The use of routine data to investigate hospital-level determinants of colorectal cancer survival in London

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Thesis submitted for the Degree of
Doctor of Philosophy of the University of London

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2008

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To Armo and Emma,

my parents

ABTSTRACT

Objective: Colorectal cancer survival varies at individual level and also geographically. This study used secondary data to investigate whether hospital organisational factors may explain colorectal cancer survival.

Methods: For 28 acute hospitals treating colorectal cancer in London, data on 15 468 patients first treated between 1996 and 2001 were drawn from the Thames Cancer Registry and their 5-year relative survival was calculated, with standard errors adjusted for clustering. The literature was examined to identify potential hospital organisational predictors of survival. Four English national data sets including measures of hospital organisation were identified and assessed for quality using a standardised method (Directory of Clinical Databases, DoCDat). Variables were assembled relating to the years 2000-2001. A multivariate relative survival model was used to investigate cross-sectional associations between the organisational measures and survival. Effects of missing data were also examined statistically.

Results: The data sets were assessed as of sufficient quality for the study. Most data by hospital were over 80% complete. Missing values for tumour stage and lack of detailed treatment information were the main limitations of the cancer registry data. Hospital organisational variables examined included hospital volume, staffing, waiting times, cancer services standards, and type (teaching/non-teaching). Individual factors in the model included age, sex, deprivation index and stage, but comorbidity could not be tested. There was a significant survival gradient across the hospitals, both before and after adjustment for individual factors. No relationship was found between survival and hospital volume, medical or nurse staffing, or waiting times for referral assessment. However, significant associations were found for teaching status, and for four of the cancer standards.

Discussion: Interpretation is limited by the cross-sectional design, temporal relationships, missing data and the limited number of hospitals. However, the study shows the potential of using hospital datasets to investigate organisational factors in cancer survival, and indicates the possible impact of teaching hospital status and some measures of cancer standards on survival. Further research is indicated to confirm these associations and investigate pathways for the effects.

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ACKNOWLEDGEMENTS

I would like to express my profound thanks to my supervisor, Professor Mark McCarthy, who has provided exceptional academic support and encouragement through all stages of this research work. Without Mark's direction and invaluable input, the successful completion of this thesis would not be possible. Also, I am very grateful for Mark's financial assistance and support with my career development.

I would also like to thank my co-supervisor, Jenny Head, who was very supportive and provided me with additional professional guidance and support, particularly on statistical analysis.

My special thanks go to Dr. Bernard Rachet and Prof. Michel Coleman from the London School of Hygiene and Tropical Medicine for their essential advice and assistance in using different statistical techniques for relative survival analysis.

This thesis received advice from many people. I specifically want to acknowledge input of all people involved in "Measures of Quality for the Improvements of Cancer Services" (MQiCS) national study, to which this thesis was related to. I am particularly grateful to Chris Sherlaw-Johnson (Department of Mathematics, UCL), Andy McMeeking (Cancer Action Team), Dr. Celia Ingham-Clark (Whittington Hospital NHS Trust) for their helpful comments, suggestions and support. Also I would like to thank my colleagues and friends from MQiCS team: Marina Thomas, Dawn Wilkinson, Arturo Gonzalez-lzquierdo, Preeti Datta, for their company, warmth, enormous support provided, encouragement and patience.

I would like to thank all individuals and institutions who provided me with datasets and assistance through all stages of my work. My special thanks to Dr. Henrik Møller (Thames Cancer Registry) and Dr. Jonathan Boyce (Acute Hospital Portfolio) who provided essential sources of data from the beginning of this study and offered continuous assistance.

The Department of Health and Cancer Action Team (Cancer Waiting Times and Cancer Services Peer Review), and NHS Health and Social Care Information Service (Hospital Episode Statistics) granted access to national datasets essential for research purposes.

Many thanks to the staff at the UCL Department of Epidemiology and Public Health, particularly Paul Phibbs, Sandy Persaud and Catherine Conroy for helping me in solving day-to-day issues and surrounding me with warmth, encouragement and assistance from the beginning of my work.

I would like to thank my friends in PhD room 309 and friends in the UK, Armenia and world-wide, thank you all for your support, friendship, patience and warmth which I felt through all stages of this study and beyond that.

I would also like to acknowledge Dr. Haroutune Armenian and Dr. Michael Thompson from the American University of Armenia (AUA) who inspired me to shift my career into public health research and provided with strong academic training in the field during my studies for Master degree at AUA. I feel their support till now.

I would like to thank Universities UK for granting me with the Overseas Research Students (ORS) Award to support my PhD studies; Armenian General Benevolent Union (AGBU) London Trust and UCL Department of Epidemiology and Public Health for essential financial assistance over the last four years.

No words would be enough to express my thanks to my parents. Their unconditional love and support has sustained and nourished me not only during this period of study but throughout my entire life. This thesis is dedicated to you!

Abbreviations

95% CI	– 95% Confidence Interval
AC	– Audit Commission
AHP	– Acute Hospital Portfolio
DCO	– Death Certificate Only
DH	– Department of Health
DoCDat	– Directory of Clinical Databases
GP	– General Practitioner
HC	– Healthcare Commission
HES	– Hospital Episode Statistics
HR	– Hazards Ratio
ICD	– International Classification of Diseases
IMD	– Index of Multiple Deprivation
MDT	– Multi-Disciplinary Team
MQiCS	– "Measures of Quality for the Improvements of Cancer Services"*[study]*
NatCen	– National Centre for Social Research
NHS	– National Health Service
ONS	– Office for National Statistics
OR	– Odds Ratio
RER	– Relative Excess Risk
RR	– Relative Risk
SDO	– Service Delivery and Organisation
TCR	– Thames Cancer Registry
UCL	– University College London

CHAPTER 1

INTRODUCTION

1 INTRODUCTION

Cancer is a major cause of death and disability in England, and improvement of cancer services has been identified as a high priority for the National Health Service (NHS). Survival for many cancers is considered to be lower in the UK than comparable European countries[1], and there are also differences between NHS regions and local areas[2;3].

Individual factors, both socio-demographic (age, ethnicity and socio-economic status) and clinical (tumour stage, co-morbidity), have an impact on survival at population level, as well as treatment through surgery, drugs and radiotherapy. But patient outcomes have also been shown to vary through organisational factors including access, staffing, hospital size and clinical specialisation. The present study investigates the use of existing datasets to assess organisational determinants of population survival for colorectal cancer in London. Particularly, the feasibility of getting and analysing the data from routine national sources, and feasibility in terms of limitations of inferences for these purposes were assessed.

1.1 Cancer policy in England

To reduce regional variations in treatment and outcome for cancer patients and to achieve more coordinated care, the chief medical officers Dr. Calman and Dr. Hine in the Departments of Health for England and Wales undertook a review of the current state of the field and in 1995 they published report which proposed new policy framework designed to reorganise cancer services[4]. The main recommendations from the Calman-Hine report came from the assumption that improved outcomes are associated with specialised care.

The new Labour government responded with the cancer summit in 1999[5], appointed a Director of Cancer Services (cancer 'tsar') as both the Government's senior civil servant for cancer policy and also to head a Cancer Action Team responsible for NHS implementation, and published a national Cancer Plan[6].

The Cancer Plan for England (2000) set out the government's programme for reform of cancer services, to reduce death rates and improve survival and quality of life. Among organisational objectives, the Plan sought to develop a service with active patient

involvement, multidisciplinary teams and across service collaborations in managing cancer patients. Its main commitment was to improve waiting times for diagnosis, referral and treatment.

The Cancer Plan developed the earlier designation by Calman and Hine of cancer centres and units, creating 34 defined cancer networks across England. These roughly corresponded with NHS decentralised boundaries at the time (regions and special health authorities), and reflect patient referral patterns for specialist facilities, and transportation links. The cancer networks were required to have a Board representing the collaborating hospitals, but were each established by local arrangements without central direction on their structures. Likewise, there were developments of cancer specific multidisciplinary teams (MDTs) at each acute hospital trust. The MDTs have been created so that each cancer patient will be reviewed and managed by the multidisciplinary team of specialists, including surgeons, oncologists, radiotherapists, pathologists and specialist nurses.

To set up and develop good local practice, the Cancer Services Collaborative was launched by government in England in 1999[7;8]. These were a series of projects at local level, intended to improve patients' experience of care by reducing delays and creating a more patient-centred approach.

The 'Improving Outcomes Guidance' has been developed by the Department of Health, and subsequently the National Institute for Health and Clinical Excellence (NICE), for a range of tumours – colorectal (1997; update 2004), breast (1996; update 2002), urological (2002) and other tumour types[9-13]. These systematic reviews mainly focus on the effectiveness of specific diagnostic and treatment procedures, and acknowledge that organisational and service level determinants of outcomes are not sufficiently scrutinised in the literature. However, they served as a source material for the development of the Manual of Cancer Services Standards (2000; update 2004)[14].

The Manual of Cancer Services Standards, published by the Department of Health in December 2000, set out how the MDTs for particular cancers should be organised[14]. In 2001, cancer units and centres were assessed against these standards by peer-review teams of health care professionals and managers to identify whether standards were or were not being met[15].

The review was undertaken by the Commission for Healthcare Improvement and the Audit Commission to assess the progress in implementation of the Calman-Hine report[16]. They showed marked variation in agreed treatment policies between hospital trusts

and by tumour type. However, they visited only limited number of hospitals and did not specifically assess the impact of reforms on the outcomes of care. The focus of this review was the range of services received by cancer patients from their initial point of contact with the NHS. Recent assessments by Department of Health and the National Audit Office of the progress in the implementation of the Cancer Plan indicated that although substantial progress has been achieved in reorganisation of cancer services and improvements in outcomes, progress varied by cancer and locality[17;18].

National Audit Office identified the following national and local stakeholders involved in cancer services in England (see Table 1.1).

Table 1.1 Key stakeholders involved in cancer services*

Stakeholder	Role
National	
Department of Health	Setting overall policy direction, securing resources and setting national standards.
National Cancer Director	Takes the lead in developing and implementing the Department's strategy for cancer. He is supported by the **Cancer Action Team**, the Department's cancer policy team and the Cancer Services Collaborative Improvement Partnership.
NHS Cancer Screening Programme	Oversees the delivery of screening programmes for breast (in over 90 units) and cervical cancer, and the development of screening programmes for other cancers.
Care Group Workforce Team: Cancer	Draws up national workforce strategies for cancer. It is supported by the lead **Workforce Development Confederation.**
NHS Information Authority	Develops information services to support the key clinical priorities of the Department of Health, including development of the national cancer dataset to provide data on the whole cancer care pathway, waiting times and support for the National Clinical Audit Support Programme.
Modernisation Agency	Supporting the NHS and its partner organisations in improving cancer services. It aims to achieve this through the individual projects within the **Cancer Services Collaborative Improvement Partnership**.
Cancer registries	9 regional cancer registries collect and collate data from their area and report the results to the Office for National Statistics.
Office for National Statistics	The **National Cancer Intelligence Centre** at the ONS collates national cancer data and carries out a range of research. It publishes definitive data on cancer outcomes in England.
Commission for Healthcare Audit and Inspection	Succeeded the **Commission for Health Improvement** from 1 April 2004. Independently inspecting service standards for cancer patients, among others, and commissions national clinical audits of cancer-related subjects.
National Institute for Clinical Excellence	Providing patients, health professionals and the public with authoritative, robust and reliable guidance on current "best practice". It is responsible for producing cancer Improving Outcomes Guidance and assessing the clinical- and cost-effectiveness of new treatments and promoting their adoption by the NHS.
Local	
Cancer Networks	The organisational model to deliver the Cancer Plan at a local level. There are 34, bringing together commissioners and providers of cancer services from the NHS, local authorities and the voluntary sector.
Strategic Health Authority	28 SHAs manage the performance of NHS services locally and develop local plans to meet national priorities.
Primary Care Trusts	Commissioning the majority of NHS services and managing the provision of community services.
Cancer units**	Normally a district hospital, offering a range of diagnostic and treatment services and care for patients with the commoner cancers. Cancer units are not separated from other hospital services but are an integrated part of the hospital.
Cancer centres**	Normally part of a large general hospital, providing services for patients with commoner cancers, as well as an additional range of specialised services which it will normally provide in support of cancer units.
Service users	Service users (patients and carers) are increasingly seen as stakeholders in cancer services who can contribute to the planning, development and implementation of cancer services.

**Source: National Audit Office. Tackling Cancer in England: Saving more lives. 2004*

***Reference: Calman K., Hine D. A Policy Framework for Commissioning Cancer Services: A Report by the Expert Advisory Group on Cancer to the Chief Medical Officers of England and Wales. 1995*

Fuller information on time-line of key policy developments in England are specified in Table 1.2.

Table 1.2 Time-line of the main developments in cancer policy/services in England

Key events	Year (one-off or first start)
Calman-Hine report	1995
Organisational changes in local cancer services - multidisciplinary teams; cancer centres and units	1996
Cancer Networks	1996
Improving Outcome Guidance for various tumour types	Breast cancer (1996; update 2002); colorectal cancer (1997; update 2004); lung cancer (1998); gynaecological cancers (1999); upper gastrointestinal cancer (2001); urological cancers (2002); other tumour types (2003-ongoing)
The New NHS white paper (waiting times policy)	1997
Dedicated funding (£10m per annum) for selected cancer types	breast cancer (1997); colorectal cancer (1998); lung cancer (1999)
Downing Street summit on cancer	1999
Appointed Director of Cancer Services (cancer 'tsar')	1999
Cancer Action Team	1999
Cancer Services Collaborative	1999
NHS Cancer Plan	2000
Cancer Information Strategy	2000
The National Cancer Research Institute	2001
Monitoring Cancer Waiting Times	2001/2002
Manual of Cancer Services Standards	2000 (update 2004)
Cancer Services Peer Review using published standards	2001 (2nd round 2005-in process)
National Cancer Patient Survey	2000/2001
Key follow-up/progress reports	
Commission for Health Improvement/Audit Commission: NHS Cancer Care in England and Wales	2001
Department of Health: NHS Cancer Plan. Three-year Progress Report: Maintaining the Momentum	2003
National Audit Office reports: Tackling Cancer in England: Saving more lives Tackling Cancer: Improving the patient journey The NHS Cancer Plan: A progress report	 2004 2005 2005

1.2 The use of routinely collected data to assess organisational predictors of cancer survival

A growing body of evidence suggests that hospital characteristics can influence the outcome of care[19;20]. Organisational level indicators, including hospital staffing levels and volume of activities, are predictors of hospital mortality in cardiology and other

specialties[21-26]. However, this association has been less explored in relation to cancer care.

Studies on cancer outcomes have mainly used in-hospital or 30-day mortality, but not long-term survival. This may be because most of the studies have been in the USA, where cancer registration is not routine and has developed only recently. In comparison, the UK has a long history of national cancer registration, and the capability of measuring survival through linkage to death certification. The National Health Service also has systematic data sets for management use and performance assessment.

It is difficult, however, to compare outcomes across hospitals when assessing provider performance, because different hospitals treat different types of patients. Hospitals with sicker patients may have higher rates of complications and death than other hospitals[27]. Therefore, crude hospital statistics can be misleading and need adjustment for case-mix to make meaningful comparisons of performance between hospitals.

In the past, an important limitation was the feasibility of voluntary, standardised data collection by health care institutions and agencies[28]. Now many of them have begun to report standardised quality data routinely, either voluntarily or in response to requirements from state, governmental bodies or accreditation agencies. Moreover, there is also a trend to report outcome data both on organizational (hospital) and individual (doctor) levels.

However, the quality of administrative databases remains a problem. The literature particularly points out variations in coding accuracy, and the lack of comprehensive clinical data on disease severity[29;30]. In addition, the accuracy of cancer statistics depends on completeness and retrieval of case notes, as well as completeness of case ascertainment by cancer registries and accuracy of primary data sources from which registrations are made[31;32].

The literature on cancer outcomes has primarily focused on the role of patient risk factors[27], including age, stage of disease and social deprivation, influencing the outcome of cancer care[33-36]. However, hospital activities are complex and their outcomes are also substantially affected by non-medical factors related to the structure and process of care[19;20]. The 'Improving Outcome' reviews accompanying the Cancer Plan for England indicated that this field was under-researched and suggest areas for further investigation[37;38]. There is general consensus that the use of clinical guidelines or compliance with standards of patients' management can improve the process and outcome of care[39-43]. However, there is inconsistent or lack of evidence in the literature that meeting proposed treatment or service targets is associated with better survival from cancer[44]. And

data are especially sparse for specific cancer sites, including colorectal.

Two studies were of particular relevance in the development and conceptualisation of this study.

In a national study of England, Jarman et al linked different sources of routinely collected data (HES; census; patient surveys; other data on hospital characteristics such as staffing levels and GP distribution) to investigate variations in in-hospital mortality over a four year period (1991/1992 – 1994/1995 financial years)[22]. They made a regression analysis, with hospital standardised mortality ratios as the dependent variable. In the study, the four year crude death rates varied across 183 acute hospital trusts from 3.4% to 13.6%, and the standardised hospital mortality ratios ranged from 53 to 137. Adjustment for age, sex, and selected indicators of comorbidity left a large amount of unexplained variation. The percentage of emergency admissions and the ratios of doctors to head of population served, both in hospitals and in general practices, were found to be significant determinants of variation in mortality. The numbers of hospital doctors of different grades were also considered as explanatory variables, but total number of doctors per bed was found to be the best predictor. However, along with the presence of co-existing diseases (comorbidity), other important indicators of patient case-mix, like stage or social status, and the severity of illness, were not assessed or taken into account in this study. Besides, the validity of the indicators of co-morbidity employed remained unclear[45].

In a study specific to cancer services, Morris studied adherence to cancer standards for colorectal cancer patients in 14 hospital teams in Yorkshire (UK) [46]. She concluded that a 25% increase in adherence was related to around 8% reduction in the risk of death after one and two-year follow-up[46]. The effect remained after adjustment for age, stage, socio-economic status and year of diagnosis. However, this association was not sustained in relation to breast and lung cancers. Adherence to the standards was assessed by questionnaire and based on score determined by the number (and then percentage) of standards that had been met. Each standard was given an equal weight. However, individual standards differ in their clinical significance, and it is difficult to interpret the meaning of the composite team score. Also, no evidence was required by the questionnaire to prove the actual compliance with the standard, as it was done in a national peer review process.

However, no other study on the relationship between compliance with published Manual of Cancer Services Standards [14], as assessed by national peer-review in England, and outcomes, was identified.

These two studies indicate the potential for using existing data sets in analyses to explain clinical outcomes, and the potential for assessing organisational determinants within cancer services. These studies, and further selected key literature, are presented in Table 2.2, *Literature Review* chapter.

1.3 Choice of tumour type for the study

Colorectal cancer is one of the four most common cancers in the UK, contributing significantly to cancer mortality. It is the second common cause of death from cancer for both men (after lung cancer) and women (after breast cancer). Five-year survival remains around 40-45%, and rates are below those in comparable countries elsewhere in Europe and in the USA [47]. According to 'Improving Outcomes' guidance[13], colorectal cancer accounts for more hospital in-patient expenditure than cancer of any other site, and for between 10% and 20% of palliative care provision.

Previous studies and published data have demonstrated wide variations in the presentation, management and survival for colon cancer between health districts, and by social group. Regional cancer survival statistics issued by the Office of National Statistics (ONS) in England show that, for patients diagnosed in 1994-1996 and followed up to the end of 2001, there was more regional variation in five-year survival for colon cancer than for either breast or lung cancer [48]. These results are similar to those in a previous report on cancer survival in the health authorities of England for patients diagnosed in 1993-1995, and followed up to the end of 2000, which showed inter- and intra-regional variations in colorectal cancer survival by health authorities and regions [35]. However, the reasons of observed differences in survival remain unclear and insufficiently studied, and differences in data quality between regional registries may partly contribute to observed variations.

In summary, colorectal cancer is a common, medium-survival cancer. This potentially allows sufficient number of patients and 'events' (deaths) for survival estimations and statistical modelling on hospital level. Local variations on hospital level

may be expected because of observed regional variations.

1.4 Aims and objectives of the study

The aim of this study is to investigate the association between organisational determinants of structure and process of care at hospital level and five-year relative survival, for colorectal cancer in London. It was also aimed to investigate the feasibility of using routine data for these purposes.

This is justified for at least four reasons: (1) the renewed interest in improving outcomes through organisational means, demonstrated within the Cancer Plan for England; (2) the evidence that organisational level indicators are associated with the outcome of health care for other diseases; (3) the fact that the relationship between organisational determinants and outcome has not been fully explored in relation to cancer care, particularly colorectal cancer; and (4) the existence of routinely collected data which reflect various aspects of cancer care.

It was hypothesised that the characteristics of structure and process of care at hospital trusts in London predict colorectal cancer survival, independently of known individual level associations. Two main study objectives were:

Objective 1: To draw available national datasets together; review their properties, assess the feasibility of using the datasets in terms of coverage and accuracy, and identify hospital level indicators for further investigation, in relation to the evidence from the literature.

Objective 2: To explore the relationship between hospital level indicators and five-year relative survival, after adjustment for patient case-mix, for colorectal cancer in London.

