loss of resources by donors which also causes changes in the structure and the weakening of actors. So the loss of resources also changes the network structure i.e. the empowering of MS patients organisations changed the status of other actors such as NICE AC or those actors who were not in favour of beta-interferon

"NICE looked very weak and caused a lot of uncertainty in other actors such as implementation bodies that would have to apply the Risk Sharing Scheme...I think people were amused by what NICE was doing" (Health Economist).

The change of structure meant for some actors not only a loss of power and resources but also loss of their credibility and, in some cases; they might be forced to leave the network. The criticism of NICE by the media made NICE look weak because actors such as the DoH,

distanced themselves from NICE and the way that things were handled. The decision on the Risk Sharing Scheme seemed to be or was presented as a compromise for NICE and a victory for MS patient groups, the pharmaceutical industry and the manufacturers of beta-interferon. Furthermore it pronounced changes to the process since a review on NICE would follow.

5.6.2 The distribution of power among actors

The actors change their methodologies during the course of learning from others thus becoming better prepared for future decisions that they might have to make.

The formation of alliances and the lobbying between actors happens because actors promote their interests. Actors, according to their interests, were forming alliances with other actors and were lobbying with them. Lobbying is a tactic that prepares actors for future action and challenges competitor actors within the network. It is also part of the power of an actor within the network. Pharmaceutical companies and the ABPI were lobbying with patient groups, the MS Society and the MS Trust and they all formed an alliance. Getting allies can cause faster changes in the structure and strengthens the position of an actor. The fact that some actors formed closer links among them, to a large extent, shaped the way things went forward.

The way in which actors interpret a decision was significant for the network. Actors could cause changes in the structure and context, not for their own interests but to serve other actors' interests.

“Alliances between actors strengthen one side against the other” (politician respondent).

5.7 Changes in the context of the network and the impact on other networks

The research referred to the NICE AC network and the changes took place so the discussion mainly refers to the particular network with some observations.

There were many changes in the network's structure and context during and after the appraisal of beta-interferon treatment, as well as in all other appraisals.

The case of beta-interferon has altered the way that appraisals were validated rendering all actors better prepared for future appraisals by having more resources or more alliances.

"This appraisal has affected people's validity and reliability and revised people's opinion on validity and reliability" (health economist).

The changes regarding the context of the network illustrated that the actors were trying to protect their interests and achieve their goals by shifting resources or allying with others who have common interests. Interdependencies among actors shift as resources shift, and alter the context of the network which adjusts to the new rules.

"Industry lobbies with patients... and NICE allies with the academic groups" (patient organisation representative)

As the pharmaceutical industry wanted to sell beta interferon to MS patients and MS patients needed funding for their treatment, the industry had resources to shift to the patients and they got resources to fight against negative guidance by NICE.

The particular case of beta-interferon set a precedent within NICE appraisals, and has shown all actors how to get organized for future action.

"This was a landmark judgement especially for those in favour of the treatment (of MS with interferon beta) that has ramifications for cash-strapped health authorities throughout Britain and will boost the case for a separate NHS fund to pay for expensive new drugs coming on the market as a result of biotechnological advances" (editorial 34, document analysis).

Moreover, it is most significant that the decision has set a precedent both for the process and the outcome. This resulted in strengthening among other networks and organisations since they had now something to base their case upon. An example had been set and they could use

it to strengthen their own arguments on similar cases, such as the appraisal of another medicine or technology.

“Lots of people in the business and in the academic world were affected” (NICE AC member respondent).

As soon as an actor breaks the rules, the rest will react and consequently might influence a change to the whole operation. The leak of the negative NICE PAD brought a lot of reactions from other actors as previously discussed, who tried to influence NICE and the appraisal process. NICE reacted as did other actors.

“The beta interferon appraisal has been a headache for NICE” (BBC News, document analysis).

For some actors, the beta-interferon appraisal was the most problematic appraisal in comparison with other appraisals. The fact that this treatment was the only available for MS patients, was putting significant pressure on health professionals and on patients since they had no alternative, it was either this medicine or no medicine.

Every appraisal is expected to bring changes or to introduce new data and the research has shown that this particular appraisal brought more changes because of the extensive publicity that it received.

When an actor appears weak, they lose negotiating power and influence. The particular appraisal of beta interferon had a greater influence into people and made patients wonder about the different results that previous appraisals might have had if actions had been different. For example, patient groups wonder what would have happened if the media had not been involved, what the outcome of the appraisal would have been then.

“The media were very important to us. Because we felt we needed every means we could obtain all of applying pressure to NICE” (patient organisation representative).

Pressure applied to the network by exogenous factors, such as the media or endogenous ones, such as the patients, seemed to refine the network's operation.

“The appraisal process had become more transparent due to the pressure applied by the media and patients” (NICE AC member respondent).

5.8 Changes in the context of the network

Actors, in order to promote their interests, are constantly modifying their strategies and do not hesitate in challenging the network. Apart from the impact and changes to the network and its actors, there is an impact for patients and the provided healthcare service. The delay in the decision regarding the treatment has worsened some patients' conditions and has caused further problems for their carers and, consequently, for their socio-economical environment.

“While the Institute appraises the only drug neurologists believed can stall the disease; patients are deteriorating past the point where they could be helped by B-interferon” (patient organisation, Document analysis).

The publicity received has also affected the broader social environment within which the network operates; the images of a difficult life of an MS patient were powerful and have provoked a lot of discussions about the moral point of the case.

Moreover, the development of a new type of policy could attract more stakeholders and actors that would like to be included in the network and decision-making process.

Naturally, for some actors, further implications might be created that they would have to face, such as budget and implementation issues for the Health Authorities that are expected to respond to the new guidelines.

However, actors perceive and evaluate changes in the structure or the context of the network

differently. This depends on how they have been influenced by the changes.

The way in which actors interpret a decision, such as the beta-interferon appraisal, was significant for the network. In this case study, some actors saw the final outcome as a failure of NICE and others as a success of the industry and the lobbyists. An interesting interpretation has been that people were driven into making the final decision on beta interferon in the line with their ethical considerations and decided to give patients the treatment. The decision making process has thus gained a moral component.

5.8.1 Actors and changes in the network structure

The changes in the structure involved new actors coming and others leaving. In order to keep an influential position in the network, an actor needs to maintain their authority otherwise the whole network remains unstable because of the many changes take place. This is due to the process of changing; for example changes into relationships between actors or changes into the network membership with new actors entering the network or other leaving the network. The final decision/guidance of NICE AC put a burden of responsibility both on policy makers and suppliers (industry).

“I think the clear message which I think it was good for NICE although it felt uncomfortable was having to go back and do it again, or having to accept that its decision was not necessarily right. But from our point of view it is very encouraging to see that the process we set in for challenge worked” (pharmaceutical industry rep).

5.8.2 Changes in the relationships between actors

Changes in actors’ relationships refer to: the changes towards NICE which has been under a lot of criticism and has been weakened, to the involvement of the media, the lobbying among

actors and the shifting of resources.