1.5 An overview of the thesis

Following the *Introduction*, the thesis is divided into five main chapters: literature review; materials and methods; results; discussion; and conclusion. The literature chapter provides a review of the use of routine data for outcome research, their advantages and disadvantages, with a special consideration of cancer related data quality issues; then discusses patient factors that affect outcomes; clinical treatment and organisational determinants of cancer outcomes. The next chapter provides with a description of the materials and methods used in the research. An account is given of the geographical location of the study; study population; research design; sources of data used and data analysis. A detailed description of the proposed model for assessment is provided. The next chapter describes the main results. The results of assessments of properties of available datasets are presented, taking into consideration the feasibility of using the datasets for the purposes of the study. Descriptive analysis of the data, as well as univariate and multivariate associations are presented too. This follows by discussion of the findings in the light of present knowledge. The associations between each predictor and outcomes and the main strength and limitations of the study are discussed. The thesis ends with concluding overview and suggestions for future research.

CHAPTER 2

LITERATURE REVIEW

2 REVIEW OF THE LITERATURE

2.1 Review strategy and selection criteria

The literature review was aimed to describe the opportunities and limitations of using routine, administrative data for healthcare research, and to identify potential predictors of cancer outcomes, both on individual and organisational level.

The review of the literature was conducted using MEDLINE and EMBASE databases for articles published from 1985 onwards. Searches used combinations of key words and Medical Subject Headings (MeSH) to identify the majority of included studies: outcome, performance, evaluation, health care institution, hospital, quality, routine, data, database, dataset, cancer, service, healthcare, mortality, survival, risk, factor, predictor, colon, rectal, colorectal, NHS. The words 'colorectal' or 'cancer' were not required to be in the abstract or title, nor to appear in the keyword or indexed terms, because many publications dealt with more than one anatomic site or nosology and thus using 'colorectal cancer' more specifically would have omitted these multiple-site analyses.

As a second stage, the abstracts and titles were screened by the researcher to identify relevant studies for inclusion in the review and full text of those articles were obtained.

In addition, review of citations and expert advice was carried out to detect studies/publications not found in the electronic databases. 'Grey literature' (papers, documents, reports and web sites prepared by a range of governmental, public and private organizations) was also searched through Department of Health and key government agency websites, and hand searching of bibliographies in official publications (where these are supplied).

Improving Outcome Guidance[9-13] was published with accompanying systematic reviews of the relevant literature. They covered material specific to the cancers they concerned, including colorectal, and main themes identified there were used for subsequent searches. However, while relevant, their main focus was on clinical aspects as relatively little direct research has been carried out on the organizational predictor of cancer

outcomes[38].

The literature search was not restricted by nationality or language. Studies were included in the literature review based on their relevance to the topic under investigation, regardless of design employed and the type of publication. Descriptive, observational studies, review and discussion papers were the most commonly found and used.

Quality of routine data

For papers on quality of routine data, the main sources for identifying the 'concept' key words were papers by Iezzoni et al within the supplement to Annals of Internal Medicine[49] which contains articles developed from the Regenstrief Conference entitled "Measuring Quality, Outcomes, and Cost of Care Using Large Databases" that was held in 1996 in USA. Experts from relevant fields were invited to the conference, and they have incorporated comments from the discussions and the audience into their papers for this supplement. In addition, Donabedian's key studies[29;50;51] on the topic were used. Thus, key issues related to the quality of routine data were identified and used to conduct subsequent searches of the literature.

Predictors

Using a combination of keywords 'outcome' + 'healthcare', or synonyms of these words, allowed distinguishing potential predictors which may affect outcomes. A subsequent searches of the literature on key identified predictors were conducted by applying a combination of key words 'volume' and 'outcome'; 'specialisation' and 'outcome'; 'guidelines' and 'outcome' and so on. This review included not only predictors which were available for the study through consequently gained access to a number of national datasets, but also important factors which were not available for the study but were shown in the literature to have an impact on outcomes of care, for example 'comorbidity' and 'specialist surgeon'.

Disease group

Studies which have a focus on cancer patients were the main ones included in this review. However, key studies examining organisational determinants in relation to other pathologies have also been considered, especially in case of insufficient or lack of evidence from cancer literature.

An overview of the chapter

Review of the literature is presented as a synopsis of identified studies with comments/critique on methods and results, as appropriate. A more detailed description of selected key references is presented in Table 2.2.

The literature review is divided into several sections which reflect three main themes: datasets (sections 2.2); patient factors to affect outcomes (section 2.3); and organisational determinants of outcomes (section 2.4).

First theme ('datasets') discusses the use of routine data to assess outcomes in health care settings. It considers strength and weaknesses of routine observational data, with specific emphasis on data quality issues (2.2.1). Particularly, the issues with clinical content, completeness of diagnosis and procedures, coding accuracy and differences in data quality across hospitals have been reviewed. A special consideration of cancer related data quality issues have been provided: death certificate only (DCO) registrations, incompleteness and retrieval of case notes, and case ascertainment and registration bias. Then the problem of temporality while using routine data in health care research (2.2.2) and the use of linkage across data sets (2.2.3) to draw more complete health care experience of patients have been discussed. It is followed by examples of risk adjusted models (2.2.4) and performance management initiatives (2.2.5), and a brief summary on advantages and disadvantages of using secondary data (2.2.6).

Then the review shifts its focus to the individual and organisational determinants of outcomes in cancer care.

Firstly, it details patient factors to affect outcomes (2.3) with reviews of the main indicators which literature emphasised: age (2.3.1), tumour stage (2.3.2), the effect of social deprivation (2.3.3), the presence of comorbidity (2.3.4), and the influence of various types of clinical treatment (2.3.5).

Secondly, the review of organisational predictors of outcomes in cancer care has been presented (2.4). Particularly, the impact of staffing level (2.4.1); hospital and physician volume of cases or operations (2.4.2); specialist care (2.4.3), including multi-disciplinary management of cancer patients; teaching status of hospitals (2.4.4); compliance with clinical guidelines and standards of care (2.4.5), and delays in referral and treatment

(2.4.6) have been reviewed

The literature review ends with a summary of literature findings (2.5) presented in above mentioned sections of the chapter, and a commentary on selected key references (see Table 2.2).

2.2 Using routine data to assess outcomes

Routine observational data can be accessed as a by-product of administering health services, and are held in databases by governmental bodies, service providers or regulatory agencies[30]. Routine data are attractive to researchers, healthcare professionals, managers and policy-makers, since the data are readily available, and include large numbers of patients across diverse geographical and healthcare settings[52;53]. Adequate data are needed to identify the population potentially affected by the change, define an appropriate comparison group(s), measure important baseline variables, and ascertain study outcomes[54].

Routine data may be used to investigate measures of structure, process and outcome that form the basis of health care evaluation[29;50;51]. Observational studies often show variations between geographical regions, healthcare providers and also individual practitioners[53]. The research challenge is to determine how far these variations are real differences rather than artefact, and how far they reflect differences in quality. Artefactual issues include both the accuracy (reliability and completeness) of the data, and the temporal relationships connecting actions with effects, while differences in quality are related to the validity of the data. Researchers may also link data sets to achieve greater depth of analysis: but the data sets were usually not originally prepared for this purpose.

Observational studies are not as strong in scientific terms as randomised intervention studies, because interpreting results must recognise the possibility of unknown confounders. However, by no means all clinical policies are based on randomised studies[55;56], and in many fields randomisation "may prove unnecessary, inappropriate, impossible or inadequate"[57]. Statistical models can be made in observational studies to attempt to exclude the effects of confounders, but these presume understanding of the confounding variables and their accurate measurement[58], neither of which are entirely possible, so that at least a moderate bias will remain.

Routine data sets can be used for comparisons between services and geographical regions, assessing the effectiveness of health care interventions in practice, and providing insights into quality, performance and outcomes of health services[53].

In relation to the design of the study of this thesis, the following sections discuss literature relevant to these themes: quality of routine data (2.2.1); temporal relationships (2.2.2); data linkages (2.2.3); risk-adjusted models (2.2.4); performance management

initiatives (2.2.5); and a summary of using secondary data for outcome research (2.2.6).

2.2.1 Data quality

The first and most obvious problem of routine, administrative data is the accuracy of the data themselves. According to A. Donabedian, a major aspect of validity "has to do with the accuracy of the data" [29].

The accuracy of cancer statistics depends on the completeness of case ascertainment by the registries and on the completeness and accuracy of the data sources from which registrations are made [59].The main data sources for cancer registration are hospital notes and data on death certificates forwarded by the Office of National Statistics (ONS) to each registry on every person dying for whom cancer is mentioned. Death certificates also enable registries to identify cases not registered in life. For instance, at Thames Cancer Registry (TCR), approximately 50% of the cases identified by death certificate notifications will already be known [59;60]. For the remainder, the death certificate is used to initiate a new registration. Those cases not traced by following up case notes at hospitals and treatment centres defined as death certificate only (DCO) registrations. According to a study on completeness of TCR data, improvements in computerised matching of records along with active tracing of unmatched deaths have reduced the DCO rate at TCR to 10.5% at the end of 1998, and TCR attains 92.1% overall completeness five years after diagnosis for all cancers[61].

- **Clinical content**

Administrative databases always contain routine demographic data. Additional clinical information includes diagnosis codes (e.g. based on International Classification of Diseases (ICD), Ninth Revision, Clinical Modification [ICD-9-CM] or Tenth Revision [ICD-10]) and procedure codes. In the United Kingdom, diagnoses are usually reported as ICD codes, and surgical procedures categorised according to the classification of operative procedures known as OPCS-4. In the United States, discharge diagnoses are reported as ICD codes, procedures as Current Procedural Terminology (CPT95) codes, and drugs as the Food and Drug Administration's NDC directory [62-65].

ICD codes can be used to make risk-adjustment of patients across hospitals [30]. For instance, patients with pneumonia can be classified as having more severe disease if the discharge abstract also contains codes for sepsis [30]. Some ICD codes may also be used to indicate technical quality of care but the specificity of the codes is uncertain [30].

Standard code systems are less available for such clinical data as test results, clinical observations, units of measure, symptoms, problems, and infectious organisms[65;66].

In addition, many of the proposed indicators for performance evaluation/outcome management depend on accurate coding of secondary diagnoses, although this is known to vary widely [30;67]. The coding, recoding, and measurement of routine patient data in hospitals may be adequate for internal management but not for outcomes evaluation [27].

- **Completeness and accuracy**

Administrative data are typically submitted in formats that limit the number of coding slots. In the UK, Hospital Episode Statistics (HES) data system contains up to 7-12 diagnosis fields (one main diagnosis, one subsidiary diagnosis and six further diagnoses) and up to 4 operative procedures fields (one main and three secondary procedures) [68]. This may be sufficient for uncomplicated cases, but is often inadequate for complicated admissions or patients with multiple or chronic diagnoses. A study of US Medicare data suggested that chronic conditions were less likely to be coded when patients died because all the coding slots were consumed by acute diagnoses [30;69]. On the other hand, risk-adjustment for co-morbidity becomes more difficult if many accessory diagnoses are recorded.

Administrative databases can be more complete than clinical ones. For example, Barrie & Marsh, who compared the Manchester orthopaedic database with the (routine) Hospital Activity Analysis dataset, found that overall completeness of the data in the orthopaedic database was 62% and the accuracy was 96% [70]. On the other hand, Fine et al concluded that a specialist database of clinical outcomes after cardiac surgery in the UK had a mean of 25% of essential data elements missing, whereas only 1% were missing in the patient records [71].

The completeness of cancer registry's data depends on completeness of primary source data (case notes). To assess biases connected with using hospital case notes by Thames Cancer Registry (TCR) in relation to colorectal cancer, Vickers & Pollock

conducted a retrospective case note study[72]. Case note retrieval rate for all districts combined was 80%. Incompleteness of case notes ranged from 38% to 62% for staging, 8% to 40% for treatment, and 70% to 25% for diagnostic tests. Information about treatment was missing in 3% to 20%; survival data were omitted in less than 5%. In all districts completeness of case notes was inadequate and in some non-retrieval compounded the problem. Missing data reduce the quality of cancer registry data and potentially undermine interpretation of epidemiological studies and evaluation of care.

The accuracy depends on the correct abstracting of data by the registration clerk and coding differences between clinical and registry's practices. Pollock & Vickers assessed the reliability of data collected by the TCR by comparing the registry's data with those within case notes, for colorectal cancer cases diagnosed in 1983 or 1988[31]. Among the 416 case notes retrieved, including 66 DCO registrations, full or high agreement between registry data and hospital notes were recorded for sex, district of residence, and dates of birth and death. Only 12% of cases had the same date of diagnosis. Lower agreement rates occurred for tumour site (87%), whether treatment occurred (84%), and treatments administered (80%, 1983; 72%, 1988). 20% of surgical treatments and 37% of adjuvant therapy, radiotherapy, and chemotherapy were not recorded by the registry. Disagreements were common among DCO registrations. In 36% of DCO registrations the patients survived more than 1 year from diagnosis which may indicate a failure of registry ability to identify incident cases. DCO registrations were a good proxy for under-ascertainment of incidence in rectal but not colon cancer, and a good proxy for under-ascertainment of treatment in both colon and rectal cancers [73].

Coding error is frequently listed as a limitation of studies using hospital discharge summary databases. Green et al showed that substantial inter-hospital variations exists, particularly in the underreporting of comorbidities and distinction between urgent and emergent admissions[74]. They also reported a 9% error rate in the coding of the principal diagnosis.

A systematic review of the literature on discharge coding accuracy in the UK hospital statistics reported median coding accuracy rates 91% for diagnostic codes and 69.5% for operation or procedure codes in studies in England or Wales [75]. There was a trend towards more accurate coding of more frequent conditions. However, reported studies were small, from a limited number of centres and of variable quality. Also, accuracy varied depending on coding system used.

There are also fears about manipulation of data, which are supported by evidence of a dramatic increase over two years of almost threefold in recorded rates of COPD and over fourfold rises in congestive heart failure [30;67]. This was likely to be due to external incentives, including changing reimbursement rules.

- **DCO registrations**

A high proportion of DCOs may bias the calculation of incidence, survival and treatment rates through inadequate coding of tumour site or cause of death, and lack of information on the date of diagnosis. For the latter reason, they are excluded from the survival analysis.

DCO cases typically have very short, poor survival times since there would be less time to register them in life[32]. A study of the TCR data showed that the following factors were associated with DCO registrations: increasing age, decreasing survival, district of residence and place of death [32]. Higher proportions of DCOs might be expected among patients diagnosed post mortem, patients dying at home, patients not receiving active treatment, patients with short survival and patients treated at centres which do not liaise with cancer registries (e.g. some private institutions).

The percentage of DCOs varies from 1% to 25% of all registrations [59]. For instance, DCO registrations accounted for 22% and 15% of all colon and rectal cancer cases, respectively [73].

Pollock & Vickers investigated variations in five-year relative survival rates for colorectal cancer and DCO proportions across four districts in south-east England by conducting retrospective case note studies in four of districts (2 with the worst survival and 2 with the best survival)[59]. In all 4 district health authorities, five-year survival decreased with the inclusion of DCO registrations. The overall reduction was 8.6% (with variation from 4.5% to 9.1% across districts). The authors pointed out the need to assess the impact of DCO registrations on national survival rates for all cancers.

2.2.2 Temporal relationships

A set of guidelines for assessing causal associations in epidemiologic studies was defined by Bradford Hill[76;77]. In modern epidemiology, the notion of 'cause' has become more complex to encompass the domains of social and population-level relationships[78]. It evolves health consequences of complex environmental, social and system interventions and processes.

One of the principal factors for judging whether association is causal is 'temporality': what is the evidence that the exposure precedes the outcome? [79].

Differentiating the timing of each diagnosis is also important for risk adjustment, since it allows separating prior risk factors from the possible problems of contemporaneous medical care [30]. However, discharge diagnoses record conditions that were diagnosed or treated at any time during the entire admission, regardless of when they occurred.

One way to address this problem is to carry out risk-adjustment by using only codes for diagnoses that are unlikely to arise "de novo" during hospitalization, such as diabetes and chronic renal failure [30;80-82]. In addition, longitudinal data could identify conditions that had been treated previously and would thus be considered chronic or pre-existing [30]

Differences in time periods covered by various administrative or clinical datasets may complicate interpretations of observational studies which incorporate data from several sources[30].The situation is particularly complicated with the inclusion of cancer registry data, with cancer survival as the outcome measure. In its essence, survival data reflect back in time[83-86]. To assess survival of recently diagnosed patients, we normally need to wait several years[84]. Thus, survival data usually preceded the organisational data in time. Overall, with observational, cross-sectional studies there is inherent weakness to ascertain the temporal relationship between the exposure and outcome[79]. This should be taken into account while interpreting the results of such studies.

2.2.3 Using datasets together

From the perspective of researchers studying health care services, the ability to track services used by patients across care settings and capture the complete health care experience of large, representative populations enhances the power of administrative data [30;87]For instance, when databases on utilization and accounting are linked, cost can be calculated for a unit of health care service and across categories of service at the patient, provider, or medical facility level [88]. Geocoding has been suggested for linking individual addresses to census data on racial or socioeconomic characteristics to obtain proxy measurements of these variables [88].

In an Australian study, a population-linked database was used to relate the cancer registry, hospitalization and mortality records of all patients with a diagnosis of colorectal cancer to assess the trends in colorectal cancer incidence and mortality in Western Australia during 1982-1995 [89]. Another study assessed some differentials in survival from 12 common cancers, including colorectal cancer, by linking the census data with the data from Norwegian Cancer Registry [90].

In the UK, cancer survival statistics are routinely produced by linking data from cancer registries with the data of death from the National Health Service records and death certificates[2]. Adjustment using census data also allows analysis to take into account differential background mortality by age and social deprivation [48;91]. However, linking data sets at individual level requires comparable identifiers, and there have been fears about confidentiality and privacy [30;65]. In some cases it may be necessary to obtain consent, e.g. from survey respondents [92]. Nevertheless, even without these identities, records can still be linked with reasonable success if sufficient demographic and administrative data are available [30;93].

2.2.4 Risk adjusted models

Pioneering work in data collection and risk analyses has been carried out by cardiac surgeons, and substantial information exists in this sphere[94-101]. Similar projects had been developed in other fields and on multinational level. The International Quality Indicator project was initiated by the Maryland Hospital Association (USA) in 1985 to assist

hospitals in identifying opportunities for improvement in patient care[25;102] All individual hospitals are anonymous and able to identify themselves only by means of a unique identification number that is allocated to the hospital on joining the project.

Another similar development on a national level is ICNARC – UK Intensive Care National Audit & Research Centre, which was established as a result of the success of the ICU UK APACHE II study, a large study conducted in the late 80s/early 90s on patient outcomes from intensive care units (ICU)[103].

Databases in cardiac care initially began using only volume and unadjusted 30-day operative mortality as outcome criteria [104]. In time, along with the progress with the building of risk models based on preoperative predictive variables, other outcome measures have been added including risk-adjusted mortality and morbidity; length of stay; quality of life; functional status; neuropsychological outcomes and long-term outcomes [104].

However, differences in the definition or coding of risk factors, or lack of data on some risk factors, may affect the validity of comparisons. Although validated indexes of disease-specific severity and functional status now exit for many acute and chronic conditions, few of these indexes are routinely measured and incorporated into clinical databases[88;105;106]. Some researchers proposed to use various factors such as the history of medical care encounters, hospitalisation, nursing home residence, and use of medications in the past year as a surrogate for case mix[54;107-110]. Whether these factors adequately capture case-mix remains unclear.

2.2.5 Comparing performance

In the UK, an example of comparing performance was the 'star' system used by Department of Health to rank NHS Trusts based on monitoring specific targets, such as 'waiting times'[111]. However, it was recognised that "there is a need to ensure that like is compared with like and over time figures will need to be 'risk adjusted' to standardise for factors such as age, severity, case-mix and concurrent illnesses". The Royal Statistical Society called for revision of the system of performance indicators to take into account statistical standards [112]. Analysis needs to examine not just overall average values of performance indicators but to look at variability through the use of plausible ranges of rank for each institution. Adjustment for context to achieve comparability also could be considered [112].

A recent study on the association between 'star' rating and outcome of adult patients admitted to critical care units within acute NHS Trusts showed that, though crude mortality for critical care admissions was significantly associated with the rating, the association was no longer significant when case-mix differences were taken into account [113]. As the authors pointed out, they did not expect to find association between the rating of the whole Trust and the outcomes of critical care units because hospitals are complex organisations containing many services: poorly rated hospital may have some excellent services and vice versa. Besides, ratings have been determined by a small number of process measures without adequate account for outcome measures. For this reason, they suggested wider use of data from specialised clinical databases such as those presented at www.docdat.org [114].

The list entitled "America's Best Hospitals", published annually by *US News & World Report* since 1990, is one of the most influential 'report cards' on the quality of hospitals [51;115] National data sources are used to evaluate measures of Donabedian's three-element model of structure, process and outcome. Data on staffing level, teaching status, equipment and volume of patients are obtained from the American Hospital Association (AHA). Outcomes are assessed on the basis of in-hospital mortality rates adjusted for case-mix that were derived from Medicare discharge claims [115]. Data describing process, are not available nationwide. Instead, board-certified physicians are asked to nominate the five 'best' hospitals in their specialties by means of questionnaires. The percentages of these physicians who nominated particular hospitals generated 'reputation' scores served as a proxy measure of high quality in the process of care. A study by Chen et al showed that the admission to a hospital ranked high on the list of "America's Best Hospitals" was associated with lower 30-day mortality among elderly patients with acute myocardial infarction [115]. A substantial portion of the survival advantage may be associated with the processes of care, namely higher rates of use of aspirin and beta-blocker therapy. Further analyses taking into account nursing home admissions; the distance from home to the hospital; deaths occurring after the first hospital day; and the census region did not affect the results substantially [116].

However, recent studies have identified a number of methodological weaknesses in the selection of top-ranked hospitals relating to all three elements of quality [115-117]. The use of hospitals' reputations as a measure of the quality of care was particularly questioned.

Since the majority of hospitals would have 'reputation' scores near zero (i.e. they were not nominated by any of the surveyed physicians), hospitals with high name recognition would dominate the rankings. Also, even good risk-adjustment procedures may not take into account systematic differences in risk among hospitals [117].

2.2.6 Using secondary data

Routine observational data / administrative databases are increasingly used to compare outcomes between health care institutions, particularly in US, and for performance management activities, in general. They can be used as an indicator of the level of performance or quality, for clinical decision making, in the evaluation and development of treatment algorithms and as measurement of cost-effectiveness [118]. The reason is that they are readily available, relatively inexpensive to acquire, usually computerized, fairly easy to use and normally include entire regional populations or well-defined subpopulations [30;119].

However, administrative databases have well-recognized limitations in characterizing patients, clinicians, and institutions [120]. Administrative data may not contain information sufficiently deep or accurate enough to adjust for systematic differences in severity of illness [30;121]. Further major problems may include poor data quality; completeness and accuracy of coding of diagnosis and procedures; missing data; lack of concurrent controls, inability to ascertain important study outcomes, and incomplete data on case mix [30;54;121].

While the total size of the databases allows the calculation of statistically significant but small effect sizes, the quality of the information in the databases may not allow sufficient adjustment for potential confounding factors [121]. The effect of random variations, which may affect the validity of comparisons between providers' results, should also be taken into consideration [27;122]. In addition, inconsistent interpretation of the data requirements for the indicators and inconsistent data collection methods may reduce their validity and reliability [123].

Many indicators for performance management are based on admission whereas hospital discharge summaries reflect conditions that were diagnosed or treated at any time during the entire admission, regardless of when they occurred[30]. Moreover, the data reflect an historic the time period, since when matters may have changed [67].Despite all these

difficulties and problems with data quality, cancer registries remain an important source of data for information on performance of cancer services and have been maintained or used by researchers for several decades. The large size of these registries, along with availability of clinical data and the possibility of long term follow-up, offers unprecedented opportunities for describing the natural history of diseases, understanding the predictors of outcomes, particularly survival, and studying the effectiveness of new therapies or disease management strategies.

However, as indicated above, completeness of cancer registries relies heavily on completeness of clinical case notes. In this context, incompleteness of case notes for tumour stage, treatment and diagnostic procedures may cause particular concerns. In addition, observed discrepancies in important clinical indicators between cancer registry data and clinical notes require cautious interpretation of results in studies which use the registry data. Also, a high proportion of cases with DCO registrations may bias survival estimates. Thus, while cancer registries have a huge potential to serve as invaluable source of information for outcomes and management of cancer services, assessment of quality of registry data is essential for any meaningful interpretations of research studies which used cancer registry data.

2.3 Patient factors to affect outcomes

Research into outcomes has primarily focused on the role of patient risk factors. With regard to cancer care, the literature notes the importance of age, stage of disease and the effect of social deprivation as the main individual level factors influencing the outcome of care. The presence of coexisting conditions or diseases (comorbidity) and the type of clinical treatment provided have been shown to have significant impact on outcome too. As indicated by the authors of the UK National Audit of Malignant Bowel Obstruction due to Colorectal Cancer (2000), patient factors such as age, urgency of operation and Dukes' stage have a major effect on mortality, and risk models to adjust for such factors should be taken into account when assessing outcomes[124].

2.3.1 Age

The literature shows that survival decreases with increasing age. In the Eurocare study, the relative risk of dying for the oldest patients (75+) was 1.39 for rectal cancer and 1.54 for colon cancer compared with the youngest patients (15-44 years) [33]. There were similar findings in the study of cancer survival in England and Wales [35].

In colorectal cancer surgery, older patients have higher frequency of comorbidity, are more likely to present with advanced stage, undergo emergency surgery and have generally worse clinical outcomes[125-128]. Also, a study of colorectal cancer patients in England showed that age was a strong predictor of non-treatment and the relative risk of not receiving treatment increased for all ages over 65 years[73].

2.3.2 Stage of disease

Differences in survival for colorectal cancer are clearly related to stage recorded at presentation [34;129]. Five-year relative survival rates by Dukes' stage may vary from 83% to 3% for colorectal cancer patients with the least and the most advanced stage, respectively [130]. However, these are unadjusted estimates and other factors play a role too. Also, studies by the Association of Coloproctology of Great Britain and Ireland showed that in univariate and multivariate models, Dukes' D stage (the most advanced) was found to be an independent predictor of postoperative mortality in colorectal cancer surgery[128;131].

However, survival is a complex indicator of cancer care. Longer survival may be due to better treatment, or more effective treatment because of earlier diagnosis, or may be simply due to earlier diagnosis of the cancer (lead-time bias). Particularly, early diagnosis through screening programmes is considered to be an effective method of improving the prognosis[132;133]. However, the increase in the length of survival for patients diagnosed in an earlier stage of disease may reflect only the fact that the time of diagnosis was advanced, not that death was delayed[134-136]. Therefore, it is necessary to consider the potential confounding effect of what is often referred to as "lead time" bias[79].

Adjustments for tumour stage at diagnosis requires careful evaluation of the investigations used to determine the stage of disease[137;138]. Stage-specific comparisons maybe biased by so-called "stage migration", or the Will Rogers phenomenon[139]: where extensive diagnostic procedures are common practice, many cancers that would otherwise be classified as localised are then accurately classified to a more advanced stage category; this shift leads to an increase in the survival of both localised and advanced groups without any change in individual outcomes.

2.3.3 The effect of social deprivation

Several studies have reported that the survival of cancer patients, including colorectal cancer, shows a negative socio-economic gradient [36;140;141]. According to Auvinen, stage of disease at diagnosis accounted for a substantial proportion of differences in survival, and treatment accounted for the rest of them[141]. Monnet et al. recommended

earlier access to care for people in lower social classes[140].

In the UK, Pollock et al have shown that emergency admissions are more frequent in socially deprived areas [142]. No association was found between deprivation and the incidence of colorectal cancer, but significantly lower 5-year relative survival rates were found for breast and colorectal cancer patients in the most deprived areas [143]. Colorectal cancer patients in the most affluent tenth of enumeration districts had a 40% relative survival ratio compared with 32% in the most deprived tenth. However, these findings were not adjusted for measures of comorbidity or stage.

Wrigley et al showed similar results but pointed out the need to consider the effect of possible confounders [144]. Significant prognostic factors for outcomes were age, specialisation of surgeon, Dukes's stage, and emergency compared with elective surgery. After adjustment for prognostic factors, the effect of deprivation on both cause specific and all cause mortality was reduced, and it was non-significant for colorectal cancer. However, the most deprived group had consistently worse survival than the most affluent.

In addition, according to the recent study on trends and socio-economic inequalities in cancer survival in England and Wales, improvements in survival were greater for those living in affluent areas than those in deprived ones [85]. This trend persisted even after correction for the differences in overall mortality between these two groups.

2.3.4 Comorbidity

Comorbid diseases are assessed by different methods, including medical records in electronic databases, medical charts, physical examination, personal interviews, and self-reports using written questionnaires[145]. Comorbidity may be estimated in several ways: by the co-occurrence of specific diseases in individuals with an index-disease by a simple summing up the number of diseases present in one individual; or by a comorbidity index that combines the number and severity of the diseases[145-151].,

A number of studies show that cancer patients with comorbid conditions have worse survival than patients without comorbidity[152;153]. This relationship has been described for a number of tumour sites, such as head and neck[154-156]; lung[157]; breast[158;159]; prostate[160;161], and colon[162]. However, its impact varied between cancer sites and even within the site if considered by stage of disease or type of treatment received[153]. Also, the definition of

comorbidity used by different studies varied substantially which may affect the comparability of the results. In fact, at present, no established way to assess the impact of comorbidity in cancer patients exist[163].

A review of the literature by Piccirillo and Feinstein (1996) indicated that the presence of comorbidity had a significant impact on five-year survival for rectal, laryngeal, and prostate cancers: the observed five-year survival rates decreased when prognostic comorbidity was present, and increased when it was absent (e.g. overall five-year survival rate for rectal cancer was 29%; in absence of comorbidity – 32%, and in presence – 11%)[152]. However, the rates presented were for impact of comorbidity alone, regardless of the stage. In fact, it was not clear to what extent these differences were due to stage of disease versus comorbidity. In addition, these results were not based on systematic review of the literature.

There is general agreement that tumour stage is the most important single factor for survival or mortality from colorectal cancer[164]. Although tumour stage is a crucial determinant of patient outcome, comorbidity increases the complexity of cancer management and, whilst unrelated to the cancer itself, may affect the choice of treatment and prognosis[150;158;161;162;165;166]. However, a study of colorectal cancer patients in the Netherlands showed that after adjustment for age and Dukes' stage, comorbidity was not associated with the resection rate[167] (see also Table 2.2). Only few studies have assessed the impact of comorbidity on observed variation in cancer survival, or proportion of variation explained by comorbidity.

In a study of lung cancer survival, Tammemagi et al showed that stage was the most significant predictor of survival and explained around 25% of the survival variation, while comorbidity, though significant, explained only 2.5% of the survival variation[168]. Another study of elderly women with non-metastatic breast cancer showed that additional adjustment for aggregate comorbidity did not change odds ratio estimates of the effect of age on the initial treatment for breast cancer[169].

Read et al using cancer registry data of more than 11 000 patients with breast, lung, colon and prostate cancer, studied differential impact of comorbidity on one-year survival in these four different cancers[153]. Comorbidity was classified into four groups: none, mild, moderate or severe, based on the Adult Comorbidity Index ACE-27, a validated chart-based comorbidity index[170]. They assessed relative prognostic impact of comorbidity by tumour site and stage, using hazard ratio adjusted for age, race, and sex. To measure the proportion

of explained variation by comorbidity within each cancer site/stage group, the authors used the method of Heinze and Schemper developed for Cox proportional hazards model[171]. The correlation between overall survival rate and severity of comorbidity was statistically significant ($p<0.001$), but fairly strong ($r^2 = 0.56$). As shown in Table 2.1, the proportion of variance in outcome explained by comorbidity ranged from less than 1% to almost 9% depending on tumour site and stage. (see also Table 2.2)

Table 2.1 Relationship between cancer site, lethality, and prognostic importance of comorbidity[153]

A colorectal cancer study in Wessex region in England found that comorbidity was associated with all-cause, but not cancer-specific, survival[144]. Comorbidity was simply scored as the number of co-existing conditions recorded in hospital notes. The authors rightly pointed out that there is little agreement about measuring comorbidity in cancer research and only few studies of colorectal cancer survival contain any health status measurement[144]. Similarly, a study of breast cancer, using US data from the SEER programme, found that comorbidity was associated only with all-cause or non-cancer specific three-year survival[150]. No studies were identified as to the impact of comorbidity on relative survival estimates, which take into account background (non-cancer specific) mortality, and thus, to some extent, indirectly reflect the presence or absence of co-existing diseases or pathological conditions on population level.

2.3.5 Clinical treatment

Surgery is the principle treatment for colorectal cancer patients[172]. Surgery with curative intent aims to remove the whole tumour: if it succeeds, the patient may be considered free from cancer. When curative surgery is not possible, patients may benefit from palliative interventions.

Current clinical guidelines suggest that radical, or curative, surgery is associated with better outcomes[172]. Curative resection can be defined as "removal of all macroscopic disease at the time of operation, backed up by histological evidence that the resection margins of the specimen submitted to the pathologist are clear of tumour"[172]. However, the term is imprecise, and it is not clear whether the observed differences in outcome were due to confounding effect of patient factors, which could also have influenced choice of surgery.

In addition, the rate of curative resection depends on the stage of the tumour[172]. The Trent/Wales and Wessex audits have shown variability in stage distribution across districts, with the percentage of tumours presenting at Dukes' stage A varying from 6% to 18%, and the percentage with distant metastases varying from 19% to 39%. The rate of curative resection varied from 31% to 72%, and this was inversely correlated with the percentage of cases with distant metastases[172].

Another factor which may influence the outcome of surgical treatment is emergency surgery. Overall, it was estimated that around a third of colon cancer patients and a tenth of rectal cancer patients are admitted as emergencies, and over 20% of patients who undergo emergency surgery for intestinal obstruction die within a month[173]. This is mainly due to poor physical status at admission.

Although lacking evidence from the randomised trials, it is widely accepted that extended resection of colon – hemicolectomy, is safer than segmental resections for tumour in surgical treatment for colon cancer[172]. In rectal cancer, however, resection technique is of greater importance[172]. A number of studies showed that total mesorectal resection for rectal cancer was associated with improved long-term survival and reduced local recurrence, as compared to other types of surgery[174-184] However, the adequacy of local resection and pathology reports may play a role in observed relationships. An audit of pathology

reporting in Wales showed marked variations in adequacy of reporting between laboratories and hospitals[185].

Systematic reviews of clinical trials show that provision of radiotherapy in combination with surgery significantly reduces local recurrence rates for rectal cancer[186-188]. However, the evidence is equivocal as to whether preoperative radiotherapy also leads to a reduction in mortality rates and survival[187;189]. Even with modern treatment methods, radiotherapy is likely to cause long-term problems with bowel function[190]. There is no evidence to support the use of adjuvant radiotherapy for colon cancer.

A systematic review of the literature for 'Improving Outcomes' guidance suggested that chemotherapy may improve survival for Dukes' stage C colorectal cancer patients, but no clear evidence was identified on the effectiveness of chemotherapy for patients with Dukes' stage B colorectal cancer[38].

However, as indicated in a previous section (see 2.2.1), the use of cancer registry dataset to study the impact of clinical treatment is limited due to the lack of data and its poor quality. [31;72]. In fact, current use of cancer treatment information is mainly limited to audit studies of specialised site-specific datasets. Particularly, recent audit by the Association of Coloproctology of Great Britain and Ireland indicated poor data quality and discrepancies between various sources of national data[191].

2.4 Organisational determinants of outcomes

Along with patient factors, the outcome of care is also dependent on the quality of care received throughout the patient's stay in hospital and the performance of considerable number of health care professionals, all of whom are influenced by the environment in which they work such as team coordination, communication, equipment and so on [20;19].

2.4.1 Staffing level

There is a general belief that increased staffing level may at least partly facilitate improvement of outcomes of care in clinical settings. The main reason for that is the speculation that it may affect the occurrence of errors, complications and other adverse events[192]. Also, staffing deficiencies may deprive patients of sufficient nursing or medical care and increase stress level among health care workers and lead to higher possibilities of mistakes. However, there is insufficient or equivocal evidence in the literature to support this notion. The literature is especially scarce on the influence of medical staffing level, while the effect of nurse staffing was explored in numerous studies.

Increase nurse staffing has been associated with lower postoperative complications[193-195]; a lower incidence of adverse events[196], lower nosocomial infection rates[197], and higher patient satisfaction[198]. Studies in the US and the UK, and a number of reviews of the literature[199-202] have demonstrated that the level of nurse staffing may affect patient and organisational outcomes, but the results were equivocal and vary by institution[203-209].

In a US study of bladder carcinoma patients, hospitals with a high registered nurse-to-patient ratios had a lower in-patient mortality risk among patients who underwent cystectomy (OR=0.46; p=0.04), after adjustment for age, indicators of social status and comorbidity[210]. However, the authors did not account for tumour stage, which is the major indicator of disease severity for cancer patients and may affect the observed relationships.

A recent large study of around 13 million patients in approximately 1500 US hospitals, commissioned by the American Nurses Association, showed the positive association between low level of nurse staffing and a number of in-hospital clinical

complications, such as pneumonia, postoperative infections, adverse drug reactions and so on[192]. Similar results have been presented by Blegen et al (1998) in an example of large university hospital in US[204]. However, both studies did not comprehensively account for patient case-mix.

Another study in one Thai hospital found that among four different nurse staffing variables, after adjustment for patient characteristics, 'total nurse staff to patients' was significantly associated with in-hospital mortality for one of four common groups of principal diagnoses, including cancer[211]. They did not specify diagnose-specific effect of observed relationship.

As detailed in *Introduction* chapter (see 1.2), a study by Jarman et al linked routinely collected national datasets to investigate determinants of in-hospital mortality in England[22] A total number of doctors per bed was found to be the best predictor to explain variations in in-hospital mortality between NHS hospital trusts. However, the severity of illness was not taken into account for, and the validity of applied measures of comorbidity, which were adjusted for in the analyses, remained unclear. (see also *Introduction* chapter, 1.2.; and Table 2.2)

The literature also indicates an association between doctor and nurse staffing and the outcome of intensive care units, particularly mortality and complications [20;212;213]. However, no study was identified that examined the relationship between staffing level and longer-term cancer survival.

2.4.2 Volume effect

Literature data provide similar evidence on association between volume and outcome of care in both cancer and non-cancer settings, such as transplantation programme, paediatric cancer care[214;215]; breast cancer surgery [216]; prostate cancer surgery[217]; trauma centres [218]. The "higher procedural volume, better outcome" relationship has an extensive literature in cardiovascular disease[21;23;24;26;214;219;220].

However, studies use various definitions of 'volume' (quartiles; quintiles; some specific cut-off points; other approaches) and consider different aspects of it: volume of hospitals; volume of doctors; volume for specific conditions/diseases; volume for specific procedures or surgery. Usually the studies have combined hospitals with similar volumes into a small number of groups and then compared the rates of outcomes among the groups. Most studies considered in-hospital or 30-day mortality as the only measures of adverse outcome [221]. Longer-term outcomes and survival were investigated to lesser extent. Studies normally controlled for differences among 'volume' groups by adjusting for the severity of patients' conditions at admission. The level and methods of adjustments differ from study to study, which make comparisons between results difficult.

Publications mainly report that high-volume hospitals have better outcomes than low-volume hospitals, at least for certain conditions and procedures. Dudley et al, in a systematic review, suggested that many deaths could be avoided if patients with specific conditions had been treated at high-volume vs. low-volume hospitals [222]. However, studies used different definitions of 'volume' and there were differences in methodology, with various degree of case-mix adjustments, which did not allow the authors performing a meta-analysis. Excluded were also studies that used other than in-hospital mortality outcome measures (e.g. 5-year survival), since they were not available from the California database of hospital discharges.

Most studies found positive associations between volume and outcomes only for high-risk conditions and complex surgical procedures[214;223-226]. A systematic review (1980 – 2000) on the relationship between hospital or physician volume and clinical outcomes by Halm et al showed that the strongest associations with high volumes were found for more complex surgical procedures, like pancreatic resection and esophagectomy (a median of 3.3 to 13 excess deaths per 100 cases were attributed to low volume) [226]. Overall, 71% of all

studies of hospital volume and 69% of studies of physician volume reported statistically significant associations between higher volume and better outcomes (see also Table 2.2). This was confirmed by Hillner & Smith, who analysed the findings of five large studies in the US [214]. These studies used hospital discharge summaries that included the ICD-9-CM coding but not the cancer staging. In addition, they showed that studies that performed more complete case-mix adjustment were less likely to report a positive effect of high volume on outcomes.

Similar conclusions were provided by other major US studies with the focus on cancer-related surgical procedures, based on the analysis of the Nationwide Inpatient Sample[224;225] and Surveillance, Epidemiology, and End Results (SEER) – Medicare linked databases [223;227] (see also Table 2.2). Adjustments for case-mix and other patient factors did not change the findings that low volume was strongly associated with excess mortality for specific high-risk surgeries. However, the Nationwide Inpatient Sample-related studies were lacking adjustments for tumour stage; and in SEER studies, around 16% of otherwise eligible patients were excluded from the cohort due to the lack of detailed data. On the other hand, a study in Canada, using electronic hospital records linked with the database of vital statistics, showed that, with the exception of colorectal resection, for some major surgical operations the inverse association between high volume of procedure and risk of 30-day postoperative mortality was not specific to the volume of the procedure being studied [228]. Shared structures and processes in hospitals that do a high volume of any complex surgical procedures may account for improved surgical outcome.

To a lesser extent, this tendency was confirmed in relation to in-hospital mortality[225;227;229] or survival [230] for colorectal cancer. For instance, a study by Schrag et al, using SEER database, examined 27 986 colon cancer patients aged 65 years and older who had surgical resection for primary adenocarcinoma diagnosed between 1991 and 1996 [227]. The authors found a small difference in 30-day postoperative mortality for patients treated at low vs. high volume hospitals (3.5% at hospitals in the top-volume quartile vs. 5.5% at hospitals in the bottom-volume quartile). (see also Table 2.2)

Hospital volume is perhaps more important than individual surgeon's volume in its effect on short-term outcomes, such as in-hospital mortality [231] and two-year survival[232] for colorectal cancer. Particularly, medium-volume surgeons achieved results equivalent to high-volume surgeons when they operated in high- or medium-volume hospitals but not in low-volume hospitals[231]. On the other hand, the results of low-volume surgeons, although

improved with increasing hospital volume, never equalled those of the high-volume surgeons.