- **Changes towards NICE:**

From the moment that the appraisal received publicity and turned negative, NICE came under attack by other actors who were aiming to overturn the negative decision and promote their interests. Actors did not want to be allies with NICE because they were afraid of being criticised.

“We show ourselves very much as being in the confrontation with NICE from the beginning” (patient organisation respondent).

A severe conflict emerged between NICE and the MS Society instigated by the later. The data show that the MS Society has strongly criticised NICE.

“There was a constant kind of push and pull between the MS Society and the MS Research Trust and again, as with the companies, it wasn’t clear until very late in the process that we were all pointing in the same direction and were actually going to work in concert rather than working separately” (patient organisation representative)

The debate has gone back to rationing issues and NICE establishment and its mission, all of which has been challenged. The media coverage and the criticism on NICE challenged also the governmental policy and the role of the government towards NICE and towards patient groups. More patients groups and other actors engaged in an exchange of announcements and statements regarding NICE, patient’s rights and treatments.

“Members and supporters are also urged to keep up the pressure on the Fair Treatment Campaign” (policy officer, document analysis).

The document analysis (editorials 4-10) shows that the publicity the appraisal received united MS patient groups from all around the world and they were campaigning against the negative

guidance regarding beta-interferon treatment, whilst it also strengthened the relationships between MS and other patients groups.

Other findings that emerged from the research underlined the importance of designing a proper appraisal process and highlighted the contrast among patient groups whose interests were common.

5.8.3 Changes in the relationships between the network and the network context

There were changes to the relationships of NICE with other networks on a national level and more of an impact on the relationship of NICE with international networks because in each country they are applying their own systems.

“NICE was a concern for manufacturers, since other countries might learn what is happening and get influenced....” (academic respondent)

The decision of NICE AC on beta interferon affected not only the network environment, and the relationships of actors in the network, but also the understanding of various issues. Many things changed for all involved in the process, such as patients groups preparing themselves to defend their positions and to look for allies if necessary.

“This politically motivated rationing is dressed up as a clinical evaluation” (Liberal democrats MP, document analysis).

There were positive and negative comments regarding NICE’s international profile and NICE had an influential role on other countries. The interaction among actors at an international level brought more information into the network.

“NICE I think has probably blazed a trail for agencies in western-European and North American Australasian countries in being prepared to carry out cost-effectiveness evaluations of medicines” (patient organisation representative).

A new context has been created within which future issues had to be resolved.

“One of the things that happened with beta-interferon is one of the appeals that they haven’t appropriately involved patients and I think that better involvement of patients is a consequence of that. They realise they have to get patients involved” (academic).

5.8.4 Other Impacts on the network

New actors joined the network such as the Decision Support Unit the aim of which was to defend patients’ rights and substantially change the structure of the network. The decision of NICE on the beta interferon appraisal had been alarming news for other networks, national and international, and there was more pressure coming through the national and international interaction between networks and particular actors. Every actor interpreted the results in a different way.

“The industry now had more responsibilities” pharmaceutical industry respondent).

“NICE looked like a weak link in the chain after the decision” (Nice AC member respondent).

The formation of relationships depends also on the amount of pressure that actors have to face at a particular moment and their potential need for more resources from the point of view of more actors coming in that could facilitate the network members.

“So I think that was one of the pressures, the workload the groups were under at time and it lead to the Decision Support Unit (DSU) (academic).

5.9 Influence of previous policy outcomes on the network

This third part (**Beyond Network versus Outcomes**) discusses the third relationship between networks and outcomes. The research has confirmed the initial assumption that previous policy outcomes had an effect on the network’s structure and the appraisal process.

People are bound to be looking at how things worked in the past. The whole appraisal process could be seen as a learning process for all involved actors; since people worked under different circumstances and responded differently to various assignments and situations. Especially, in cases like beta-interferon appraisal, which have received extended media attention and publicity, and consequently became subject to increased public pressure.

Previous policy outcomes influence all actors but especially those who have more benefits from the outcome of the appraisal.

Actors involved in the Beta-interferon case were influenced by what had happened in the network in the past i.e. in the case of zanamavir treatment appraisal. If some actors were putting pressure on the decision-making process because they were trying to strengthen or to preserve their position within the network, the other actors were concerned. These others often felt provoked to maintain their position, resisting the powerful interests and their pressure but it was very difficult to maintain their initial position under these pressures from either media attention or the interests of some key players who were in control of the network. Additionally, it could be argued that this links to the discussion on individual characteristics and that strong personalities make a difference to the network.

5.9.1 Changes in the structure of the network

Changes in the network related to how strongly some relationships were built on previous outcomes during the decision making process. For example, whether relationships that had developed among different actors in the network were hostile or perceived as an alliance. This probably most distinctively influenced the structure of the current network in which some groups may have been under-represented, such as the patient groups or health authorities.

Testimonials by the respondents showed that the formation of bonds and responsibilities in

the network were mostly stable. They are not easily modified or transformed, even in circumstances when actors are commanded to cooperate among themselves, either by the government or an authority derived from the network's structure itself. An established relationship between two actors is very difficult to change. For example, one respondent described the relationships between NICE and the pharmaceutical industry as follows:

“When they said „no'to one of the biggest pharmaceutical companies, the biggest in the UK, and one of the biggest multinationals I am sure that introduced a very noticeably—I think-hostility between the industry and NICE and I think it has taken quite a lot time for that hostility to come down and in fact it might never come down” (NICE AC member respondent).

Actors didn't know NICE before the first appraisal, so they had underestimated it. During the appraisal processes they learned adapt more efficiently to the new requirements interact more frequently with NICE. The more interaction there is between them the better actors respond to each other. Furthermore, actors personal beliefs are influencing them and their actions towards NICE and their organizations. There is also the issue of preserving personal and professional status. To preserve this status means to be in control and able to handle things. As actors are learning through the process, they are better prepared to react and to solve their problems. As previously discussed, there are formal and informal rules within the network and when actors break them, they might be excluded.

“The industry said "a new organisation, but we don'tneed to worry about this”, they thought they would not need to worry about NICE” (NICE AC member).

5.9.2 Previous policy outcomes and their influence on the network

In general, there are changes on every level of the network and every actor appreciates them

differently, accordingly to the losses (or profits) made in previous outcomes. Changes in the network structure might well initiate conflicts among the actors. Actors and mainly very powerful actors might underestimate others and misinterpret the process but people's attitude could change because of the previous appraisals.

Personality and leadership are very important features for a person leading an organisation.

Who is in charge of the organisationsometimes makes a difference in negotiating power, shifting of resources such as money, consultation, promotion, and expertise.

5.9.3 Changes into actors' strategies

Since the formation of the network it has been difficult for actors to know exactly what their role is. In a way they learn about their role on the go and from their interaction with the other actors. There is a framework that actors set which involves the "exchange" of data. The context or the framework is both formal and informal. There are some things imposed by every government on a democratic western society, as Kenis and Schneider (1991) argue and there are rules or deals or agreements between actors that show the interdependency between them. Every actor has something that another one needs; even those excluded from the network have a role to play and some kind of influence even this is in the future in some other appraisal.

In this respect actors' roles were negotiable, not fixed. Actors adjusted their strategies in response to the new environment and the more they realized how the network operated they better they understood their role and also the role of the others.

In this appraisal there was a discursive switch, from the discourse of cost-effectiveness of the treatment to the humanitarian discourse and focus on the patients and their right to receive treatment. The whole philosophy of the process was differentiated this time and actors

changed the way they defended themselves.

Some actors started choosing to interact with others and new alliances were formed along with resources shifting. Actors were forced to form new alliances or to lobby with others in order to promote their interests better.

Regarding the factors that lead into the restructuring of the networks, the research has generally put forward three issues:

- (1) The influence of internal factors such as the linking of the processes and actors to politics cannot be easily changed.
- (2) The influence of exogenous factors, in this case the media and pressure groups, has played a significant role on the network's operation.
- (3) Actors show concern regarding further network implications.

Besides, the network's flexibility depends on the outcomes within every group of actors. The members of an organisation often disagree with the official line of the organisation. If the outcome is positive there might be more flexibility and future cooperation, if the outcome is not welcomed there might be less and there might be more tension in future cooperation.

5. 9.4 The Impact of the outcome on the network

The evidence based outcome means that there is a quite fluid network and all actors are influencing the decision making process. Although the aim is to produce a scientifically valid decision based on valid science, there is always going to be a problem with that in the political arena. Additionally, the outcomes depend on the kind of evidence provided and how that evidence is ranked. It is interesting and also true that the outcome is the product of collected efforts of everybody involved in the process and of the applied methodology. For example, a respondent highlighted "*how difficult it is to say how much of the NICE work has*

influenced the particular outcome” (health economist respondent).

There was a lot of uncertainty about the evidence and it will always be possible to challenge the validity of the evidence. Evidence does not always point very clearly to one or another direction, so it depends on how actors will make use of it. The research has shown that there is the possibility of purposefully misinterpreting the evidence. For example, it was said by a member of the NICE AC that NICE Secretariat “*tidies up*” reports or is “*ignoring them*” to avoid bad criticism and further implications.

5.9.5 The impact of the appraisal process outcome on actors

There were positive and negative effects on actors regarding the outcome of the appraisal process. During the empirical data collection different issues emerged while discussing with the respondents such as regarding “who sets the agenda” and under which criteria technologies were selected to be appraised. It seems that positive appraisals by the NICE AC had no coverage and nobody knows their real impact or whether there are any other alternatives and what their implications would have been.

Therefore, who sets the agenda is a rather crucial role within a network and for some actors, the outcome has shown that NICE was not eager to provide positive guidance, implying that the role of NICE was to introduce negative appraisals. This led to NICE and the DoH being accused of formulating a new healthcare rationing method and their intentions were proved by the case of beta-interferon. However, NICE has had further criticism that, since its establishment, it was handed technologies of no particular importance to appraise and every actor felt happy at the end with the positive outcome by NICE (Caines, 2000), implying that its role was unimportant. Therefore, the work of NICE might have been underestimated. However, in the appraisal of beta-interferon where NICE’s guidance was negative for this

particular treatment, there were strong reactions and NICE had shown that its work was not to be underestimated.

“Policies say „yes”, everybody is happy, policies say „no”and everybody is unhappy, «it is cynically black and white” (DoH respondent).

5.10 Additional Outcomes and impact

Every actor evaluates the outcome from various perspectives at different times. What could be a successful outcome for one actor would not be for another.

For example, the ABPI and the manufacturers thought that NICE in the case of beta interferon appraisal had failed while members of the NICE AC thought that NICE had delivered its work and has completed the appraisal of the treatment.

Also, an actor’s views would influence others and those who have more resources to allocate might communicate their views better. In the case of beta interferon appraisal industry had the resources and communicated its views: it spread the rumour and brought NICE into a rather difficult position by inquiring and reviewing NICE, a governmental body. However, NICE, could not react in a similar way and as a NICE Appraisal Committee member said “it had no resources and no interest in doing so”.

The relationship of NICE with the industry and of course with many other actors was redefined after the appraisal of beta interferon. During this appraisal there were various conflicts and antitheses that would be reflected on future collaborations of NICE and the other actors. The redefining of actors’ relationships influences also the structuring and membership of future networks.

NICE’s role has been to contribute to the formation of a policy and not to make policy. This was how it had been received by other actors in every other appraisal except the two negative

ones and mainly the one for beta-interferon where NICE had in a way taken the blame for what would have been a new MS policy on beta-interferon.

Another element is that most actors again kept a distance from NICE, as some of the results demonstrated and especially the DoH who asked for the reviewing of NICE. This has further influenced the role and position of NICE and subsequently of the other actors too.

The research has also stressed that the participation in the network of some actors such as the patient groups should have been predicted somehow and this may have led to many problems been avoided. However, the relationship between the actors will always be *“very complex since bargaining, negotiating and manoeuvring”* (Health professional respondent) will always be an issue amongst them.

“People will use other people to take up positions and get what they want” (health professional).

Actors believed that their roles and their influence should vary and should depend on the issue being evaluated. More flexible networks and more flexible processes should also depend on the actors’ internal outcome which means that an actor has realized what their role is.

However, the question of personality arises and how strongly an individual feels so as to defend their position. Additionally, it arises whether individuals are able to realize their power as experts so as to influence the outcome and whether they can obtain more resources.

Some of the actors have a special role within the network and part of that role is to promote certain values.

Another related question was what the overall outcome for the network was, if there was one. Was it to ration healthcare services, to reduce the costs for the NHS, or to provide guidance? Of course one does not exclude another but again it is up to the actors, their needs and existing circumstances to offer an interpretation

“If NICE was established in order to save the NHS some money then the whole plan does not work since the outcomes have not saved any money; moreover they have increased spent money” (NICE AC member).

The outcome created further impacts for some actors with respect to the implementation and the funding of the treatment within the health authorities but also released people from the pressure of making a decision on the funding of the treatment and taking the responsibility for their choice.

The fact that others decided made implementation easier. Implementing hard policies is maybe as difficult as making them and nobody likes to take that responsibility. In implementation, things are more difficult because people might know each other and relationships are usually more personal so ethical dilemmas arise for individuals.

An outcome or an output becomes an input to a different network, and naturally it has a further impact on the actors. Appraising new products has become common practice in many countries and there is an influence on the different networks but also an impact on the manufacturers that must prove the effectiveness of their products.

“For the industry the appraisal process has become very expensive while the challenge for the companies became global” (pharmaceutical industry respondent).

As there were two kinds of resources identified, one could argue that there are also two kinds of inputs: the quantifiable input such as the data and the non-quantifiable input such as being a patient with MS, or being an expert. In terms of the quantifiable input, the network might not have affected the outcome but, in terms of the non-quantifiable input, the network has most probably affected the outcome.

The characterisation of the outcome by actors gives an overview of the different interpretations and the different expectations of every actor.

1. The outcome was characterized as balanced since it satisfied ethical matters, such as treating patients, and considered matters beyond the scientific evidence.