In a multilevel Cox proportional hazards model, after adjustment for patient characteristics (age, sex, Dukes' stage, Townsend deprivation quintile), surgeon's caseload had no significant effect on colorectal cancer mortality at 2 years[232]. Hospital workload did have a significant impact on survival. However, missing tumour stage and social deprivation information for around 11% and 6% of patients, respectively, imprecise case-mix adjustment and in-exact measurement of clinician specific rates (the name of consultant surgeon was taken into account regardless of whether the surgery was actually performed by consultant or surgeon in training or both) are limitations for the study.

2.4.3 Specialisation

Along with the volume-outcome studies, there is extensive literature about the impact of specialisation on outcome of care. In fact, some studies showed that specialist care was more important and beneficial than volume effect [233;234;235].

For instance, according to one Finnish study, there were no significant differences in the rates of postoperative mortality, morbidity, and long-term overall survival between the volume groups[233]. On the other hand, in patients with colorectal cancer, there was a trend for better survival and fewer local recurrences for those operated on by the surgeons specialising in gastrointestinal surgery.

However, the definition of 'specialist care' provided in studies has varied and included membership in professional site-specific associations [235;236]; surgical subspecialty [230;233]; broader certification in surgery [236]; or being treated at multi-disciplinary specialist units [237]. Some authors did not provide with the formal definitions employed [238].

There is no systematic information about specialisation in the UK. While literature, in general, discusses the effect of specialist care in terms of 'specialist surgeon', in the UK, the approach is on multidisciplinary teams - 'specialist teams', as opposed to the notion of 'specialist surgeon' prevailed in the literature. Since publication of the Calman-Hine report on reorganisation of cancer services in England and Wales, cancer centres and units in NHS hospital trusts adopted a multidisciplinary team (MDT) approach with the aim of providing specialist care to cancer patients.

No evidence was identified on relationship between multi-disciplinary team management of primary colorectal cancer and outcome of care, namely survival. A study in Scotland showed that ovarian cancer patients who were referred to multi-disciplinary team at a joint clinic had improved survival[239]. However, there were few studies dealing with some aspects of organisation and functioning of MDTs[240-243].

Particularly, a study by Kelly et al aimed to ascertain nation-wide implementation of colorectal MDTs as part of the NHS Cancer Plan[242]. Another survey by Jenkins et al, taken during early stages of establishment of breast cancer MDTs (February – August 1999), showed that there were some discrepancies within MDT members' views and expectations of their own and each other's roles in providing different kinds of information to women with breast cancer[241].

A prospective audit of the management of colorectal cancer patients by Smith et al investigated factors associated with variations in survival observed within the former UK Wessex region [235]. The greatest benefit was observed with respect to specialists versus non-specialists, in terms of a lower postoperative mortality rate (OR=0.67 (95% CI 0.53 to 0.84); lower anastomotic leak rates (OR=0.46 (0.31 to 0.66); higher local recurrence-free survival (hazard ratio 0.56 (0.44 to 0.71) and better long term survival (hazard ratio 0.76 (0.71 to 0.83) [235]. However, the definition of 'specialist' employed as "a member of the Association of Coloproctology of Great Britain and Ireland with a commitment to and special interest in coloproctology", may not be completely adequate since there is no agreed 'specialist' definition in the UK. In fact, there is no requirement for a specialist to be a member of the Association and, vice versa, membership does not necessarily mean that someone is practising as a specialist. (see also Table 2.2)

The beneficial effect of specialist care in colorectal surgery was apparent also in studies in the US [236], Canada [230], as well as the Stockholm Rectal Cancer Study Group [244]. However, some of the results of the latter study were of borderline statistical significance. Similar to colorectal cancer cases, specialist care appeared to bring about survival advantage also for patients with other tumours, namely breast[237;238] and ovarian[234].

No evidence was identified on the effectiveness of specialised colorectal cancer nurses, possibly because there are very few such nurses [37;38]. One published audit of a nurse-led colorectal cancer clinic within a London teaching hospital was identified [245]. This retrospective study of 600 cases diagnosed at a nurse-led one-stop diagnostic colorectal cancer clinic for patients aged 50 years or older reported high patient satisfaction with less anxiety and time waiting for results, although no comparison data and few quantitative results were presented.

Better outcomes for specialist vs. non-specialist care are probably related to the differences in processes of care. Particularly, audit review conducted in one hospital in England showed that colorectal specialists were more likely to comply with published guidelines, performed fewer abdomino-perineal resections and tended to perform more extensive lymphadenectomy [246]. Also, prospective study of emergency colorectal surgery in Oxford gives evidence for process variability between surgical teams headed by specialists and non-specialists[247]. However, no information was provided in either of these studies as to whether specialist care led to better outcomes.

Data on 750 consecutive patients in the Lothians and Borders Large Bowel cancer

project (1990-1992) revealed that five out of 28 consultants were responsible for over 50% of patients with rectal cancer[248]. There was no evidence that these five were more likely to achieve anastomosis than the others. However, when the anastomosis was performed, it was less likely to leak if performed by one of the five with the highest volume (4% vs. 14%; $p<0.05$). It is not clear whether the data were adjusted for differences in case-mix.

2.4.4 Teaching status of hospital

There is a general assumption that the teaching (or academic) hospitals provide better care than non-teaching (or non-university) hospitals due to greater concentration of clinical expertise, a focus on clinical research, adherence to clinical guidelines and technological superiority [214;249-252] (see also Table 2.2). According to the literature data, most of the survival differences could be attributed to differences in the processes of the care, e.g. greater use of beta-blockers and aspirin after acute myocardial infarction [249] or recommended breast-conserving surgery[253].

Studies in Canada[254] and USA[115;250] assigned teaching status of hospitals according to the formal classification of hospitals available in their countries, particularly Canadian Hospital Directory, which defines teaching hospitals as those with membership in the Association of Canadian Teaching Hospitals, and American Hospital Association's annual hospital survey, respectively. No UK study or taxonomy was identified to provide with the definition of 'teaching hospital'.

However, the effect on the outcome of hospital's teaching status was not shown to be consistent [255;256] and appeared to vary between different nosologies [250] or even within the same condition studied [254].

For instance, Chaudhry et al in Canada showed that survival advantage of breast cancer patients treated at teaching hospitals was apparent only among women with larger tumours [254]. Differences in age, socio-economic status, stage of disease or treatment variables did not explain the observed variations in survival between two types of hospitals. Another study of breast cancer patients by Richards et al, using data from the Thames Cancer Registry (1984 – 1988), indicated that despite marked variations in practice according to the type of hospital to which patients presented, among patients who underwent surgery, the type of hospital in which this was undertaken did not appear to influence survival significantly [255].

Also, there was insufficient and equivocal evidence in relation to teaching status of hospitals for colorectal cancer outcomes.

A Stockholm Rectal Cancer Study Group showed lowered risk of death (in-hospital mortality) for patients operated on in university hospitals (RR of death from rectal cancer 0.8, 95% CI 0.7-1.0) compared with community hospitals [244]. However, the results were of

borderline statistical significance.

A study from Manchester (UK) of 578 patients treated for colorectal cancer in the north-west of England compared survival after surgery in teaching and non-teaching hospitals[256]. The number of operative mortalities and 5-year survival figures for all causes of death and for colorectal deaths alone were similar in teaching and non-teaching hospital patients. It was not clear whether the authors adjusted for patients' case-mix. However, it was noted that a greater proportion of elderly and emergency patients were treated in the non-teaching hospitals.

2.4.5 Compliance with clinical guidelines and standards of care

Compliance with guidelines was assessed in the literature mainly in terms of specific clinical interventions[40-43;257;258]. A systematic review by Grimshaw and Russell[259] concluded that in most published studies, compliance with clinical guidelines seem to improve process of care in the direction proposed by the guidelines and the outcome of care. However, the size of improvements varied considerably.

A review of the literature by Smith & Hillner described the impact of clinical practice guidelines on improvement in processes of care and outcomes in oncology[260]. Improvements have been demonstrated in compliance with evidence-based guidelines or evidence-based medicine, and in short-term length of stay, complication rates, and financial outcomes. The data suggest that patient satisfaction can be maintained despite a shorter length of stay. However, there was a lack of comprehensive evidence on whether compliance with guidelines affects long-term outcomes, particularly survival.

More recent reports have indicated links between treatment guidelines and long-term survival for breast[41;42] and ovarian[40;43] cancer patients.

Variations in compliance with rectal cancer treatment guidelines and its effect on long-term outcomes were also investigated with data from the Munich Cancer Registry[257]. Patients diagnosed between 1996 and 1998 with an invasive primary rectal tumour were included in these analyses (n=884), and median follow-up was 5.7 years. Compliance with treatment guidelines was associated with significant survival advantage only in patients with more advanced stages. However, in examining multivariate associations, Cox proportional hazards model was employed and, thus, the analysis did not take into account background mortality. Also, no adjustment for social deprivation was carried out within the model.

In a Swedish study[261] on colorectal cancer survival, university hospitals appeared to be more in compliance with clinical guidelines than district hospitals; and an audit study[246] in England showed that colorectal specialists were more likely to comply with published guidelines. However, they did not relate compliance with survival.

As described in *Introduction* chapter (see 1.2), Morris studied adherence to cancer services standards for colorectal cancer in 14 hospital teams in Yorkshire (UK)[46]. Adherence was determined by questionnaire (not peer review assessed), and a composite

score was used based on the number of standards that had been met. The study concluded that 25% increase in adherence was related to 8% reduction in the risk of death after one and two-year follow-up. However, it is difficult to interpret the meaning of the composite score as it combined standards of different importance. No evidence was required to prove the actual adherence as was the case in a national peer review process. (see also *Introduction* chapter, 1.2.; and Table 2.2)

2.4.6 Waiting time

There is inconclusive evidence in the literature on the impact of referral and treatment delays on survival for cancer patients. Studies used different types of treatment and various tumour types. Also, there were differences in the degree of case-mix adjustment and definitions of 'waiting time' used.

A systematic review of the literature by Richards et al suggested that delays between the onset of symptoms and start of treatment for breast cancer patients were associated with a lower survival[262]. However, the quality of reviewed studies and levels of adjustments for patients' case-mix and other predictors of survival varied considerably, which made interpretations of these findings equivocal. In studies that controlled for stage, longer delay was no longer associated with shorter survival. Also, in another study of breast cancer patients, multivariate analyses indicated that the adverse impact of delay in presentation on survival was attributable to more advanced stage[263] (see also Table 2.2). However, within individual stages, longer delay had no adverse impact on survival. Evidence for an association between age and delay by patients and providers for breast cancer patients was presented in a systematic review by Ramirez et al[264]. Indeed, a number of studies have described and discussed the so called phenomenon of 'waiting time paradox', when patients with shorter waiting times have worse outcomes or more advanced disease[265-268].

No significant correlation of waiting time from diagnosis to surgical treatment with recurrence rate was found in a German study of prostate cancer patients[269]. Likewise, there was no significant difference in seven-year survival according to delay from surgery to radiotherapy in Canadian study of breast cancer patients, although the risk of local recurrence for those who received radiotherapy more than 12 weeks after surgery was increased with borderline statistical significance[270]. However, a retrospective study of breast cancer patients by Mikeljevic et al (2004) in the UK Yorkshire region showed that patients with surgery to the start of radiotherapy intervals longer than 9 weeks had a trend towards an increased relative risk of death[271]. This reached a statistical significance at 20-26 weeks (RR 1.49, 95% CI (1.16-1.92). Also, another Canadian study using data from Ottawa Regional Cancer Registry concluded that after adjustment for multiple prognostic tumour and treatment parameters, longer diagnosis to radiotherapy waiting times were

associated with diminished survival for patients with cervix cancer[272].

No primary evidence was identified on associations between waiting times and colorectal cancer survival. Two studies explored factors related to diagnostic delay (patient, primary care, referral, secondary care) for main cancers, including colorectal, using data from the National Cancer Patient Survey in England[273;274]. This showed that breast cancer patients experienced the shortest delays (mean 55.2 days), while the longest delays were observed for colorectal and prostate cancer patients (mean 125.7 and 148.5 days, respectively). Patients who saw their GP prior to diagnosis experienced considerably longer total diagnostic delays than those who did not [273]. Findings from generalised linear modelling showed that for colorectal cancer the significant factors associated with diagnostic delays were marital status and age [274].

2.5 Summary of literature findings

Administrative databases can contribute to the assessment of the quality of care, case-mix and patient outcomes because they have advantages of population coverage and systematic collection. Factors that can influence the quality of such data are the methods by which the data are collected, standardisation of definitions and appropriate analytic techniques, as well as completeness and accuracy.

A factor in the use of routine data in assessing clinical outcomes is their ability to differentiate patients according to the severity of illness. Review of the literature showed that studies that performed risk adjustment by using clinical data were less likely to report significant associations than were studies that adjusted for risk by using administrative data.

Another aspect need to be considered in relation to the use of routine data for outcome research is temporal relationships between data elements. Temporality is important for risk adjustment and clarifying the order in which the exposure and outcome occur, thus making causal inferences. In this context, the use of cancer registry data to assess the effect of current changes in clinical management or organisational characteristics has particular limitations, since survival data reflect back in time.

Research into outcomes has primarily focused on the role of patient risk factors. Organisational determinants of outcomes have been investigated to a lesser extent, particularly in relation to cancer. In general, fewer studies were identified in relation to predictors for colorectal cancer outcomes as compared with other tumour types, particularly breast cancer. The majority of studies presented their results after adjustment for patient case-mix. However, the degree and completeness of this adjustment varied which may affect the comparison of the results.

Tumour stage is the crucial individual level determinant of the outcome for cancer patients. The literature also stressed the importance of age, social deprivation, type of admission (emergency vs. elective), and the presence of coexisting pathological conditions or diseases (comorbidity). On the other hand, compared with other diseases, comorbidity appears to have less impact on cancer survival, which is strongly dependant on tumour stage and age of patients. No robust measures to assess the impact of comorbidity in cancer patients were identified in the literature.

Relatively large number of studies on organisational determinants of outcomes analysed the effect of volume and specialisation both in cancer and non-cancer settings.

Literature mainly supports the notion of 'higher volume, better outcome', particularly for high-risk conditions and complex surgical procedures. To a lesser extent, these associations were shown significant for colorectal cancer. As suggested in a number of studies, hospital volume is perhaps more important then individual surgeon's volume in its effect on survival. However, studies used various definitions of 'volume' and 'specialisation'. In fact, as opposed to the current UK approach towards specialisation in terms of 'specialist teams', most studies in the literature consider the effect of specialisation in relation to 'specialist surgeon'. Most studies considered short-term outcomes, particularly in-hospital or 30-day mortality. Also, as in case of other organisational determinants, the degree and robustness of case-mix adjustment varied considerably between studies, which made comparisons between them difficult.

A number of studies showed survival advantage of patients treated in teaching hospitals as compared to patients in non-teaching hospitals, suggesting differences in expertise, equipment and processes of care. The evidence is, however, equivocal, and the impact of hospital's teaching status appeared to vary by disease studied. Differences in case-mix and referral patterns may have an effect too.

There is equivocal evidence in the literature on the impact of referral waiting times and delays in treatment and diagnosis on survival for cancer patients. Studies used different definitions of 'waiting time' and different degrees of case-mix adjustment. No primary evidence was identified in relation to waiting times and survival of colorectal cancer patients.

The literature also indicates an association between staffing level and outcomes of care. While relatively large number of studies examines the effect of nurse staffing, there is scarce evidence on the impact of medical staffing, especially in cancer settings.

Clinical guidelines and standards of care are essential for effective management of quality and performance in healthcare settings, including cancer care. However, their impact on outcomes of care have not been comprehensively studied in the literature. While some studies suggest that compliance with guidelines for specific clinical interventions is associated with improved outcomes, others limited to the audit of compliance unrelated to the outcomes of care. Moreover, this association has been less explored in relation to standards on organisation of services.

Studies usually used Cox proportional hazards model to assess the potential associations between predictors and outcomes (crude survival, does not take into account

background mortality of population). Very few studies employed relative survival modelling (takes into account background mortality of population) which was the main method of current study.

More consideration of findings from the literature, in relation to the methodology and results of this study is presented in *Discussion* chapter of the thesis.

Table 2.2 Selected articles

Paper	Commentary
INTERNATIONAL COMPARISON	
Berrino et al (1995)[1] International Agency for Research on Cancer "Survival of Cancer Patients in Europe. The Eurocare study" Between-country variations in Europe observed for all cancer sites examined using cancer registry data. Absolute differences in survival were small ($\leq$6%) for most cancer sites with poor prognosis, larger (>10%) for cancer sites for which the therapy choice and survival are significantly influenced by stage at diagnosis. Relatively smaller differences were observed for cancers sensitive to cytotoxic therapy (testis, Hodgkin's disease and ovary) especially at younger ages. Access to care is considered an important cause of between-country survival differences for these cancers.	Methodological differences that may bias survival comparisons must be taken into account - completeness of case ascertainment; completeness of follow-up; timeliness of survival statistics; differences in availability of diagnostic means and registration practices. Also, differences in representativeness in terms of involvement of number of cancer registries and their coverage, per country available for research groups. Problems in comparing survival between populations may also arise within the same site-morphology, since not all cancer registries have detailed classification to the level of sub-sites. Further artefacts that affect survival analysis interpretation include so-called 'stage migration', lead-time bias, and 'pseudo-cancers' found in screening but would have never progressed to give clinical signs.
USING SECONDARY DATA	
Jarman B. et al (1999)[22] BMJ "Explaining differences in English hospital death rates using routinely collected data" To explore factors which best explain variations in standardised hospital death ratios in England. Included 8 million discharges from NHS hospitals for diagnoses accounting for 80% of inpatient deaths. Weighted linear regression analysis of data sets over four years: HES, patient survey, staffing levels and GP distribution. Comorbidity indices included the number of bodily systems affected by disease; presence of one of the 15 common diagnoses; combination of top two or three comorbidity diagnoses; and the percentage both of cases and of deaths with comorbidities. The four-year standardised hospital mortality ratios ranged from 53 to 137. The percentage of emergency admissions and the ratio of hospital doctors per bed and GPs to head of population were found to be predictors of observed variations in mortality.	The paper uses secondary data from several sources and makes a cross-sectional analysis to explain differences in death rates. HES dataset for 1991/1992 – 1994/1995 did not contain patient identifiers, so could not distinguish repeat admissions leading to over-counting patients (only from 1997 was 'HES-ID' introduced). The paper was criticised (Bunker & Black, BMJ, 1999;319:854) for limited clinical data to assess patient case-mix as a confounding factor. The impact of differences in time periods covered by different databases on study results was not discussed.

Table 2.2 Selected articles *(continued)*

Paper	Commentary
Iezzoni L.A. (1997)[30] Annals of Internal Medicine "Assessing Quality Using Administrative Data" A review of the quality of administrative data which need to be taken into account in outcome research. It also discusses whether administrative data could produce useful judgements about the quality. She identified and described major producers of routine datasets in the US. The following issues related to the quality of routine datasets were identified and reviewed: clinical content; coding accuracy; completeness of coding; differences in data quality across hospitals. Administrative datasets contain limited clinical information to inform quality assessments. The accuracy of diagnosis coding affects data quality.	The paper provides an extensive overview of the issues connected with the quality of routine, administrative data. It is not a systematic review, but rather a consideration of main challenges connected with the use of datasets, based on key studies identified in the literature. Also, some of the issues identified and conclusions forwarded are specific to the US insurance-based health care system, and thus may not be applicable to other countries. The paper provides an overview of data quality issues in general, not nosology-specific. There is no specific discussion on cancer-related data-quality.
CANCER REGISTRATION	
Pollock A.M. (1995)[31] Quality in Health Care "Reliability of data of the Thames cancer registry on 673 cases of colorectal cancer: effect of the registration process" Retrospective study of completeness and accuracy of the Thames Cancer Registry data on 673 cases of colorectal cancer, using case notes as a standard, diagnosed in 1983 or 1988. Registry data on district of residence; sex; dates of birth, diagnosis, and death were highly reliable, but treatment and tumour site data were less so. Lack of follow up in death certificate only registrations and failure to monitor treatments during follow up period seemed to be associated with disagreements.	17% of cases in which diagnosis and treatment seem to have occurred outside the district of residence, were excluded from the study. An unspecified number of case notes without a date of diagnosis or a date of death were excluded, which could affect the results of this audit study. The major disagreement between the cancer registry and case notes in relation to treatment, tumour site and date of diagnosis could have serious implications on reliability of cancer statistics. However, the study reflect the situation in mid to late 80s, and improvements in registration, informed by this study, since then were put in place.

Table 2.2 Selected articles *(continued)*

Paper	Commentary
COMORBIDITY	
Read W.L. et al (2004)[153] Journal of Clinical Oncology "Differential Prognostic Impact of Comorbidity" The study investigated the impact of comorbidity on survival in 11558 patients with breast, colon, lung and prostate cancers recorded at one US hospital 1995-2001. Severity of comorbidity was classified on a 4-point scale using chart review according to a validated index (ACE-27). For each cancer site, there was a significant correlation between 1-year overall survival rate and the adjusted hazards ratio for comorbidity. The proportion of variance explained by comorbidity ranged from less than 1% to almost 9% (for colon cancer 0.6% to 5.5%) depending on tumour site and stage.	Data were for one hospital only. However, the sample size had sufficient statistical power. The staging system used was similar to other accepted tumour-specific staging, e.g. Dukes' stage for colorectal cancer. Reliability of the comorbidity coding was not recorded. No adjustment was made for social deprivation. Comorbidity has greater effect on survival in tumours of early stage, and little in advanced tumours. Overall, the effect appears relatively small at less than 10%. The results have been quoted by other cancer population survival researchers (Janssen-Heijnen M L G, Coebergh J W W. Comorbidity in elderly NSCLC patients. Thorax 2005;60:704.)
De Marco M.F. et al. (2000)[167] European Journal of Cancer "Comorbidity and colorectal cancer according to subsite and stage: a population-based study" To investigate comorbidity in colorectal cancer patients, by age, sex, Dukes' tumour stage, treatment and short-term survival. The study used data on 3355 patients with colorectal cancer diagnosed in the period 1993-1995 and registered in the Eindhoven Cancer Registry (NL). Comorbidities were recorded using adapted version of Charlson index. Approximately 35% of patients below 70 years of age and 61% of patients over 70 years of age had serious comorbidity, these proportions being higher for male than females. After adjustment for age and stage, comorbidity was not associated with the resection rate but was negatively associated with short-term survival	The authors did not indicate whether patients with unknown stage had similar to stage D survival or whether their characteristics were similar to any of known stage groups. It was not clear what type of modelling or methodology was used to estimate survival. The comorbidity index used number of concurrent diseases or separate pathologies. It was developed and validated on the basis of cases in one hospital only, and did not use the standard Charlson index. Also, under-registration was found for specific conditions, particularly cardiovascular – around 20% of cases. Results indicate co-morbidity has less effect on survival in advanced cancers.

Table 2.2 Selected articles *(continued)*

Paper	Commentary
VOLUME	
Begg C.B. (1998)[223] JAMA "Impact of Hospital Volume on Operative Mortality for major Cancer Surgery" To determine whether hospital volume was inversely associated with 30-day mortality, after adjusting for case-mix. Incident cases (1984-1993) were cancer patients aged 65 or older (n=5013) who underwent major cancer surgery. Retrospective cohort study using SEER database using modified version of Charlson index. Higher volume was linked with lower mortality for pancreatectomy, esophagectomy, liver resection, and pelvic exenteration but not pneumonectomy. The results are particularly noticeable for esophagectomy, for which the 30-day mortality dropped from 17.3% (95% CI 13.3%-22.0%) in the lowest volume hospitals to 3.4% (95% CI 0.7%-9.6%) in the highest volume hospitals. Adjustments for case-mix did not change these findings.	The study involved complex surgical procedures for which mortality differences were expected to be detectable between hospitals. The SEER database is only 10% sample of US population. A co-morbidity index was derived from SEER database records of up to 5 diagnosis codes and up to 3 procedure codes, but completeness and reliability of these were not assessed. Case-mix was not adjusted for deprivation category. 'Volume' in the model was a continuous variable, due to the lack of sound cut-off points: this implies a linear relationship between 'volume' and 30-day mortality, which may not be the case. Reliability of 30-day mortality is not reported.
Schrag D et al. (2000)[227] JAMA "Influence of Hospital Volume on Outcomes Following Surgery for Colon Cancer" To determine whether hospital volume predicts survival following surgery. 27 986 colon cancer patients aged 65+ who had surgical resection for primary adenocarcinoma, 1991-1996. Retrospective cohort study of SEER data linked to Medicare database. Hospital volume in quartiles. Romano's modification of the Charlson comorbidity index was used. Procedure volume was related to overall survival (P<0.001) after adjusting for age at diagnosis, sex, race, cancer stage, comorbidity, socio-economic status, and acuity of hospitalisation. 5-year overall mortality for patients operated on at the very high-volume hospitals was 54.8% compared with very low-volume hospitals 50.4%. Similar results are obtained for colon cancer-specific survival (P<0.001). Comparing 30-day mortality data, 45% of the survival difference can be attributed to the immediate postoperative period and 55% to the later period.	Patients enrolled in a health maintenance organisation (HMO) were excluded from the cohort (16.5% of patients) because detailed claims are not submitted by HMOs to Medicare: this exclusion may affect the generalisability of study results. No association between adjuvant therapy and procedure volume: differences in dosage and intensity of chemotherapy could not be examined. Although the association between postoperative mortality and hospital procedure volume is statistically significant, the absolute difference is small (1.7%-2%). Compared with the 7% to 15% differences observed by Begg et al[223] for pancreatectomy and esophagectomy In the US, colon cancer surgery is performed at many hospitals with very low-case volumes. In this study, the top 5% of hospitals cared for 25% of patients.

Table 2.2 Selected articles *(continued)*

Paper	Commentary
Halm E.A. (2002)[226] Ann Intern Med "Is Volume Related to Outcome in Health Care? A Systematic Review and Methodologic Critique of the Literature" Systematic review of the research 1980-2000 years for English language on volume and outcomes. 272 studies reviewed, 137 met inclusion criteria and covered 27 procedures and clinical conditions. Mainly, in-hospital mortality, however, other clinical outcomes were also considered. Most studies (60%) used administrative data to adjust for some combination of age, sex, and discharge diagnoses. Approximately 28% of studies used clinical data in their risk adjustment models; among this group only 10 studies (7%) reported risk adjustment models that were robustly discriminating and well calibrating. Overall, 71% of all studies of hospital volume and 69% of studies of physician volume reported statistically significant associations between higher volume and better outcomes. The strongest associations were found for AIDS treatment and for surgery on pancreatic cancer, esophageal cancer, abdominal aortic aneurisms and paediatric cardiac care. Volume-outcome relationship for CABG surgery, coronary angioplasty, carotid endarterectomy, other cancer surgery and orthopaedic procedures was of much smaller magnitude.	Studies included in systematic review were very heterogeneous in terms of outcomes employed (in-hospital, 30-day mortality, other clinical outcomes), units of analysis (hospital and/or physician volume), sample size, methods used, type and degree of risk adjustment and definitions of 'high' and 'low' volume employed, which made formal meta-analysis impossible and affect comparability. Only few articles reported on long-term survival. The review showed that studies that performed more complete case-mix adjustment were less likely to report a positive effect of high volume on outcomes. Therefore, it is possible that differences in severity of patients' condition between hospitals and incomplete adjustment for case mix may partly explain the observed associations between hospital volume and outcomes. Also, as in case of literature reviews, in general, it is impossible to exclude the possibility of 'negative publication bias' that may diminish the number of studies with no or 'negative' associations.

Table 2.2 Selected articles *(continued)*

Paper	Commentary
SPECIALISATION	
Smith J.A. E. (2003)[235] British Journal of Surgery "Evidence of the effect of 'specialization' on the management, surgical outcome and survival from colorectal cancer in Wessex" This is the rare study which explored the role of 'specialization' on colorectal cancer outcomes within one region in England. The study took place during a time when adjuvant oncological treatment (radiotherapy or chemotherapy) was unusual and formal multidisciplinary review was not established and is therefore predominantly an examination of surgical expertise and management. 5173 patients (including 4562 surgically treated) with colorectal cancer diagnosed between 1991 and 1994 were followed up for 5 years. Details of referral, diagnosis, surgical treatment, postoperative complication and outcomes were collected. There was an association between high volume operators (more than 50 operations per year) and specialisation. Specialists had lower postoperative mortality rate and complications, and better 5-year survival. Improved outcomes following specialist treatment persisted, over and above allowance for case-mix factors. Benefits in short-term and long-term outcome were associated only with surgical caseloads exceeding 50 patients per year.	The definition of a "specialist" may not include all surgeons who treat colorectal cancer patients. Also, defining 'high volume' in colorectal surgery is subjective, in general, as no evidence-based cut-off points are proposed in the literature. Unstaged patients were excluded from all multivariate analyses. Although they constituted very small proportion of less than 5% of the data set, they may differ from the rest by other factors which may affect prognosis. Multivariate model was adjusted for main known predictors of survival for colorectal cancer patients, but not deprivation. Although including a number of significant diseases which could affect the outcomes, the comorbidity score employed in the model did not reflect severity of concurrent conditions.

Table 2.2 Selected articles *(continued)*

Paper	Commentary
STANDARDS	
Morris E. (2004)[46] PhD thesis, University of Leeds "The Impact of the Calman-Hine Report on the Processes and Outcomes of Care for Yorkshire's Breast, Colorectal and Lung Cancer Patients" The study aimed to quantify if Calman-Hine recommendations of multidisciplinary team formation and surgical site specialisation had been translated into practice by 2000, in the Yorkshire region of the UK, and were associated with improvements in the outcome of colorectal, breast and lung cancers. The author studied reported adherence to cancer services standards for colorectal cancer patients in 14 hospital teams in Yorkshire. Multilevel binary logistic regression models were use to assess the associations with the outcome (survival), including age, gender and deprivation score (ecological), stage (Dukes') and Calman-Hine implementation scores. A 25% increase in adherence was related to around 8% reduction in the risk of death after 1 and 2-year follow-up. The effect remained for colorectal cancers after adjustment for age, stage, socio-economic status and year of diagnosis. However, this association was not sustained in relation to breast and lung cancers.	No evidence was required by the questionnaire to prove the actual compliance with the standard, as it was done in a national peer review process. Self-reported standards lack validity and may show confounding - for example, lower morale in hospitals with greater workload or more deprived patients. Standards were summed with equal weighting However, individual standards differ in their clinical significance, while adding together standards will give an undue bias in areas where more standards were collected. A sample survey by the Audit commission in 2001 showed that about 2/3rds of hospitals had implemented multidisciplinary teams. The temporal relationship between team formation and treatment was not defined.
GUIDELINES	
Wolfe C.D.A. (1997)[252] European Journal of Cancer "Management and Survival of Ovarian Cancer Patients in South East England" Effect of adherence to regionally developed guidelines on survival in women with ovarian cancer. A prospective audit of 118 newly diagnosed cases of ovarian cancer in seven district health authorities of South East Thames, U.K. In multiple regression analysis, death was significantly more likely in women who had been inappropriately managed, those with more advanced disease and those with postoperative complications.	Despite the development of guidelines, investigation and management of ovarian cancer varied considerably between hospitals. Pre-operative and operative management was inappropriate for the majority of women and this significantly influenced survival.

Table 2.2 Selected articles *(continued)*

Paper	Commentary
WAITING TIMES	
Richards M.A.[263] British Journal of Cancer "The influence on survival of delay in the presentation and treatment of symptomatic breast cancer" 2964 breast cancer patient admitted to Guy's Hospital (London) between 1975 and 1990. Duration of symptoms prior to hospital referral was recorded. The impact of delay (defined as having symptoms for 12 or more weeks) on survival was measured from the date of diagnosis and from the date when the patient first noticed symptoms to control for lead-time bias. Differences in survival rates were statistically significant. Multivariate analyses indicated that the adverse impact of delay in presentation on survival was attributable to an association between longer delays and more advanced stage. However, within individual stages, longer delay had no adverse impact on survival. Analyses based on 'total delay (i.e. the interval between a patient first noticing symptoms and starting treatment) yielded very similar results in terms of survival to those based on delay to first hospital visit (delay in presentation).	Recall bias – patients were asked by questionnaire to report on duration of symptoms. Also, this will not completely eliminate the effect of lead time bias, although will minimise it. Study is limited to one institution. It was indicated that unspecified number of patients over the period of the study were entered into clinical trials. It is not clear how this would affect the results of the study. Cut-off points (as admitted by the authors) were arbitrary. Stage was considered but not comorbidity or social status adjustments. Study was not able to define the relative contribution of patient or GP delay.

CHAPTER 3

MATERIALS AND METHODS

3 MATERIALS AND METHODS

3.1 Study Design

The design of the study is descriptive and observational (analysis of secondary data). Five data sets from administrative sources, the cancer registry, and special surveys have been assessed for content and reliability, and used to relate colorectal cancer survival with predictors at organisational level.

The following datasets have been used:

Cancer Services Peer Review was conducted in 2001. Expert regional teams assessed the compliance of cancer units and centres throughout the country with the published cancer standards.

Hospital Episode Statistics (HES) contain information on all admitted patients treated in National Health Service (NHS) hospitals in England (started 1989 and ongoing). Each record includes administrative, clinical and patient information describing the care and treatment a patient received while in a hospital.

Acute Hospital Portfolio (AHP) is a collection of ongoing audit reviews which are conducted by the Healthcare Commission (previously by the Audit Commission). They started audit surveys from 2000/2001 financial year, with the focus on service areas and resources and are not cancer specific.

Cancer Waiting Times are collected by NHS Trusts on patients referred by GPs with suspected cancer (from 20001/2002 financial year - ongoing). The primary target used up until 2005 was the "two week wait".

Thames Cancer Registry (TCR) is one of (then) 12 population based cancer registries in the UK and covers the residential population of London, Surrey, Sussex, and Kent (since

1960 - ongoing). The registry collects information about new cases of cancer and these are linked to death certificates to produce information on cancer prevalence and survival.

Further details and assessment of these datasets are presented in *Results* chapter (see 4.1).

3.2 Setting

The study was based on 28 NHS acute hospital trusts in London that provide colorectal cancer services (see Table 3.1). London is the second biggest region in England (after South East region) with population more than 7 million people[275].

3.2.1 Hospital trusts in London

Hospitals in the National Health Service (NHS) in England are managed as 'hospital trusts'. Many hospital trusts are sited on two or more different hospital locations. Hospital trusts are the standard level for analysis of much NHS administrative data and for performance management and comparison purposes. According to the NHS London Modernisation Board[i], there are 43 hospital trusts in London which provide hospital and mental health services: 27 acute trusts; 10 mental health trusts; 5 specialist trusts; 1 ambulance trust. Within specialist hospital trusts, there are two trusts which provide specialist cancer care – Royal Brompton and Harefield Hospital NHS Trust and Royal Marsden NHS Trust. (The Royal Brompton and Harefield NHS Trust provides specialist cardiothoracic, including lung cancer, care and therefore was not included in the study.) St Mark's hospital, which is a part of North West London Hospitals NHS Trust, is a centre for intestinal and colorectal disorders.

The Thames Cancer Registry (TCR) contains data on hospital level. A 'look-up table' was provided by TCR to link individual hospitals into hospital trusts. The other data sources used only hospital trusts.

[i] http://www.london.nhs.uk/aboutus/nhstrusts.htm

Table 3.1 List of all hospital trusts in London considered for the study

1. Barking, Havering & Redbridge Hospitals NHS Trust
2. Barnet and Chase Farm Hospitals NHS Trust
3. Barts and The London NHS Trust
4. Bromley Hospitals NHS Trust
5. Chelsea & Westminster Healthcare NHS Trust
6. Ealing Hospital NHS Trust
7. Epsom and St Helier University Hospitals NHS Trust
8. Guy's & St Thomas' Hospital NHS Trust
9. Hammersmith Hospitals NHS Trust
10. Hillingdon Hospital NHS Trust
11. Homerton University Hospital NHS Trust
12. King's College Hospital NHS Trust
13. Kingston Hospital NHS Trust
14. Lewisham Hospital NHS Trust
15. Mayday Healthcare NHS Trust
16. Newham Healthcare NHS Trust
17. North Middlesex University Hospital NHS Trust
18. North West London Hospitals NHS Trust
19. Queen Elizabeth Hospital NHS Trust
20. Queen Mary's Sidcup NHS Trust
21. Royal Free Hampstead NHS Trust
22. Royal Marsden NHS Trust
23. St George's Healthcare NHS Trust
24. St Mary's NHS Trust
25. University College London Hospitals NHS Trust
26. West Middlesex University Hospital NHS Trust
27. Whipps Cross University Hospital NHS Trust
28. Whittington Hospital NHS Trust

Based on agreement with custodians of the datasets, names of individual hospital trusts will not be disclosed while presenting the results of the study.

3.3 Study population and time period considerations

3.3.1 Study population: Datasets with hospital level data

Out of five datasets available for the study, the following two datasets contained hospital level data.

3.3.1.1 Acute Hospital Portfolio (AHP)

All NHS acute hospital trusts are covered by the dataset. However, not all indicators within the AHP were available for all 28 hospital trusts considered in this study (see Table 4.2).

3.3.1.2 Cancer Services Peer Review

All cancer units and centres at NHS hospital trusts in England are covered by the dataset. Out of 28 hospital trusts included in the study, data for 3 hospital trusts have not been considered for this part of the analyses, due to differences in structure of hospitals between the Thames Cancer Registry and the Cancer Services Peer Review datasets.

3.3.2 Study population: Datasets with individual (patient) level data

The following three datasets collected data on patient level.

3.3.2.1 Hospital Episode Statistics (HES)

HES contain data on inpatient and day cases admitted to NHS hospitals in England. It includes private patients treated in NHS hospitals, patients who were resident outside of England and care delivered by treatment centres (including those in the independent sector) funded by the NHS[ii].

3.3.2.2 Cancer Waiting Times

Cancer Waiting Times contain data on all urgent GP referrals of patients with suspected cancer seen by a specialist. Patients' records are aggregated at NHS hospital trust level. They include patients who may not turn out to have cancer and do not include patients

[ii] http://www.hesonline.nhs.uk/Ease/servlet/ContentServer?siteID=1937&categoryID=456

diagnosed by another route to have cancer. Data for all 28 NHS hospital trusts included in this study were available in the dataset.

3.3.2.3 Thames Cancer Registry

The study used colorectal cancer cases incident in London residents during the six-year period 1 January 1996 to 31 December 2001, and followed up until 31 December 2001. The endpoint of the study was defined as 31 December 2001, and all patients alive were censored on that day. Patients who emigrated from the country or were lost to follow-up were censored at the time of emigration or loss to follow-up by TCR. This approach ('right censoring') is a standard practice in cancer survival analysis, to avoid biased over-estimation of survival by retention in the analysis (as alive) of patients who can no longer be followed up to the date of death[2].

Patients who satisfied all of the following **inclusion criteria** were considered during the study:

1. Diagnosis of primary colorectal cancer based on ICD-10: C18-21[iii]
2. London residents
3. Age range 15-99
4. Treated at acute or specialist NHS hospital trusts in London

The TCR dataset contained data on 17493 colorectal cancer incident cases among London residents, aged 15-99, during the years 1996-2001.

Patients diagnosed from a death certificate only (DCO) were excluded from analysis (548 cases have been excluded in this category). DCO cases cannot be included in survival estimates because their date of diagnosis and subsequent follow-up information is not known. The direction of any potential bias as a result of this exclusion is unpredictable and remains an unresolved issue in cancer survival statistics[276].

Patients with primary treatment at non-London hospitals or classified as 'home';

[iii] International Classification of Diseases, Tenth Revision (http://www3.who.int/icd/currentversion/fr-icd.htm)

'hospice'; 'independent' (non-NHS) hospitals were excluded from the study, according to the inclusion criteria specified above (1442 cases have been excluded in this category).

Three patients with missing deprivation (IMD-2000, income quintile) information were excluded, since complete deprivation information was necessary to calculate relative survival rates based on sex and deprivation-specific life table.

Also excluded were 35 cases with no information on hospital of treatment.

After taking into account inclusion and exclusion criteria specified above, the final study population comprised of 15465 patients treated at 28 hospital trusts in London.

- **Hospital of treatment**

It is possible for cancer patients to be treated at more than one hospital if they need specialist forms of treatment (surgery, radiotherapy, chemotherapy, specialist palliative care and so on) available at different places.

There are three potential approaches in allocating the hospital of treatment. One is to consider all hospitals where a patient has been treated: however, this approach may lead to over-counting of patients and is difficult to employ for practical purposes. A second way is to consider hospital of first treatment. Thirdly, hospital of treatment could be assigned to the hospital of first attendance.

The TCR data showed that the "hospital of first attendance" variable had no missing values, while "hospital of first surgery" and "hospital of highest surgery" (main surgery) variables both had more than 11% missing values. Moreover, in more than 98% of cases, hospital of first attendance and hospital of first surgery were the same hospitals, and in more than 97% of cases hospital of first attendance was the same as hospital of main ('highest') surgery. Taking into consideration the completeness of data, and the fact that the hospital of first attendance was the place of main surgical treatment for more than 97% of cancer patients, for research purposes, hospital of first attendance was considered as the hospital of treatment.