2. The outcome was the result of a negotiation and political compromise; nothing further. Moreover, it is rather uncertain whether the negotiation had been between big actors with similar degrees of power and influence or between very powerful and less powerful actors.

The process involved politics which means that the decisions were political. Cost-effectiveness became a political issue. Although the decision itself was based on scientific evidence, the criteria against which it was made were not only scientific and based on scientific data but also other factors had influenced the final outcome/decision; for example criticism and pressure from patients groups and the media

Many things took place during the process and the only way to find out about them was to be part of that process. The “secret” interacting served one purpose; to influence the outcome. There were things that were not made public because they would damage others and disrupt confidence, as happened in the case of the NICE FAD. However, this had happened with the purpose of reversing the decision by NICE.

“Deals being done and threats to get to the outcome” (health professional respondent).

The findings demonstrated that the role of health professionals in the network was or had to be the promotion of clinical excellence and the advancement of standard care for patients.

As the findings suggest, networks affect outcomes or at least as an interviewee said “*we hope that they do*”, meaning that one of the reasons for the formation of this policy network had been formed was to produce, through a relatively fair process, a relatively fair outcome or “*A scientifically valid decision*” (health economist).

In general, the outcome is not the product of pressures applied to the network among actors which nobody finds out about in order to get one which favours all. It is also defined by the

different kinds of resources and power that actors hold and the relationships between actors on an organisational and on a personal level, as individual characteristics and the existing social, political and economic situation matter.

5.11 Summary

This chapter presented the findings of the research in relation to the case study questions and the Dialectical Model relationships. The key points of the chapter could be summarised by the following. A network has been identified, the NICE AC network where different actors interacted and contributed to the outcome to prescribe beta interferon treatment for patients with MS. Within this network, there were actors either very influential, or less influential or without influence. Their influence depends on the resources that they are (or are not) holding, which in turn guides their actions. Important roles are played by the individual characteristics of actors, and a series of variables endogenous to the network, such as political authority or exogenous, such as pressure from the media. The findings are discussed in depth within chapter 6.

CHAPTER 6

CONCLUSIONS

6.1 Introduction

The aim of this thesis has been to study the policy decision-making process in the healthcare services network and to offer some understanding of the behaviour of some of the most important actors involved in the UK health network. It also sought to inquire into the use of the “policy networks” approach, and the application of the Dialectical Relationships Model in the healthcare service network.

6.2. The three Dialectical Relationships

6.2.1. Structure and agency

The first relationship issue concerned the actors who form the network, and by extension, concerned the question of who is the network. To address this issue, a three step approach was adopted:

- Initial document analysis aimed at identifying the main actors in the network and forming a list of actors to be included in the qualitative research.
- In-depth interviews with the main actors in the network as suggested by the document analysis.
- Detailed analysis of the documents to further explain issues that emerged during the interviews and justify limitations in the quantity of interview data.

The analysis verified the existence of a network and identified its actors. Furthermore, it showed that different actors have had a different perspective of the structure of the network,

which consists of different subsets of actors. In theory, certain actors were seen as being included in the network but, in practice, these actors were not seen as being influential within the network. This suggested that there were different inclusion and exclusion criteria, which were used for the assessment of who forms the network. Furthermore the network's membership has been influenced by exogenous and endogenous factors.

In theory, the membership of the network was defined by the government. This was in accordance with governmental policy on evaluation and provision of new treatments by the NHS. The network's membership also reflected the governmental intention to control the power struggle between the different actors: physicians, health professionals, manufacturers and patient groups, to bring balance to the network and, therefore, to provide better possibilities for initial cooperation. Networks need to be flexible. Whether they become stronger or weaker depends upon the outcome within the group. When the NICE network was formed, the Institute was still a new organisation and, as such, it was lacking in many aspects such as resources or scientific input. Many did not know whether they should be involved or not. Once people interacted, they started to understand their roles within the network and, thus, relationships grew stronger.

As an organization, NICE was set up to act independently. However, it also was designed as a means used by the government to express its policy. Actors that joined the network did know the rules of network cooperation in advance. These rules aimed to form particular structures that would respond to governmental needs and policies at certain times. By joining the network, members accepted these rules. Consequently they also accepted the central role of NICE.

The role of the government was proven to be crucial in network formation. It had to bring together a variety of actors and regulate their performance according to the agenda formulated by the government. Although all the members formally knew the rules of operation in the network and they generally respected them, actors' own interests might have overridden governmental and network regulations.

The governmental inclusion-exclusion criteria for the network's membership were conditioned by the broader socio-economic and political context of the society. The government intervened in the formation of the network in response to past events causing conflicts and disagreement. A body like NICE was supposed to moderate this conflict and influence better outcomes, by bringing more balance to represented interests. The existing network had significantly encouraged such intervention in order to be re-regulated and restructured.

The criteria for inclusion in the network influenced the parallel exclusion of those groups that were anticipated to disapprove of the government's policy. For example, patient organizations were not initially included in the process as they would disapprove of a governmental policy that would ban beta interferon from NHS prescriptions. Many other inclusion criteria emerged from the research, one of which concerned the disposable resources of an actor, which he/she needed to enter the network. Another criterion for network membership was institutionalization, which in broad terms meant the participation of organizations in the network and simultaneously excluded the non-organized groups. Past conflicts and the power and status of the different organizations were reflected onto the actors' relationships and the network's membership and were seen as further criteria for the inclusion of actors in the

network. Finally, the network's composition was seen to be influenced by the role of individuals within their organization and to shape other actors' behaviour.

Network membership was influenced by many other factors, both endogenous and exogenous to the network. Among the exogenous factors was the operation of other networks. Endogenous factors included, for example, actors' personal interests and interaction. The study has shown that not only were organizations influencing the network and shaping actors' behaviour but individuals within organizations also mattered. Strong personalities could influence the network. What was common was that actors were seen as individuals and through them organizations were perceived.

The second theme that emerged from the study referred to actors' relationships and how they were structured. The relationships could be divided into two kinds: formal and informal. In the formal type, these relationships were defined by the government and required the collaboration of actors. Informal relationships, in contrast, could be argued to have been those relationships between actors that were not set by an authority such as the government or NICE, but were established between actors for serving their own aims based on their work in the network. The term „structure“ referred to all kinds of relationships established between actors, formal and informal, which were set by actors to facilitate and constrain their operation within the network by maintaining the network.

A two-step approach was applied to reveal the structure of the network. The first step involved drawing relationships as a link between the actors pictured on the map. The links were drawn according to how the initial document analysis defined actors' collaboration; for example, the collaboration of the academic review teams with NICE. The second step was to

ask respondents" views about the relationships between the network actors during the conducted interviews.

Interviewees outlined their perspectives and their answers placed particular emphasis on the relationships of their group to other network actors. The information they shared was, therefore, based primarily on their personal experience. The relationships and structure of the network were shaped by government rules that reflected past conflicts and the socio-economic and political context and expressed governmental policy. Governmental intervention also influenced relationships between network members beyond the exchange of necessary resources and referred to the control and regulation of power within the network, as well as the authority/ability of the government to maintain balance between the different actors.