3.3.3 Time frame

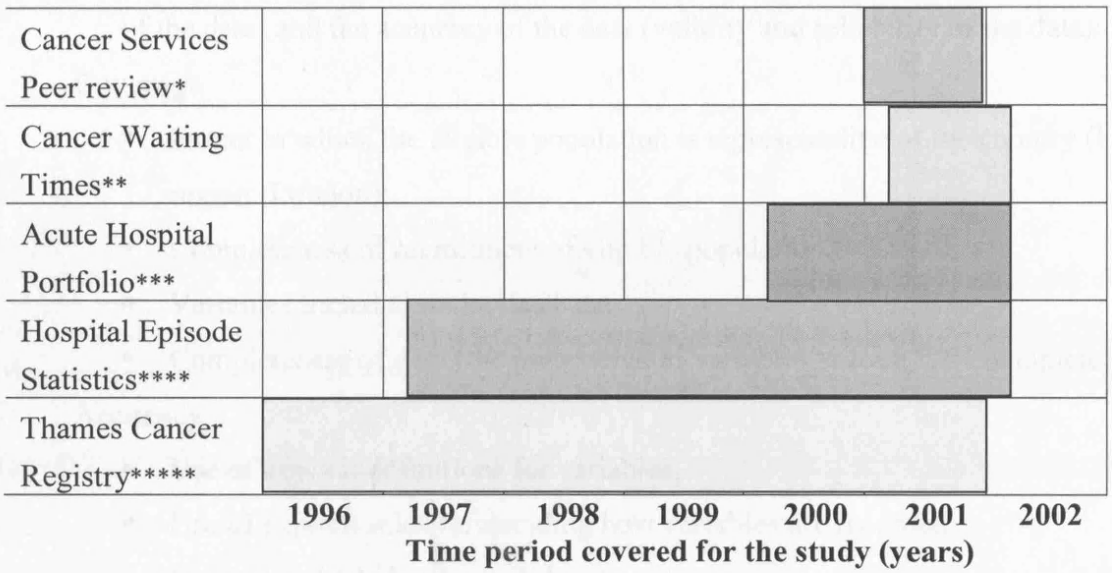
The most recent available cancer registry data (incident cases 1996-2001, followed to 31 December 2001) were used for the study. This time frame allowed estimation of five-year survival using 'complete analysis' approach (see 3.6.2) and provided adequate power (sufficient numbers of events –"deaths") to conduct survival analysis on hospital level (see 3.6.4).

For this reason, the time period of the other datasets, if feasible, were chosen to be the closest possible to the cancer registry time frame, that is, the period from 2000 to 2002 years (see Figure 3.1). For three of the data sets, this period was the first period of collection. The cancer registry data provided survival at this point, but related to earlier incidence and treatment. Therefore, it should be noted that cancer registry data preceded most of the organisational data in time.

The study used the data on hospital staffing from the Acute Hospital Portfolio for 2000-2002 years since no data were available for earlier time periods. Compliance with cancer standards was first assessed by the national peer review survey in 2001 (the repeat of this survey is currently in process); therefore, this time period was employed in this study. Cancer Waiting Times statistics was formally launched in 2001-2002 years. For that reason, data for 2001/2002 was used in this study. Finally, to estimate hospital volume of patients, only the data from 1997 from the Hospital Episode Statistics were used, since special patient identifiers, which allow distinguishing each individual patient admission within a year, had been introduced in 1997.

A distinction need to be made between datasets covering 'calendar' and 'financial' year(s). While cancer registry data reflect calendar years, i.e. from 1st of January to 31st of December, and peer review survey was conducted over 2001, all other datasets reflect financial years, i.e. from 1st of April to 31st of March (see Figure 3.1).

Figure 3.1 Time period of datasets used for the study



*for more information, see 4.1.1

** for more information, see 4.1.3

***f or more information, see 4.1.2

**** for more information, see 4.1.4

*****f or more information, see 4.1.5

3.4 Review of the properties of available databases

The properties of the datasets were reviewed using Directory of Clinical Databases (DoCDat) assessment tool developed at the London School of Hygiene and Tropical Medicine[277]. This provides a framework to determine general characteristics and completeness of data.

The assessment covers the following aspects:

1. **General aspects** of the database, such as when it was set up, who it includes and what geographical area it covers;
2. **Data set**, such as how many individuals are included, data linkage, data security and confidentiality and a copy of the data collection questionnaire;
3. **Outputs**, including who can analyse the data, how frequently standard audit reports are produced, and a bibliography of published work;

4. **Management** of the database, such as who is involved in running it and who funds it;
5. **Data quality**, including several aspects of the coverage of the data (generalisability of the data) and the accuracy of the data (validity and reliability of the data):

Coverage

- Extent to which the eligible population is representative of the country (UK) or region (London);
- Completeness of recruitment of eligible population;
- Variables included in the database;
- Completeness of data (the percentage of variables at least 95% complete).

Accuracy

- Use of explicit definitions for variables;
- Use of explicit rules for deciding how variables are recorded;
- Extent to which data are validated.

The assessments were done using the DoCDat proforma adapted for employed datasets (see *Results* chapter and Appendices 11-15). Only 7 out of available 10 data quality criteria[iv] were used for the assessments due to their relevance to employed datasets. Descriptive statistics, analysis of data manuals or dictionaries, other supporting documents, information from source websites were used while carrying out assessments. In addition, custodians of dataset were contacted, when appropriate, to clarify any unclear issues. Also, literature search and 'grey literature' in form of reports and other documents were used. A detailed review of the properties of the available datasets is attached (see *Results* chapter and Appendices 11-15).

[iv] http://www.docdat.org

3.5 Model specifications

Donabedian's classic studies in quality of health care identified three dimensions: 1) structure; 2) process; and 3) outcome[29;50;51]:

Structure

The 'structure' component relates to the conditions under which care is provided. These may include material resources such as facilities and equipment; human resources such as the number, variety, and qualifications of staff; organisational characteristics such as the organisation of the medical and nursing staff; and the presence of teaching and research functions.

Process

The 'process' component relates to the activities that constitute health care, including diagnosis, treatment, rehabilitation, prevention, and patient education, usually carried out by professional personnel, but also including other contributions to care, particularly from patients and family.

Outcomes

The 'outcomes' component is taken to mean changes, desirable or undesirable, in individuals and populations that can be attributed to antecedent health care. These may include changes in health status; changes in knowledge and behaviour of patients and family members that may influence future health; and satisfaction of patients and their family members with the care received and its outcomes.

3.5.1 Study model

This framework served as a basis for the model to assess organisational determinants of survival for colorectal cancer in London. In addition, case-mix adjustment has been introduced because outcomes partly depend on the severity of patients admitted to hospital. Particularly, these three dimensions of structure-process-outcomes of care (plus

'case-mix adjustment') were incorporated into four main parts of the model, as shown in Figure 3.2, depending on the type of data available for the study: hospital level indicators (structure and process of care); clinical treatment (process of care); individual level indicators (patient case-mix); and outcome (five-year relative survival).

This means that the relationship between various indicators of structure or process of care and cancer survival has been assessed after adjustment for patients' case-mix (thus, the solid lines in the model, from both 'hospital level indicators' and 'clinical treatment' parts towards the 'individual level indicators' part). The explanation of 'dotted line' between 'hospital level indicators' and 'clinical treatment' parts is given below (see 3.5.3).

The assessment is mainly directed towards exploring the predictors of survival using routinely collected data. The choice of indicators considered in the model was based on findings from the review of the literature (see 2.5, *Review of the literature* chapter) and sources of data available for the study (see 4.1, *Results* chapter).

Model also specifies key indicators which have been identified through the literature review as potential important determinants of the outcomes of cancer care, but which were not available for the study: *(a)* 'specialisation' under 'hospital level indicators' (see 2.4.3, *Review of the literature* chapter); *(b)* 'adjuvant therapy: radio- and chemo-therapy' under 'clinical treatment' (see 2.3.5, *Review of the literature* chapter) ; *(c)* 'comorbidity' under 'individual level indicators' (see 2.3.4, *Review of the literature* chapter); and *(d)* 'emergency admission' under 'individual level indicators' (see 2.3.5, *Review of the literature* chapter). Further considerations of these limitations of the study are provided in *Discussion* chapter.

Another important issue to take into account while considering the model is the temporal relationships between its data elements. One of the main limitations of the current study was that the patients' treatment preceded the organisational data in time. The underlying assumption was that compliance with cancer standards or other organisational determinants estimated in 2000-2002 reflected similar values across the five years for which patients were first accrued. The issue of temporality was introduced in the *Review of the literature* chapter (see 2.2.2), then presented in *Materials and Methods* chapter (see 3.3.3), and further reviewed in *Discussion* chapter (5.3.5). Time periods covered by indicators, if applicable, are indicated in brackets. This was particularly relevant to 'hospital level indicators'. 'Individual level indicators' and 'clinical treatment' were available from the Thames Cancer Registry. For this reason, time period covered by

registry data (1996-2001) is only indicated under the 'outcome' part of the model.

All sources of data were linked together at NHS hospital trust level and a single dataset had been created which contained all indicators considered within the model (see *Results* chapter). Due to confidentiality, no individual identifiers were provided for either the HES dataset or the cancer registry data, so it was not possible to link them at individual (patient) level.

3.5.2 Hospital level indicators

Hospital level *'structure of care'* indicators included *(1)* compliance with 35 colorectal cancer-specific MDT standards; *(2)* several indicators of medical and nurse staffing level; and *(3)* teaching status of hospital trusts. Except for 'teaching status' and 'staffing level' indicators, which refer to the hospital trust, in general, all other indicators were colorectal cancer-specific. 'Teaching status' refer to the organisation and functioning of the hospital trust as a whole. Regarding general staffing level, the underlying assumption was that general staffing level reasonably reflects cancer staffing, since no systematic information on specialisation is available in England, and most colorectal cancer patients are managed by general healthcare personnel (not colorectal cancer-specific).

Hospital level *'process of care'* indicators included *(1)* waiting time – 'meeting two week wait' target; *(2)* hospital volume of cases; and *(3)* specialisation – not available for the study. Although the literature mainly supports the belief that specialist care is associated with improved outcomes in cancer care, there is no systematic information on specialisation in the UK. Therefore, the effect of 'specialisation' per se, meaning 'specialist surgeon' – the main concept discussed in the literature, was not considered in the analysis. However, some of the cancer standards which considered under the 'structure of care' hospital level indicators, reflect the organisation of multi-disciplinary teams, which specifically aim to provide specialist care to cancer patients in England. Therefore, the impact of 'specialist teams' within the 'compliance with cancer standards' have been assessed in the model.

3.5.3 Clinical treatment

The 'Clinical treatment' part of the model reflects indicators of *process of care* (see 4.1.5, *Results* chapter, for detailed description of variables). They included *(1)* type of

surgery and *(2)* adjuvant therapy – radio- and chemo-therapy. TCR data contain limited and insufficient information on clinical treatment: only broad categories of (mainly surgical) treatment are recorded. Also, the information on adjuvant therapy was largely missing or not recorded, and, thus, was not considered in the analysis. Therefore, no comprehensive analysis of the influence of clinical treatment on survival was carried out. The type of surgical treatment was considered as a separate variable, and its impact on survival was assessed after adjusting for available patient case-mix indicators.

There is also a possibility of a 'hospital' effect working through 'treatment' (thus, the dotted line in the model), but due to limited treatment information potential interactions between hospital level indicators and indicators of 'clinical treatment' were not considered in this study.

3.5.4 Individual level indicators: patient case-mix

The 'Individual level indicators' part of the model reflects patient case-mix. Patients vary in their medical and social characteristics, features that can of themselves influence outcome either independently of process or structure or by interacting with them. This necessitates correction for differences in such characteristics – a procedure known as "case-mix adjustment". The following variables were drawn from the TCR and used for case-mix adjustment:

a) age

Patients' age was divided into 6 categories: 15-39; 40-49; 50-59; 60-69; 70-79 and 80-99 years old, in accordance with the current national cancer statistics produced by ONS[v].

b) sex

Sex of patients was entered into the model as a categorical variable: male and female.

c) tumour stage (see 4.1.5, *Results* chapter, for detailed description)

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[v] http://www.statistics.gov.uk/statbase/Expodata/Spreadsheets/D7899.xls

d) indicator of social deprivation (IMD 2000 income quintile)

In the absence of individual data on personal conditions in the cancer registry, the socioeconomic status of cancer patients is routinely determined using an ecological approach. A census-derived or area-based score reflects aspects of material deprivation or socioeconomic status in the geographic area in which a person resides [278].

In this study, social deprivation was measured by income domain of the Index of Multiple Deprivation 2000 (IMD 2000)[279]. The IMD 2000 income domain score was calculated based on electoral ward of residence as defined in 1998. Its purpose is to show proportions of the population experiencing income deprivation in an area. The income domain is the most comparable one to Carstairs index, and according to ONS, "in general, the same pattern of health inequalities exist using either the Townsend Index or the Index of Multiple Deprivation 2000" [280]. The indicators in this domain are in the form of non-overlapping counts of people in families in receipt of means tested benefits[vi]:

- *Adults in Income Support households (DSS) for 1998*
- *Children in Income Support households (DSS) for 1998*
- *Adults in Income Based Job Seekers Allowance households (DSS) for 1998*
- *Children in Income Based Job Seekers Allowance households (DSS) for 1998*
- *Adults in Family Credit households (DSS) for 1999*
- *Children in Family Credit households (DSS) for 1999*
- *Adults in Disability Working Allowance households (DSS) for 1999*
- *Children in Disability Working Allowance households (DSS) for 1999*
- *Non-earning, non-IS pensioner and disabled Council Tax Benefit recipients (DSS) for 1998 apportioned to wards*

Based on the literature, another important factor which may influence the outcome of cancer care is the type of admission of patients to the hospital (elective vs. emergency). It has been shown that up to a third of colorectal cancer patients are admitted as emergences and over 20% of those patients died within a month after operation (see 2.3.5, *Review of the literature* chapter). However, due to confidentiality policies, it was not possible for this study to link HES data with cancer registry data on individual level; only hospital-level linkage has been conducted. For this reason, the information on urgency of admissions could not be considered in the analysis.

For similar reasons, the information on patients' comorbidity, contained within the HES dataset, was not used for the analysis. The lack of adjustment for comorbidity and the

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[vi] Indices of Deprivation 2000. Regeneration Research Summary, Number 31, 2000. Department of the Environment, Transport and the Regions.

possible impact of unknown confounders on study results are considered in *Discussion* chapter.

However, as indicated above, tumour stage, as well as age, sex and social deprivation (IMD 2000, income quintile) have been accounted for in the model as indicators of patient case-mix. The impact of all organisational determinants of outcomes assessed in this study has been considered after adjustment for these factors. Also, it should be noted that the study used relative survival as outcome measure, while most studies in the literature used crude survival. Relative survival estimates take into account background (non-cancer specific) mortality, and thus, to some extent, indirectly reflect the presence and impact of comorbidity on population level.

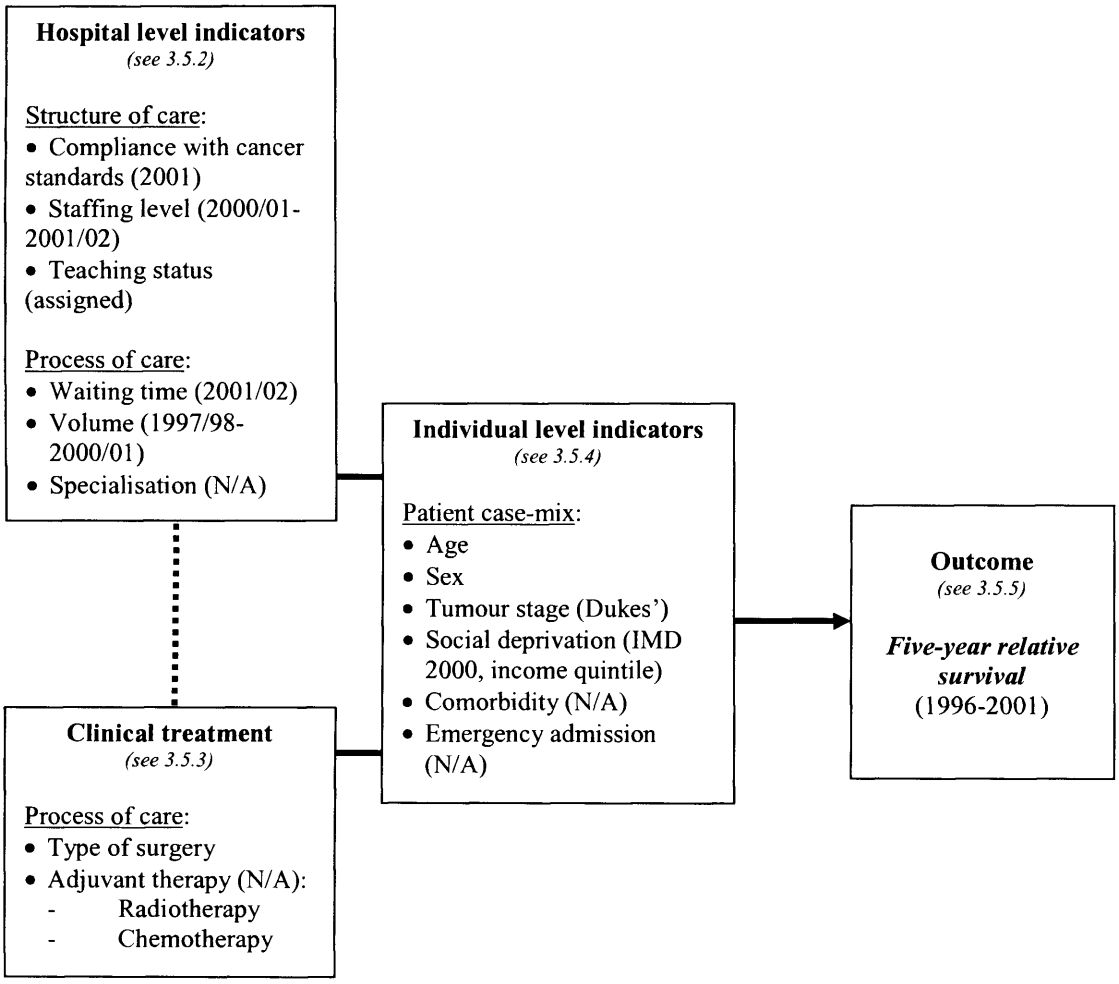
3.5.5 Outcome (dependent variable) - five-year relative survival

To compare performance of healthcare institutions, most studies in the literature have used short-term mortality rates, e.g. in-hospital mortality, 30-day mortality. However, in contrast to most chronic diseases, long-term mortality (or survival) for cancer can be measured and is being routinely monitored through cancer registration. In the present study, the main outcome indicator (dependent variable) was five-year relative survival, as measured based on cancer registry data.

Other outcome measures, such as cancer recurrence rate, quality of life after discharge, postoperative complications (or complications after chemo- or radio-therapy) are not addressed here, since routinely collected data for these indicators are not available. Another measure of the outcome of care, patient experience of care, as measured based on the National Cancer Patient Survey[281], could be a subject for a separate study. It should be noted that the information on selected indicators of patients' experience of in-hospital care was missing for more than a half of hospital trusts included in the study.

Figure 3.2

PROPOSED MODEL FOR ASSESSMENT



3.6 Statistical considerations/methods

Statistical analyses were conducted using Stata statistical package (Intercooled Stata 8).

3.6.1 Data management

Data have been checked for completeness, unusual reporting frequencies and inconsistencies. Data errors and missing values have been verified by contacting custodians of appropriate data sets.

3.6.1.1 Handling missing data

Three approaches were used in this thesis to handle missing values, particularly for tumour stage (20.9% of missing values) and type of surgical treatment (11.6% of missing values).

Firstly, the study used 'complete case analysis', which means that cases with missing values are excluded from analyses. However, this approach excludes a proportion of patients from analyses and implies 'missing at random' assumption, which is difficult to prove.

Secondly, analyses of potential predictors of survival were repeated by creating an additional 'not known' category for each variable with missing values. Although widely used in the literature, the latter approach was shown to produce biased estimates with unpredictable results[282;283].

Thirdly, analyses of potential predictors of survival were repeated using multiple imputation approach, which is suggested as a method of choice in dealing with missing data[284]. A five-fold multiple imputation was applied to the data used for modelling analyses to accommodate particularly missing tumour stage data. Multiple imputation is an unbiased method of imputing plausible values using an imputation model when data are missing at random[285-287]. Even when data are not missing at random, multiple imputation has been shown to perform well[288]. With multiple imputation, the uncertainty about the missing data is accommodated, as a number of complete data sets are created. It has been shown to be superior to the 'complete case' approach which analyses only cases for which no

information is missing, or the 'indicator' approach where missing data are grouped into a separate category in regression analyses[289]. 'Rubin's rules' enable the recombination of multiple imputed estimates and their variances to provide one 'complete data' estimate and confidence interval for each parameter in the model[286]. The method of multiple multivariate imputation of missing values was employed using Royston's programme developed for Stata statistical package[290]. However, this method is still under development and only recently became available to use with Stata statistical package for categorical variables[290].

3.6.1.2 Categorisation

To simplify interpretation, continuous variables, such as 'volume of patients', 'staffing level' and 'meeting two-week wait target', were grouped into discreet categories. It should be noted that no agreed or clinically important cut-off points for these variables are suggested in the literature. As there do not appear to be logical (in a clinical sense) divisions, the values were ordered and split into quartiles. In addition, income domain of IMD 2000 had been assigned to individual patients within the Thames Cancer Registry in form of quintiles of ward-level deprivation scores. This approach is advantageous from the statistical viewpoint as it ensures reasonable numbers in each category.

The relationship between predictors and outcomes is based on pooled data for all trusts, as is usual for regression modelling (including relative survival modelling). The number of patients is divided into equal quartiles based on predictor values. Because Trusts are of different sizes, the total of Trusts may differ.

Alternatively, the actual values themselves could be considered and risks calculated, for example, per 1% increase in meeting two-week wait target. In many way such an approach is better as it 'uses all the data', but the statistical methods for analysis would assume that the risk is linear, which may not be the case[291].

3.6.2 Choice of the method for survival analysis

The presence of censored data (cancer registry data) makes analytic techniques which handle censored observations the main methods to use.

In traditional survival analysis of failure-time data, the proportion of subjects who have not yet experienced the event of interest is calculated for one or more time points after they are first exposed to the risk of experiencing the event. In such 'cohort' analyses, each subject in the study population has the potential to be followed for an equal and fixed period of time. Consequently, survival probabilities at a given interval since diagnosis cannot be calculated until the full period of follow-up has elapsed and the potential follow-up time of all subjects is equal to, or exceeds, the interval of interest. For this reason, cohort measures of cancer survival are less up-to-date than concurrent measures of incidence or mortality. This is because, for example, the proportion surviving five years after their cancer diagnosis can only be established from patients who were diagnosed five or more years ago, whilst the incidence and mortality rate can be calculated from the most recent data available.

Complete analysis of survival includes in the calculation the experience of patients who have not had the opportunity to be followed for the full period of time. A complete analysis of five-year survival would include the probability of surviving one year estimated from the experience of patients diagnosed up to one year ago, the probability of surviving two years from patients diagnosed up to two years ago, and so forth. Where survival is improving, or where an effective new treatment has been recently introduced, survival estimates using this method are higher than those obtained using the cohort method. This is because the estimation of the survival probability includes more recently diagnosed patients who have higher survival. Accordingly, complete estimates are more up-to-date than cohort estimates of survival. In this study, complete estimates of five year survival were estimated for patients diagnosed during 1996-2001.

Traditionally, in the literature, Kaplan-Meier crude survival estimates and Cox proportional hazards models are used to analyse survival data. However, these methods do not take into account population background mortality. For this reason, relative survival modelling and its estimates were the methods of choice in this study.

Relative survival is the ratio of the survival observed in a group of cancer patients to the survival expected if they were only subject to the general (all cause) mortality in a standard population. Relative survival may be interpreted as survival corrected for background mortality [79]. Relative survival takes into account the underlying mortality in the population from which the cancer patients are drawn, and can be used to adjust for

differences and trends in background mortality in each age, sex and socioeconomic group and over time.

The cumulative relative survival rates by hospital trusts were calculated according to the Esteve's maximum likelihood method using the 'strel' program[292;293]. Also, 95% confidence intervals for cumulative relative survival rates were estimated.

3.6.3 Multivariate relative survival model

The impact of potential predictors on survival has been examined using a multivariate relative survival model (generalised linear model) as described by Dickman et al [294]. In such a model, the risk function is the sum of an expected mortality risk (background mortality) and an excess mortality risk which represents the effect of the cancer since its diagnosis. The background mortality is that would have been expected for patients with the same characteristics (namely, age, sex, calendar period, deprivation category) as the general population [295] and were taken from sex, calendar period (1996-2001) and deprivation-specific London life table [296].

As was indicated earlier in this chapter, five-year relative survival has been considered as the main outcome measure. The relationship between potential predictors and five-year relative survival has been assessed using the estimates of relative excess risk of death (RER)[vii]. The estimates of RER were calculated after adjustment for differences in years of follow-up, age, sex, deprivation category and tumour stage. The statistical significance of each of these case-mix variables was initially tested in the univariate relative survival model.

Bivariate correlations among all covariates were examined to avoid potential problems due to collinearity, which might confound the analyses[297;298]. Collinearity inflates the variances of the parameter estimates, and may reduce statistical significance of individual independent variables while the overall model may be strongly significant. Collinearity may also result in wrong signs and magnitudes of regression coefficient

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[vii] The *excess* risk of death in a given group of patients within, say, five years of diagnosis is the risk of death *over and above* what would have been expected if they had experienced only the death rates seen in the general population for the same age, sex and deprivation. The *relative excess risk of death* reflects the extent to which the excess risk of death differs from the excess risk in a baseline group, after adjustment for other co-variates.

estimates, and consequently in incorrect conclusions about relationships between independent and dependent variables.

Standard errors were adjusted for a clustering effect of hospital trusts (using the 'robust cluster' command in Stata). It adjusts for 'nested' effects within trusts: for example, cancer patients within a specific trust might be more similar to each other (perhaps with similar referral patterns, or catchment areas) as compared with the whole population of cancer patients [299]. Failure to adjust for clustering by hospital trust could lead to underestimation of standard errors [300].

The relationship was considered as statistically significant when $p < 0.05$ (or 95% confidence interval (CI) did not contain "1"). Likelihood-ratio and Wald tests were used to compare the goodness of fit of models and assess statistical significance of categorical variables within the survival model. The relationships between various independent and dependant variables were also assessed by Spearman rank correlation tests.

As with the Cox proportional hazards model, the key assumption here is that the relative excess risk of the event in any group is a constant multiple of the risk in any other. This assumption implies that the relative excess risk curves for the groups should be proportional and cannot cross. 'Proportional hazards' assumptions were tested by creating interaction terms of covariates with the follow-up time (time dependent covariates) and assessing their statistical significance. If the interaction term for any of covariates assessed was statistically significant, then it was considered a violation of the assumption and therefore left in the model[viii].

For comparative purposes only, the assessed relationship was also tested using a Cox proportional hazards model, taking into account that this method is traditionally used in the research of cancer outcomes. However, the results obtained using these two methods were generally similar, and hazards ratios from the Cox model are indicated in few examples with cancer standards, for illustrative purposes only (see *Results* chapter).

[viii] http://www.ats.ucla.edu/stat/stata/faq/test_proportionality.htm

3.6.4 Sample size and statistical power considerations

The power of a survival analysis is related to the number of events rather than the number of participants. According to the literature, simulation work has suggested that at least 10 events ("deaths") need to be observed for each covariate considered, and anything else will lead to random instability and then unreliable estimates [301]. With the total sample size of 15465 patients treated at 28 hospital trusts and number of events ("deaths") equal to 8059, this study had enough power to determine the effect of each covariate considered.

3.7 Ethical permission

No contact with patients was sought or required, and patient identifiers were not needed. Therefore, formal ethical approval was not necessary for this study. However, as was noted before, current research work was related to the MQiCS study which was sponsored by Department of Health and received permission from the South East Research Ethics Committee[302].

Permission to gain access to the data was obtained from custodians of each dataset employed in the study.

CHAPTER 4

RESULTS

4 RESULTS

Introduction

The focus of this chapter is to describe the datasets providing hospital and individual data relating to colorectal cancer survival in London, and to present analyses of the data. Because these datasets were assembled for the first time in this way for this study, and because only certain parameters were eventually drawn for the explanatory analysis, details are presented here in the *Results*, showing the feasibility of the datasets for the study.

Cancer registry data provide individual level factors, such as age, sex, social deprivation and tumour stage. They also contain information on clinical treatment of patients received within the first six months after diagnosis, and the place of treatment. Further hospital explanatory variables were sought from outside the cancer registry dataset, using existing data that were already collected nationally, and that were available for the London region. The five datasets employed to draw hospital level indicators, along with indicators of clinical treatment, were Cancer Services Peer Review, Acute Hospital Portfolio, Cancer Waiting Times, Hospital Episode Statistics, and Thames Cancer Registry.

4.1 Datasets for the explanatory variables

The literature review indicated that using routine or administrative datasets for research purposes has limitations depending on content and the quality of data. Therefore, before exploring hospital level indicators within the frame of the proposed model, it was necessary to consider the feasibility of using these datasets for the study.

As indicated in the *Methods* chapter, the properties of the datasets were reviewed using DoCDat assessment tool. The feasibility of using the datasets was considered depending on whether necessary parameters (predictors) identified by the literature review were in datasets, and whether they are reliable enough to use in the model and draw conclusions. Detailed assessments using the DoCDat approach are provided in Appendix 1. Key summary results are presented below. Further discussion on the feasibility of using available routine datasets to investigate hospital-level determinants of survival for

colorectal cancer in London is provided in the *Discussion* chapter.

Data quality (coverage and accuracy) was assessed using a 4-point scale, where "4" indicates the highest level of quality, and "1" - the lowest level of quality, in accordance to DoCDat assessment tool[ix] (see Figures 4.1 - 4.10).

4.1.1 Cancer Services Peer Review

The Peer Review was undertaken in 2001. It was based on the Manual of Cancer Services Standards[14] published by the Department of Health in 2000, and which had developed standards based on professional advice. The Peer Review assessed the compliance with the standards by cancer units and centres in hospital trusts throughout the country. It was undertaken by visiting teams of clinicians and healthcare professionals, organised regionally.

Source: The Cancer Services Peer Review (2001) dataset was provided by the NHS Cancer Action Team.

Content: The Peer Review dataset contains data on compliance with all standards specified within the Manual. There were altogether around 200 standards which covered 10 topics for each main cancer types. The topics assess compliance with non cancer type-specific standards, such as patient centred care, diagnostic services, oncology, radio- and chemo-therapy, training, communication, and tertiary services. Only standards on multi-disciplinary teams (MDT) were designed for particular cancer types (breast, colorectal, lung and gynaecological cancers).

Variables chosen for the study: The 35 colorectal cancer-specific MDT standards were included in analyses. In the Cancer Standards Peer Review, teams assessed compliance with standards as absent, partially present or fully present. Relatively few standards were recorded as completely absent, so it was chosen to amalgamate contrast absent/partially

[ix] http://www.docdat.org

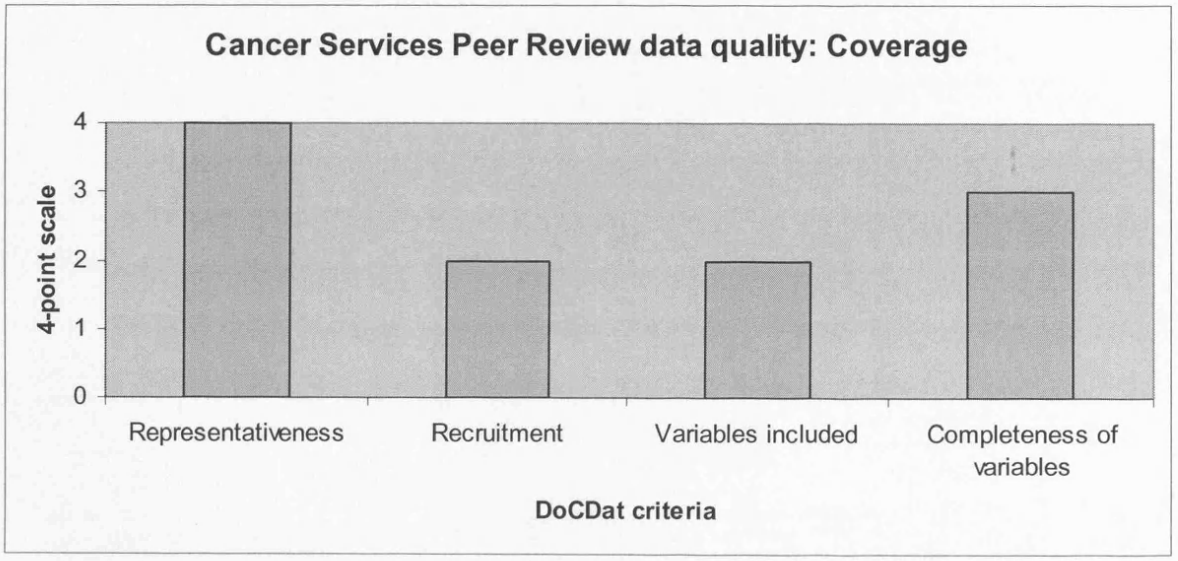
present against full compliance.

The Standards are grouped in themes in the Manual: some of these standards are different in character, others are overlapping (see Table 4.1). Moreover, they differ in their clinical importance in relation to outcome as opposed to organisational arrangements. Therefore, along with the composite score for all 35 standards, it was subsequently decided to analyse all 35 of them separately in the model.

Coverage: All cancer units and centres in England are covered by the dataset. Six regions used the final version of the cancer services standards (Manual of Cancer Services Standards, 2000), while Eastern Region used the draft version and Trent used "Trent Standards". London used the national version.

Out of 28 hospital trusts included in the study, data for 3 hospital trusts could not be included in the analysis of associations of compliance with cancer standards and survival, because of differences in structure of hospitals between the Thames Cancer Registry and the Cancer Services Peer Review datasets. Therefore, only data on 25 hospital trusts in London were considered in the model.

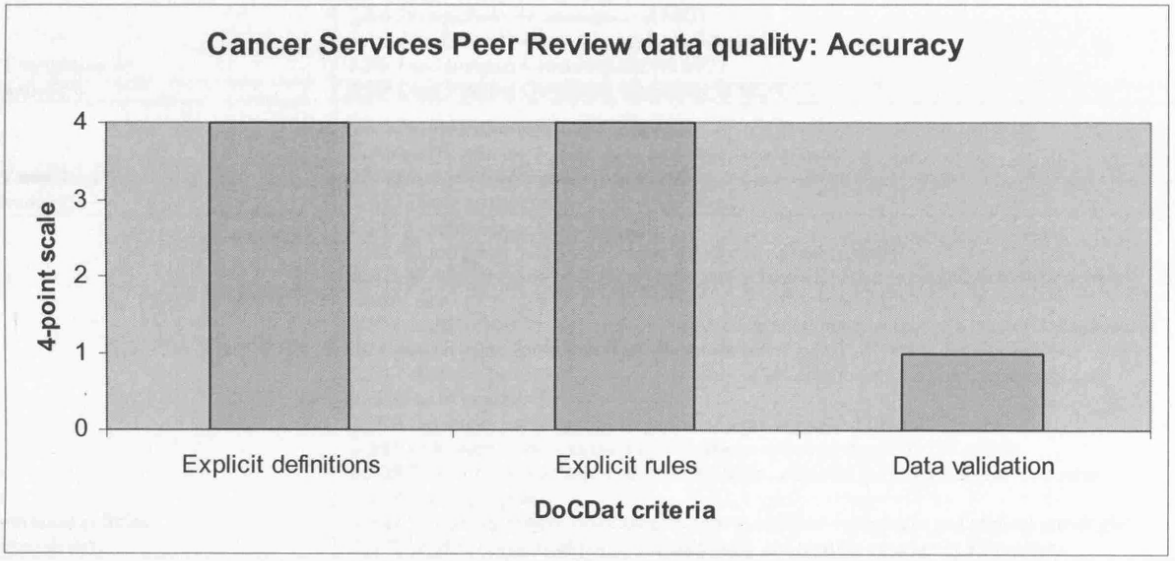
Figure 4.1 Cancer Services Peer Review data quality: Coverage[x]



[x] assessed using DoCDat 4-point scale (http://www.docdat.org)

Accuracy: Clear definitions of all variables are available in the Manual, although no clear rules on how to code variables in the dataset were specified. However, the "Manual of Cancer Services Standards" (Department of Health, 2001) sets out for each standard the information that would demonstrate that the standards have been complied with. No published information has been identified as to whether data have been validated.

Figure 4.2 Cancer Services Peer Review data quality: Accuracy[xi]



[xi] assessed using DoCDat 4-point scale (http://www.docdat.org)

Table 4.1 shows definitions of the standards taken from the Manual of Cancer Services Standards (2000) [14]

Table 4.1 The list of colorectal cancer MDT standards (extract from the Manual of Cancer Services Standards, 2000[14])

4.1.2 Acute Hospital Portfolio

The Acute Hospital Portfolio (AHP) is an annual, rotating national collection of selected indicators in acute hospital trusts in England and Wales. They are not cancer-specific and have a focus on key service areas or resources, e.g. medical and ward staffing, radiology and so on. The data sets were developed to assist the work of the Audit Commission (Healthcare Commission) from 2000/2001 financial year onwards.

Source: The Acute Hospital Portfolio (2000 - 2002) dataset was received from the former Audit Commission (AC), currently Healthcare Commission (HC).

Content: Literature suggested that levels of staffing may influence the outcome of health care, including cancer survival. The evidence, however, is equivocal, as shown in *Review of the Literature* chapter.

The data of the earliest period of AHP (for 2000/2001-2001/2002 financial years) were used in this study, since it was the most comparable with other datasets in relation to time period covered. Within that time period, the following national reviews on various indicators of staffing level were published by Audit Commission/Healthcare Commission (indicated years are 'financial' years – 1st of April to 31st of March) and available in Acute Hospital Portfolio:

- Medical Staffing 2001/02
- Radiology 2001/02
- Ward Staffing 2000/01; 2004/05

Variables chosen for the study: There were many variables available in Acute Hospital Portfolio for each specific topic. For instance, only one field of 'Medical Staffing' contained more than 190 variables. Only selected indicators which reflect medical, ward or radiology staffing level, were considered because of their relevance to study objectives, in relation to the literature findings, and completeness. They were presented as rates and are not cancer-specific.

The general staffing level indicators selected for the research are:

- medical WTE[xii] per 1000 admissions;
- consultant WTE per 1000 admissions;
- medicine consultant WTE per 1000 admissions;
- anaesthetist consultant WTE per 1000 admissions;
- pathology consultant WTE per 1000 admissions;
- radiology consultant WTE per 1000 admissions;
- radiographers per 1000 FCEs[xiii];
- clinical nurse specialists per 1000 FCEs.

There are no agreed (from research or clinical practice point of view) cut-off points as to what level of staffing is appropriate, sufficient or necessary target to achieve. For this reason, and to simplify interpretations, staffing level variables were used as categorical, divided into quartiles, where the 1st quartile is the lowest level and 4th quartile – the highest level of staffing.

Coverage: All NHS acute hospital trusts in England are covered by the dataset. However, not all indicators within the AHP were available for all 28 hospital trusts included in the study (see Table 4.2). According to personal communications with the representatives of the Healthcare Commission, this was due to the failure by some trusts to provide the data. It was often unclear whether the absence of data was due to it being missing or not relevant.

For two Trusts (Barking, Havering & Redbridge Hospitals NHS Trust and Barnet and Chase Farm Hospitals NHS Trust), mean of estimates for hospital sites within the Trust was presented, since in the dataset they were separated according to the sites.

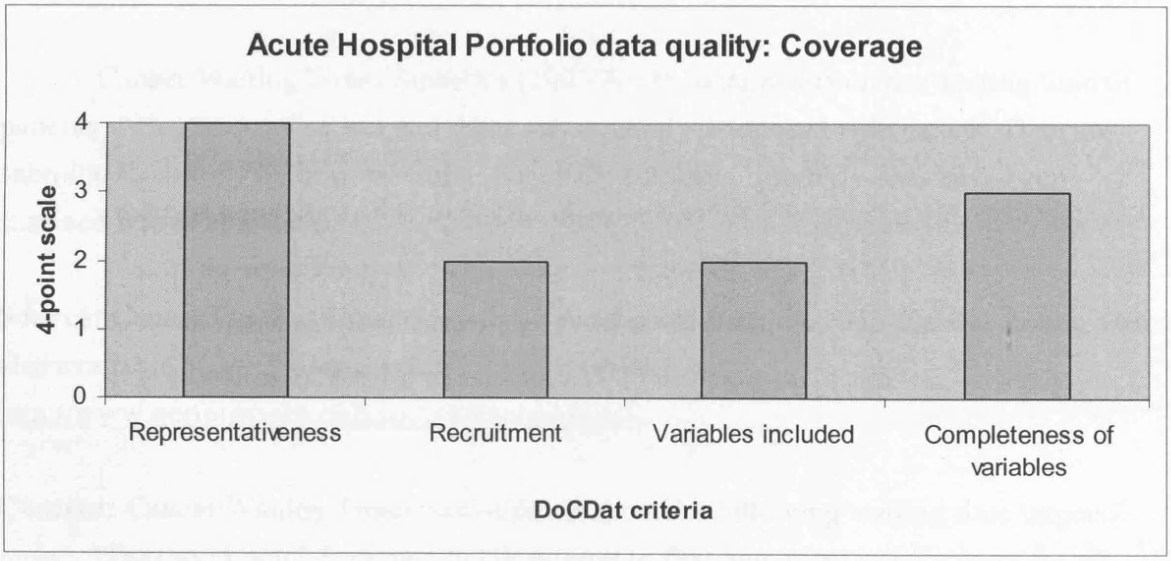
[xii] Whole time equivalent (WTE)

[xiii] Finished consultant episode (FCE)

Table 4.2 Number of hospital trusts available for each indicator of staffing level

Indicator	No. of hospital trusts
Radiographers per 1000 FCEs	27
Radiology consultant WTE per 1000 admissions	25
Consultant WTE per 1000 admissions	25
Medicine consultant WTE per 1000 admissions	25
Anaesthetist consultant WTE per 1000 admissions	25
Pathology consultant WTE per 1000 admissions	25
Clinical nurse specialist WTE per 1000 FCEs	24
Medical WTE per 1000 admissions	23

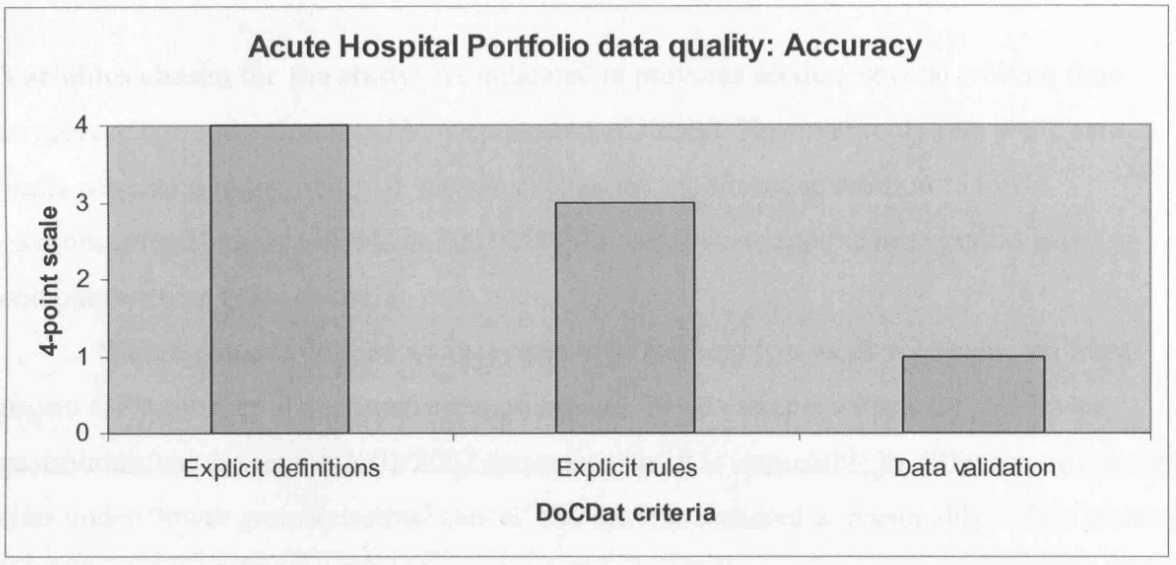
Figure 4.3 Acute Hospital Portfolio data quality: Coverage[xiv]



Accuracy: The definitions of most of variables are provided in national overview reports or published guides to indicators. Clear rules on how to code variables in the dataset were available for indicators of medical staffing and radiology, but not for ward staffing. No published information has been identified as to whether data have been validated.