Moreover, relationships were formed using the same criteria applied for actors" inclusion in the network and were also influenced by factors endogenous and exogenous to the network. Relationships were initially shaped by governmental rules, but they were also defined by the resources that actors were holding within the network and the exchange of resources between them. The exclusion of actors occurred in a different way. While some actors were, in theory, included as actors, in practice they were not seen as such. Those actors who did hold a significant quantity of resources formed sub-networks within the network. Respondents identified so called „active" actors, who were actors with power, and passive actors, namely actors present in the network but without any real influencing power. The most powerful actors formed smaller and tighter networks. Actors also formed alliances with other actors on occasions when their interests were threatened and they needed to maintain their position and

status. The alliances might have involved the exchange of resources or the formation of side deals between actors.

Past conflicts between actors were also reflected in the network's structure and defined the formation of new relationships. Since relationships define the structure, every change in relationships also meant changes in the structure of the network. Relationships and, subsequently, the structure of the network were bound to change, since interaction was a learning process for the actors.

The relationships between actors in a network were also shaped by endogenous factors such as the breach of confidentiality. Exogenous factors included the role of international pressure groups lobbying with the MS patient organizations. The relationships between the actors were also influenced by individuals' actions. The fact that individuals participated in more than one group, and there were overlaps between groups, exerted influence. The research showed that the relationships between actors were also defined by actors' extended interests and relations to other networks and there might be pressure being exercised on those outer relationships.

The third theme regarded actors' resources and power in relation to actors' position in the network. Resources were shown to have different meanings for every actor, and every actor's view on the most important resources and the most powerful actors within the network also differed. However, all interviewees agreed that money was the most significant resource. An interesting distinction drawn regarding resources was that between quantifiable ones, such as money, and non-quantifiable ones such as expertise.

There was asymmetry in resources and this asymmetry reflected the socio-economic and political context. The government intervened by regulating and correcting this asymmetry. This was also linked to previous discussions regarding ethics and the fairness of the decision-making process for more equitable policies. The government, by applying its authoritative power, was exercising control of power and balance within the network. It required actors to share their resources with others but, as the research has shown, this was done at a cost.

The appraisal process was characterized as necessarily political by a health professional. Moreover, it seems that there were no straightforward scientific decisions because, although a decision itself was based on scientific evidence, the criteria against which it was measured were not necessarily scientific. Unfortunately, decisions could not be uncoupled from the political arena and cost-effectiveness had become, unavoidably, a political issue.

The study has shown that individuals' skills constituted an important resource; they added power to an actor and had further influence on the network. Interviewees emphasized the fact that people and not the organizations influence the network and, consequently, the outcome. It was not only organizations shaping individuals' behaviour but also individuals influencing the outcome within an organization.

One of the research questions, posed in parallel with the questions generated by the model, has been how personal behaviour influenced the process. It was interesting to see that the role of individuals was acknowledged strongly. What also emerged from the research during the interviews, which could perhaps be called „the observed data“¹, was that the role of

¹Observations made by the researcher during the interviews. This data involves details such as the atmosphere between the researcher and the interviewee.

individuals was highlighted by the way that people talked and the language used when referring to their role within their organization.

Several points can be made regarding the role of the individuals in the network. Although individuals' behaviour was shaped by their organization's beliefs, people maintained their own views and separated themselves from the organizational position they held. For example, when interviewees were defining network membership, they spoke from a professional position as well as from a personal perspective; this explained the inclusion in the network of actors who had no resources and, therefore, were excluded by the government. Furthermore, people have higher morals, as the research has shown, and this also explained why organizations shaped individuals' behaviour.

Another interesting point was that no one seemed to be keen to be considered as the most powerful party; there was something unethical in that and in having the most resources, when there was such asymmetry. A possible explanation could be that nobody likes to be connected with the responsibility of making or participating in a negative decision; or to be accused of having, somehow, obtained so many resources while others have not.

6.3 Structure and Context of the network

Changes in the structure were expected by actors as part of a learning process taking place between them while they interact. The interaction established communication codes: the more they interacted, the better they communicated since they were learning to appreciate their own needs more as well as the needs of others. There were interdependencies between actors, meaning that they interacted because they had to exchange their data with the data of others

so they could all survive in the network and preserve their status position. Preservation of that status occurred not only at an organizational level but also at a personal level, since every individual had to respond to their own needs.

The research had shown that the appraisal of beta interferon was a learning process for everybody in the network. There were many changes in the network that influenced the context and the structure during and after the appraisal of beta-interferon treatment. The changes in structure and context were given different interpretations by each actor. Changes in the network consistently affected the context and the structure. Governmental intervention had initially set a context within which the network had to operate and had shaped the network's structure. During the appraisal process, the interaction of internal and external factors influenced the context and changed the structure. However, at times, it was difficult to define a factor as internal or external since they could be either, depending upon the interpretation attributed by an actor.

Some internal factors, highlighted by the research, involved changes in the actual appraisal; for example, the time taken to complete the appraisal process of the treatment. Another internal factor was the formation of sub-networks and alliances within the network. There was also political pressure on the government from other networks and actors, which led to the breakdown of existing rules and the formation of new ones. Other factors included financial pressure coming from the industry, societal pressure from the public, individual MS patients appearing on the media or other patients with conditions as serious as MS who were forming pressure groups and protesting in favour of patients' rights to receive available treatments not only for MS but other incurable diseases like cancer.

The study showed that the appraisal processes for the new treatment were receiving international recognition and were increasing the possibility of external factors influencing the network. At the same time, however, they were also increasing pressure on the actors in the network. Feeling part of an international community had become very important for every actor in the network. This had an impact on the network itself with a tendency towards a sense of international community and involvement with other networks.

A further finding of the research was an overlap in individuals between organizations within the network. One reason for this was the lack of experts which led to certain individuals being forced to operate within more than one organization. There was a question regarding ethics and conflicts for an individual if working for different organizations and, therefore, being guided by different interests. But as the research illustrated, network members relied on individuals' good will and ethics to make non-biased decisions while working for competing interests. This issue was, however, underlined by the fact that people placed emphasis on the importance of personal relationships and contacts. This could mean that, due to good personal relationships in the network, the formal rules and code of ethics might occasionally be ignored.

6.4 Network and Outcome

The first theme that emerged involved influence from previous policy outcomes and changes in actors' strategies to promote their interests. The research indicated that previous policy outcomes had affected the structure of the networks. Actors changed their strategies in response to new situations. The appraisal process proved to be a learning curve, with previous policy outcomes and appraisal procedures playing a significant role in the appraisal process of

beta interferon. In general, previous policy outcomes constituted a reference point for actors in the network and, therefore, it could be argued that outcomes affect networks in the same way that networks affect outcomes.

The research has shown that outcomes were interpreted differently by different actors. This was in accordance with the benefits that actors gained because of the outcome. The study showed that the main factors causing the restructuring of the network were both internal and external to the network. Key internal factors were governmental policy or politics, and actors' interests. Actors' interests can be seen in quantifiable and non-quantifiable terms, ranging from money to well being, and high morals. Internal politics and strategies were very influential factors for network organization and functioning, while actors interacted with each other for their own benefit and in order to influence the outcome. As the research demonstrated, powerful actors were forming sub-networks which operated in parallel to the main network, and additionally they were interacting with others and forming tighter relationships. Every sub-network within the network produced an outcome. In this case, there were more dilemmas and it was more difficult to reach a balanced outcome. To some extent, the existence of a wide-ranging network composed of networks and sub-networks that occasionally interacted.

External factors were also seen to influence the network, such as interaction with other networks leading to additional implications for the network. One example was government concerns about further politico-economic and social implications that an outcome might have. This factor could also be seen from the perspective of individuals within an organization. Their behaviours were shaped by their organisation's scope but also by their anxiety regarding

their own successful performance within the organization and, subsequently, their private lives. An interviewee said that the industry had been working with dedicated and skillful teams of people, which was not coincidental. Actors changed their strategies because they were developing, through interaction, a better understanding of their own role and of the role of others within the network.

Changes in strategies were seen to be influenced by the outcome inside an organization. The outcome was defined within the organization, and action was taken by its members. Individuals played an important role, made a difference and had further influence on the appraisal process, so success within an organization was also a matter of individuals and of leaders within it. In the case of the MS Society, for example, the Society's leader played a key role to the success of the case. As the input to the appraisal process involved quantifiable and non-quantifiable resources, the outcome had an impact on actors and brought in quantifiable and non-quantifiable benefits, especially for the patients' organizations, while links between actors were strengthened with some of them confirming their powerful status.

The findings highlighted the importance of individuals' roles and their ability to influence the outcome of the network; health professionals in particular had power that came from expertise and knowledge to influence the outcome thus gaining additional resources. Interviewees stated that some of the actors held a special role within the network and part of that role was to promote certain values.

The interpretation of the outcome did not involve only network members but the wider network as well. Reference could be made to the role of individuals in relation to the

outcome. Individuals were involved in the implementation of the outcome, and performed better when they had not participated in the formation of a non-positive policy or decision. In this way, pressure was taken off employees at health authorities that would have had to deny the treatment. An outcome was, at the same time, an input for the same network or for a different network, although through continuous interaction and restructuring a network hardly remained the same and naturally had further impact on actors. Appraising new products has become common practice in many countries. Influence between different networks occurs but there is also an impact on manufacturers who must prove the effectiveness of their products.

Networks affected outcomes in two ways: either via formal processes and interaction or through informal rules that dominate the network's performance. A significant variable regarding the outcome and the network was that the network had scientific grounding while the outcome reached was based on ethics. Interviewees stressed that, in the case of beta interferon, the outcome was not influenced by the network because it was different from the outcome predicted by the appraisal. This could happen to healthcare networks more than other networks due to the importance of the overall outcome of providing healthcare service.

The outcome was defined by the current political situation and governmental policy. Decision making processes should have been taken away from the political arena and decision-making for medical care should have been completed not only on a long-term basis; time should also have been allowed for implementation. Despite many changes, not enough time was permitted for their implementation. Constant changes in the political scene led to new policies that were favoured by different governments.

The interviewees' description of the outcome illustrated once more the different perspectives of each person and, to an extent, actors and their different expectations. Moreover, each of these observations could be argued to form a response to questions regarding what defined the outcome of the appraisal process: balanced in terms of inputs, political compromise, ethical and moral reasons, scientific validity, data uncertainty, pressure groups, big resources, socio-political and economic context, strong personalities, side deals and threats.

The research findings brought forward suggestions on the improvement of the network. These included the exclusion of certain actors from the appraisal process, or the focus on certain actors within the network such as doctors; the exclusion of actors such as NICE whose presence dominated the decision making process and, finally putting off clinical and cost effectiveness methods and the evaluation of new technologies. The case study on beta interferon and the concept of networks might have sounded slightly suspicious for candidates because of the extensive publicity that it had received. Despite the fact that the approach might have influenced the interviewees, during the interview they appeared relaxed and the interviews were performed in a very friendly atmosphere.

6.5 Limitations of the research

The study was bounded by two limitations. The first related to the bias that was brought into the research because of the researcher's personal perspective, as well as her cultural and professional background, all of which influenced the research. There was not extensive experience of designing and conducting a study and, as Cresswell (2003) has suggested, the only way to reduce bias was for a researcher to be honest. Personal perspectives and cultural background were the reasons for the decision to conduct an explorative study on the policy

making process and there was bias in the researcher's decision to study the particular topic of policy making in health care through the concept of policy networks.

Coming from a country where there was a lot of speculation regarding the health policy making process and the substantial role of key-actors, such as clinicians and the pharmaceutical industry, was the reason for added caution in drawing conclusions when studying another country's processes as things appeared different. Any hesitation influenced the setting of the study from the point of view that, even though the Model was applied in a certain way and the questions were formed in a particular way, there might be impact on the findings of the study, although on the surface the concept of the study had not changed. Nevertheless, the researcher's perspective and work contributed to the outcomes of the research.

The second limitation related to the actual study. Although the concept of policy networks is not new, it has not been widely applied to the study of healthcare policy. The Dialectical Model has not been widely applied either. The wording and the structure of the questions felt repetitive at times and so interviewees might have felt that they were repeating their statements. Moreover, small details in the use of words such as "consequences" instead of "impact" could have been avoided. The practical limitations were that there was no funding, the transcriptions were done by the researcher and all expenses came out of the researcher's budget.

The interviews were conducted when the appraisal had been completed so interviewees were reflecting on things from a different perspective than they might have had if they had been

interviewed during the appraisal. There was too much tension between actors during the appraisal.

Last but not least, there was a poor turnout regarding the number of candidates invited to be interviewed. This influenced the whole structure and the validity of the study. There was a poor turnout of respondents because the NICE AC chairperson did not allow other people to be interviewed on the beta-interferon case. In a way, though, this refusal supported certain hypotheses made in the study about the role of individuals within the network and the fact that organizations shape people's beliefs.

6.6 Future research

The findings of this research study point future research in two directions. The first one involves the establishment of new rules in health policymaking process; new rules for a process that would be primarily patient-oriented. Every other actor's interest would have to be served within a new framework with very strict rules that would not easily be broken. It could be a real challenge for a government to set up this type of network.

The second one refers to the way in which resources and power are distributed within the network. Resources should be allocated in different ways while actors with limited resources could have a real influence on processes without the need for lobbying and alliances to be formed. For example, media coverage would be made under strict rules on new projects. NICE has already introduced the appraisal of certain applied technologies and treatments so as to evaluate whether they should continue to be funded by the NHS.

6.7 Summary

It has been interesting to observe the appraisal process in terms of actors and networks and actors' interaction. It is important to see all these approaches adapted by network members during their interaction for the promotion of their own interests. The results of the study and the application of the Model verified the existence of health policy networks whereby various actors interact and are identified as the network members.

A very important element has been to see how people interpret their success and how they comment on others and, moreover, what the impact for the appraisal process, the network and the final outcome is. Furthermore, it has been useful to observe part of the policy-making process through the network's interaction and transformations.

The questions posed by the study and the Model gave a good view of the network's structure and context. A number of factors, internal and external to the network, were seen to interact and determine policy decisions while subsequently influencing the process and the outcome.

The research has shown that there are formal and informal rules within the network and that actors interact according to what has been agreed. Actors are working and cooperating in order to produce a favourable outcome, and interact accordingly in different situations. As demonstrated by the research, individuals interpret actions differently within the network but adjust to the new conditions between actors by maintaining formal relationships.

A further important research finding has been the role of individuals within organizations and within networks. The network is generally influenced by external and internal factors that

influence the role of actors and of individuals within them. Past conflicts, asymmetry in resources and power, the socio-economic and political context within which the network operates and governmental intervention, were some of the factors noted to be influencing the operation of the network. In addition, the Dialectical Model provided important information on structure and networks and their interaction with other networks

The findings of the research suggest that networks operate in a similar way. There are key actors and less influential actors, and the behaviour of both groups is shaped by the way they promote their interests. The structure and context within which networks operate are shaped by governmental intervention and actors' behaviours.

APPENDIXES

APPENDIX A

List of Consultees in the appraisal of beta interferon treatment

- Association of British Neurologists
- Biogen Ltd
- Department of Health
- Faculty of Pharmaceutical Medicine
- MS Research Group of the Association of British Neurologists
- MS ResearchTrust
- National Assembly for Wales
- Neurological Alliance
- Royal College of General Practitioners
- Royal College of Physicians
- Royal Pharmaceutical Society
- Sherhing HealthCare Ltd.
- Serono Pharmaceuticals Ltd.
- Teva Pharmaceuticals Ltd.
- The Chartered Society of Physiotherapy
- The Multiple Sclerosis Society of Great Britain and Northern Ireland
- The National Hospital for Neurology and Neurosurgery

APPENDIX B: COVER LETTER

Health Services Management Centre
Park House, 40 Edgbaston Park Rd
Edgbaston B15 2RT

Birmingham,/2003

Dear

My name is Theodora Kostikou. I am a PhD student at Health Services Management Centre, University of Birmingham. I am sending you this letter to ask you if you are willing to participate, as an interviewee, in a study that I am conducting.

My research topic is “policy networks and health care policy” with a case study on the National Institute for Clinical Excellence (NICE) and the Appraisal Process of Beta-Interferon, for the treatment of Multiple Sclerosis. In this project I am trying to study the role of the participants/actors in the policy-making process based on the “policy networks” approach.

The interview would last up to 1 hour. The questions discuss the role of the participants in the health policy-making process.

I would be very grateful if you are able to spare me up to one hour of your time. I am very happy to come and see you in your office at any time convenient to your timetable. It would be helpful if you could suggest two or three alternative dates that we could schedule the interview.

I would like to conduct the interviews between the 1st of April and the 30th of May 2003. I live abroad so I would really appreciate it if you could respond by email on the following address: [REDACTED]

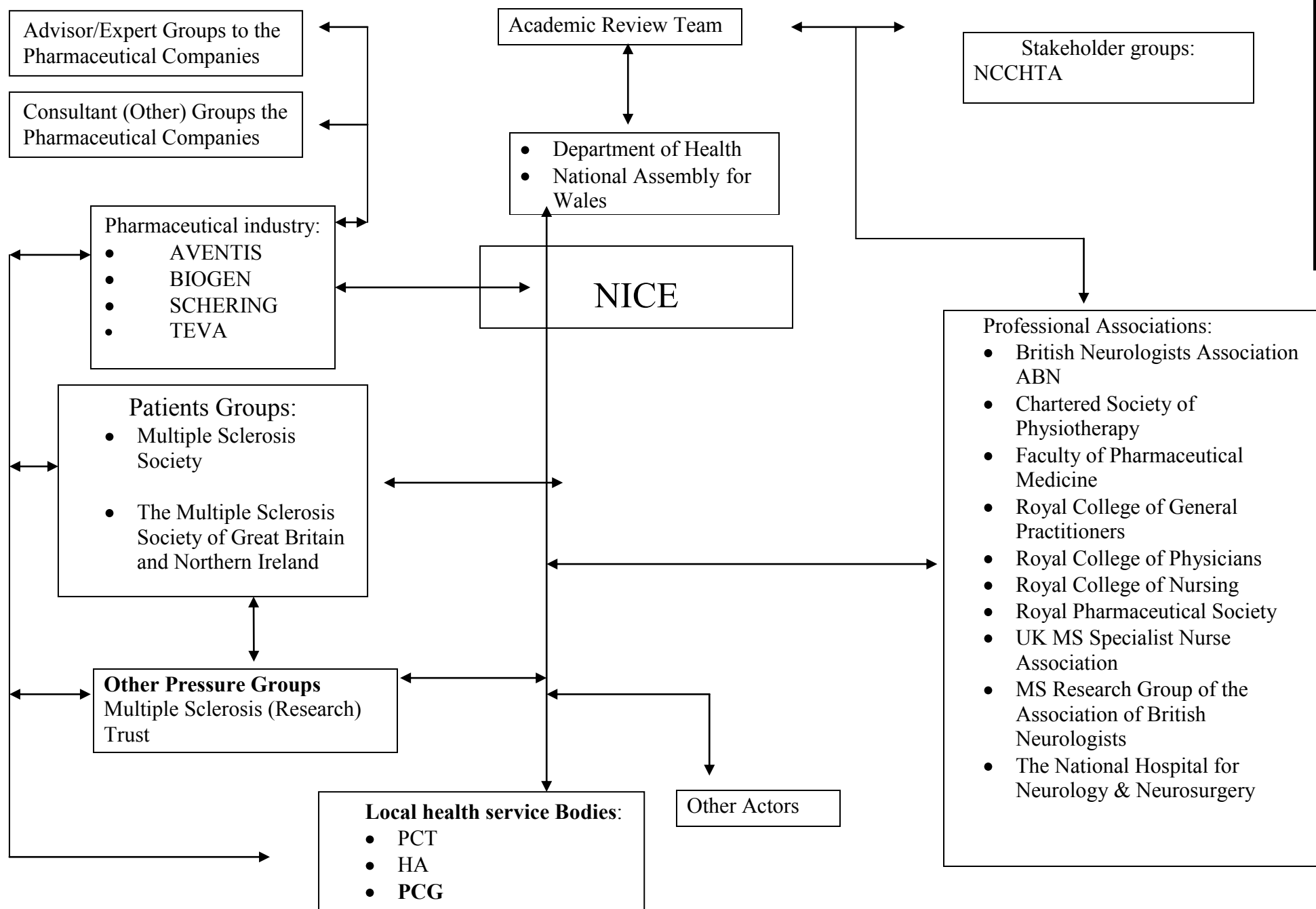
I would like to assure you that the interview would be conducted anonymously and that everything discussed during the interview will remain confidential, and data will be used in a non-attributable form.

Please contact me (preferably by email) if you would like any further information.

I look forward to hearing from you

Yours sincerely

Theodora Kostikou



APENDIX D: Interview schedules for research subjects

Introduction: Thank you very much for agreeing to participate in this study. As I was mentioning in my email this pilot study would be part of my PhD Thesis.

Before we start I would like to tell you that the interview is conducted anonymously, and to assure you that everything discussed during this meeting would remain confidential. Data will be used in a non-attributable form.

I would also like to ask your permission to tape record this interview.

We are studying the policy-making process in the UK healthcare service network, and, more particularly the role of the actors within it, and the impact that this might have to the policy outcomes.

The approach that we are applying is that of “policy networks”. The term of “policy networks” is defined as the “established relationships between public and private actors in order to produce a good or service”. “Actors” in policy networks are of course individuals, but as these are mostly members in the role of organization representative, organizations can also be considered as network actors. For practical reasons, and, of course since NICE is an organization with a significant role in the NHS, we have chosen to study this particular branch of the network revolved around NICE. Furthermore, we have selected as our case study the appraisal of the Beta Interferon treatment for Multiple Sclerosis.

The model that we are using suggests that the study of the network should be based in the discussion of three different relationships. The first one is about the actors and the network; the second is about the network and the framework in which it operates and the third one is about the network’s operation in relation to the outcomes.

-I1:Q1. What we are trying to do is to get a complete picture of actors and relationships within the network. We have identified as actors (network members) in this case study the organizations and groups involved in the Beta-interferon appraisal, as they were presented in a series of documents and the NICE website. I would like

Questions

Part 1

Q1. What we are trying to do is to get a complete picture of actors and relationships within the network. We have identified as actors (network members) in this case study the organisations and groups involved in the Beta-Interferon appraisal, as they were presented in a series of documents and the NICE website. I would like you to tell me what you think, (i.e. would you see more actors than those appeared in this documentation or less etc.)

Q2. Has the network structure changed since the beginning of the appraisal of Beta-Interferon by NICE and after the NICE guidance?

How the process has changed and what factors might have interacted?

Q3. What resources do these actors have? Would you say that some actors are more powerful than others are and why? (Assuming that power stems from the „amount“ of resources i.e. money, clinical data, and state authority, that an actor has).

Q4. What about human resources, do individuals“ skill matter? How important source of power would that be considered?

Second Part:

Q5. Has the changing of the process in the Beta-interferon appraisal had any consequences for the healthcare service network beyond that part that we described in this case study? (NICE with other appraisal, groups of patients)

Q6. Are there any consequences for NICE and its relationships with other networks, in a national and international level?

Third Part:

Q7. Have previous policy outcomes affected the structure of the network? (i.e. The first appraisal of zanamavir)

Q8. Having discussed the changing of network structure and possible for this change factors, how would you perceive this relationship between networks and outcomes?

Q9. Do you have something to add or any comments to make? Is there something elsethat you would like to say?

End of the interview: Thank you very much for your participation. I would like to remind you that everything discussed today would remain confidential and that the data would be used in a non-attributable.

APPENDIX E: RESEARCH INFORMATION SHEET 1.

Study Title:

Policy networks and health care policy: a case study on the National Institute for Clinical Excellence (NICE) and the appraisal of Beta-Interferon.

2. Invitation:

You are being invited to take part in a research study. Your participation is voluntary and you have the ability to withdraw at any time you wish. Please take time to read the following information carefully and ask the researcher if there is anything that is not clear or if you would like more information

3. What is the Purpose of the study?

The purpose of the research is to explore the role of the different organisations involved in the health policy-making process in the UK. More particularly it aims to explore the role of the participants in that part of the policy making process which is related to the National Institute for Clinical Excellence and the appraisal of various technologies. The appraisal of beta-interferon has been selected as a case study. The exploration of the relationships of the actors within the process will allow a better understanding of the policy-making process, and, potentially the explanation of policy outcomes. This research project is being undertaken as part of researcher's PhD thesis

4. Why have I been chosen?

You have been chosen because of your participation in the beta-interferon appraisal by NICE, and/or you are a representative of a group or organisation involved in the NICE policy network and the specific appraisal. The selection of participants for this research was informed using documentation relating to the beta-interferon appraisal (such as minutes from meetings of the Appraisal Committee).

5. What will happen to me if I take part?

You will be interviewed on one occasion and the interview will last up to one hour. The interview will be tape-recorded, if you agree, and a copy of the transcript will be sent to you so to check for accuracy. The tapes will be kept in locked filing cabinets until the assessment of the Ph.D. thesis, and will be destroyed immediately afterwards.

Unfortunately, the research budget does not allow us to pay expenses to participants. The researcher will come to meet you at a convenient time and place or the interview will be conducted by telephone.

6. What will happen to the results of the research study?

Data will be treated as confidential and will be used in a non-attributable form. A short summary of the main findings of the research will be posted to all participants. The research will be presented as part of my PhD thesis. In addition, papers will be presented in conferences and publications will be submitted to academic journals.

7. Contact for further information:

Miss Theodora Kostikou

HSMC, Park House, 40 Edgbaston Park Rd Birmingham

B15 2RT. E-mail: [REDACTED]

APPENDIX F

CONSENT FORM

Title of Research Project:

Policy networks in health care policy: a case study on the National Institute for Clinical Excellence and the appraisal for Beta-Interferon.

Name of researcher:

Miss Theodora Kostikou, PhD student, Health Services Management Centre, University of Birmingham

I confirm that I have read and understand the information sheet datedfor the above study and had the opportunity to ask question

Yes / No

☐

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason

Yes / No

☐

I know that records relating to me will be kept confidential. No information will be released or printed that would identify me.

Yes / No

☐

I am happy for the interview to be taped recorded.

Yes / No

☐

I agree to take part in the above study.

Yes / No

☐

Name of participant:

Date

Signature

Researcher:

Date

Signature

(1 copy for research subject & 1 for researcher)

APPENDIX G

List of analyzed documents

1.	ABPI statement (2002) Agreement on provision of MS medicines. http://www.abpi.org.uk/press/press%20releases_02/020204.hm
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6.	Anon (22/1/?) Lewisham News Shopper Fury over MS drug holds up
7.	Anon (23/6/2002) UK drug body launches review after MS controversy
8.	Anon (6/2001) Not so easy for NICE Health Insight
9.	Anon (9/8/2001) Wales should go it alone on beta interferon if necessary
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22.	BBC News (7/8/2001) Concern as MS drug „rationed“. UK. http://news.bbc.co.uk/1/hi/health/1476084.stm
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APPENDIX H: EVALUATION FORM

Evaluation/ Feedback Form

Please fill in this form with comments and suggestions, or any other observations that you might have.

- a. Content of the Interview (clear, difficult questions, examples)
- b. Structure of the interview: (i.e. coherency, sequence of the questions)
- c. Interviewers style (i.e., probing, listening)
- d. Please make any suggestions that you believe could help in improving the interviews.

Thank you very much for your participation in this pilot study. Please return this form to the address below

(Please use the envelope provided):

Theodora Kostikou

HSMC, Park House

40 Edgbaston Park Rd

Edgbaston B15 2RT Birmingham

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