[xiv] assessed using DoCDat 4-point scale (http://www.docdat.org)

Figure 4.4 Acute Hospital Portfolio data quality: Accuracy[xv]



4.1.3 Cancer Waiting Times

Cancer Waiting Times Statistics (2001/2002) contain data on the waiting time of patients with suspected cancer and those subsequently diagnosed with cancer. Data are submitted quarterly by hospital trusts. For study purposes, quarterly data have been summed into annual data.

Source: Cancer Waiting Times Statistics was received from the NHS-Cancer Action Team; also available on the Department of Health website:
http://www.performance.doh.gov.uk/cancerwaits/

Content: Cancer Waiting Times Statistics monitors the following waiting time targets:

- 'Two week wait' from urgent GP referral to first outpatient appointment for all patients with suspected cancer.
- 'One month wait' from urgent GP referral to treatment for children's cancers, testicular cancers and acute leukaemia.
- 'One month wait' from diagnosis to treatment for breast cancer.
- 'Two month wait' from GP referral to treatment for breast cancer.
- 'One month wait' from diagnosis to treatment for all cancers.

[xv] assessed using DoCDat 4-point scale (http://www.docdat.org)

- 'Two month wait' from GP referral to treatment for all cancers.

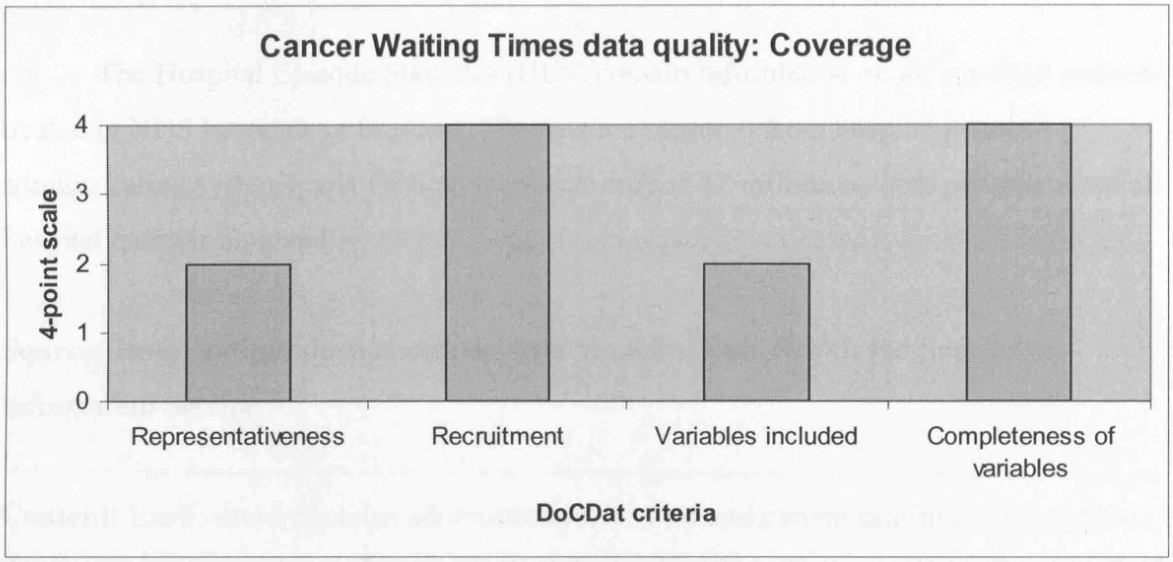
Variables chosen for the study: As indicated in previous section, several waiting time targets are currently monitored by Department of Health. However, only two week cancer waits were used in this study. It was the only target monitored in relation to lower gastrointestinal cancer patients in 2001/2002 financial year; and the time period was comparable with other datasets.

Waiting time is defined as a percentage of meeting two week wait standard from urgent GP referral to first outpatient appointment for all patients with suspected lower gastrointestinal cancer for 2001/2002 financial year. It is impossible to differentiate cancer sites under 'lower gastrointestinal cancer' though it is assumed to reasonably reflect waiting times for colorectal cancer.

To simplify interpretation, compliance with meeting the waiting time standard was considered as categorical variable – divided into quartiles. Separately, the two week wait standard was assessed for referrals received within 24 hours, as was presented in original dataset.

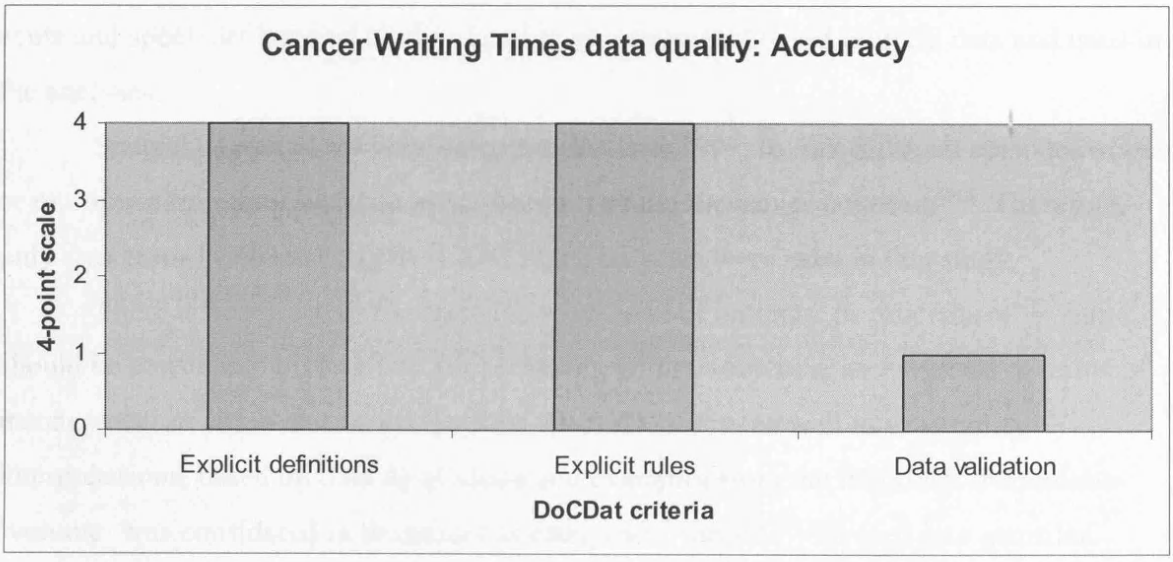
Coverage: All urgent GP referrals of patients with suspected cancer are included in the Cancer Waiting Times dataset, including those whose diagnosis was not subsequently confirmed. On the other hand, the dataset does not include cancer patients with non-urgent GP referrals and those who admitted to the hospital without GP referral. All 28 hospital trusts included in this study, were covered in the dataset. It is difficult to determine to what extent the recruitment of eligible population is complete, since it depends on reporting from each NHS Trust.

Figure 4.5 Cancer Waiting Times data quality: Coverage[xvi]



Accuracy: Clear definitions of all variables are available on-line (http://www.performance.doh.gov.uk/cancerwaits/) and in published Health Service Circulars. All variables have clear rules on how to code them in the dataset. However, no published information was identified as to whether data have been validated.

Figure 4.6 Cancer Waiting Times data quality: Accuracy[xvii]



[xvi] assessed using DoCDat 4-point scale (http://www.docdat.org)

[xvii] assessed using DoCDat 4-point scale (http://www.docdat.org)

4.1.4 Hospital Episode Statistics

The Hospital Episode Statistics (HES) contain information on all admitted patients treated in NHS hospitals in England. The data are captured from hospital patient administration systems, and HES now collects around 12 million records per year from all hospital trusts in England.

Source: Hospital Episode Statistics received from the NHS Health and Social Care Information Service.

Content: Each record contains administrative, clinical and patient information describing the care and treatment a patient received while in a hospital. There are more than 160 fields available for each patient.

Variables chosen for the study: Due to confidentiality regulations, it was not possible to receive data with the level of identifiers to allow linkage with cancer registry at individual level. For this reason, the data on comorbidity of patients and type of admission (emergency vs. elective), as well as other individual level variables from HES dataset, were not used in this study. The average annual volume of colorectal cancer patients at each acute and specialist hospital trust in London was estimated based on HES data and used in the analyses.

Special patient identifiers were introduced in 1997, to link different episodes of care or multiple admissions within a year, thus preventing their over-counting[xviii]. Therefore, only data from 1997/1998 to 2001/2002 financial years were used in this study.

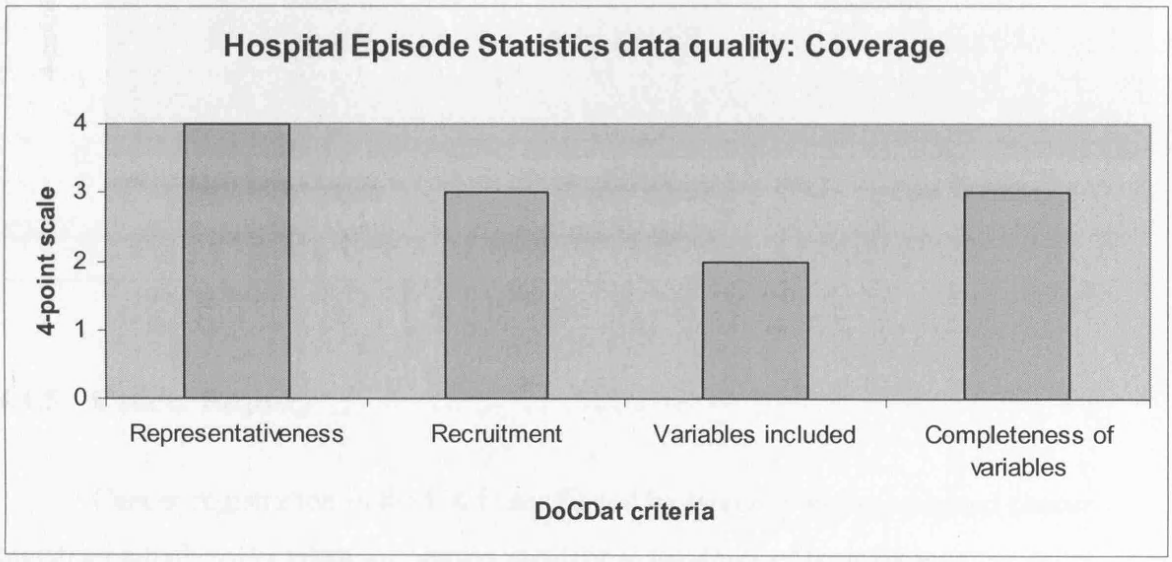
There is no agreed definition as to what level of patients' or procedures' volume should be considered high or low while making volume-outcome assessments in terms of management of colorectal cancer patients. For this reason, as well as to simplify interpretations, based on data distribution and examples from the literature, the variable 'volume' was considered in the model as categorical variable – divided into quartiles.

Coverage: HES contain data on inpatient and day cases admitted to NHS hospitals in

[xviii] http://www.hesonline.org.uk/Ease/servlet/ContentServer?siteID=1937&categoryID=571&dirID=110731&headerID

England. It includes private patients treated in NHS hospitals, patients who were resident outside of England and care delivered by treatment centres (including those in the independent sector) funded by the NHS[xix]. Out of 28 NHS hospital trusts included in this study, only data for patients treated in one hospital trust were not available in the HES dataset.

Figure 4.7 Hospital Episode Statistics data quality: Coverage[xx]



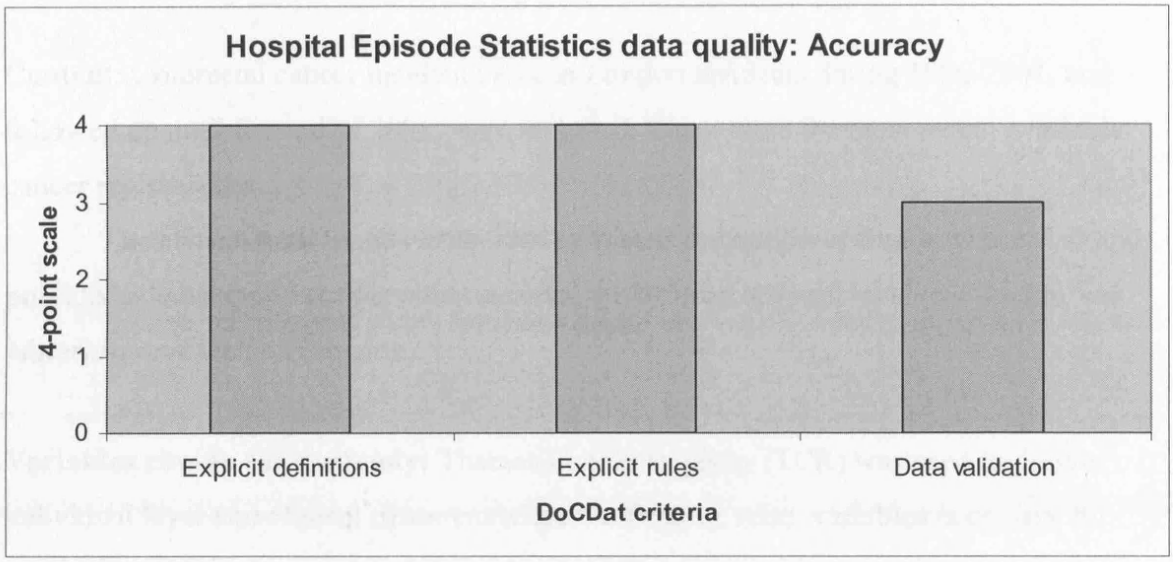
Accuracy: All or almost all variables (>97%) have clear definitions and rules on how to code them. Definitions of variables are available in HES Data Dictionary (http://www.performance.doh.gov.uk/hes/dictionary/index.html)

Data were validated using range and consistency checks (continuous auto-cleaning followed by validation). There was no rigorous validation at source. However, the NHS Information Authority conducts periodic external audits.

[xix] http://www.hesonline.nhs.uk/Ease/servlet/ContentServer?siteID=1937&categoryID=456

[xx] assessed using DoCDat 4-point scale (http://www.docdat.org)

Figure 4.8 Hospital Episode Statistics data quality: Accuracy[xxi]



4.1.5 Cancer Registry

Cancer registration in the UK is conducted by twelve population based cancer registries which collect data on cancers incident in residents of their regions.

Cancer registries receive routine (often electronic) notifications from a variety of sources. These sources include district general hospitals, cancer centres, hospices, private hospitals, cancer screening programmes, other cancer registers, primary care, nursing homes and death certificates forwarded by the Office of National Statistics (ONS) to each registry on every person dying for whom cancer is mentioned. Data are frequently received from several sources within an individual institution (e.g. pathology departments, medical records and radiotherapy databases). Increasingly the main sources of data for cancer registries are computerised hospital systems within pathology, oncology and other departments.

Death certificates also enable registries to identify cases not registered in life and initiate a new registration. Those cases not traced by following up case notes at hospitals and treatment centres defined as death certificate only (DCO) registrations.

Source: The Thames Cancer Registry (TCR).

[xxi] assessed using DoCDat 4-point scale (http://www.docdat.org)

TCR covers the residential population of London, Surrey, Sussex and Kent, approximately 14 million. London forms about half the total population.

Content: Colorectal cancer incident cases in London residents during 1996-2001, and followed up until the end of 2001, were included. These were the most recent available cancer registry data.

The chosen time frame (1996-2001) allowed estimation of five-year survival and provided adequate power to conduct survival analysis on hospital level (for details, see *Materials and Methods* chapter).

Variables chosen for the study: Thames Cancer Registry (TCR) was used to derive individual level and clinical treatment related indicators. Also, variables necessary for survival estimations were drawn from the registry data.

The variables from the TCR dataset used in this study are: age; sex; Index of Multiple Deprivation 2000 (income domain) quintile; tumour stage; hospital of first attendance/treatment; type of treatment/surgery; date of diagnosis; days to end of follow-up; vital status at the end of follow-up. Date of diagnosis; days to end of follow-up; and vital status at the end of follow-up were used for survival estimations.

- **Individual level variables of patient case-mix**

As noted in the *Methods* chapter, indicators of patient case-mix, such as age, sex, tumour stage and social deprivation measured by IMD-2000 income quintile, taken from the TCR, were essentially complete, except for 'tumour stage' which contained 20.9% of 'not known' values.

There were two tumour stage variables available in TCR dataset: clinical stage (mainly Duke's) and TCR stage. TCR stage is an in-house system which is based on WHO recommendations and means that the majority solid tumours are assigned to a stage [TCR, personal communication]. This is similar to Dukes' staging and allows cancer registry personnel to assign broad stage groupings as follows (see Table 4.3).

Table 4.3 Comparisons between Dukes' and TCR in-house staging system

Dukes' stage	Definition	TCR stage	Definition
A	Tumour is confined to the bowel wall	Stage1	Local: The tumour is confined to the organ of origin
B	Tumour penetrates the bowel wall into serosa or perirectal fat	Stage 2	Direct extension: The tumour has spread to surrounding tissues and organs
C	Lymph node metastasis is present	Stage 3	Local nodes: There is local nodal involvement
D	Distant metastasis is present	Stage 4	Metastases: Distant metastases are present

For case-mix adjustment, TCR in-house staging was employed since it contained only 20.9% 'not known' entries as compared to more than 42% of 'missing' values and 'not known' entries under the clinical stage variable.

Income quintile of IMD 2000 was routinely assigned by TCR to cancer patients' registration. This facilitated linkage between TCR data and sex and deprivation specific life table to estimate relative survival.

- **Clinical treatment**

Thames Cancer Registry contained information on surgical treatment and adjuvant therapy (radiotherapy and chemotherapy).

Data on type of surgery were available for all 28 hospital trusts included in the analyses. It was divided into broad surgical categories at initial intervention. No information on specific surgical operations was available for the study. Type of treatment (surgery) variable was considered in the model in two ways – as divided into two or five categories. Categories were defined according to information recorded by the registry.

Type of treatment (2 categories):

1. Any surgical operation;
2. Investigative procedure only

Type of surgery (5 categories):

1. Total removal of organ – 'radical';
2. Partial removal of organ – 'radical/sub-radical';
3. Tumour/lymph node removal – 'non-radical';
4. Non-tumour removing surgery – 'non-radical';
5. Investigative procedures only.

However, information on surgical treatment was missing for 1793 patients (11.6%). In addition, information on radiotherapy or chemotherapy was overwhelmingly missing in the dataset (in 87.3% and 73.6% cases, respectively), therefore was not used in the analyses (see Table 4.4). It was not possible to distinguish whether the data were missing because patients did not receive adjuvant therapy or because the information was not recorded. For these reasons, the assessment of the impact of surgical treatment on survival within the study model has limited explanatory value.

Table 4.4 Completeness of data on clinical treatment

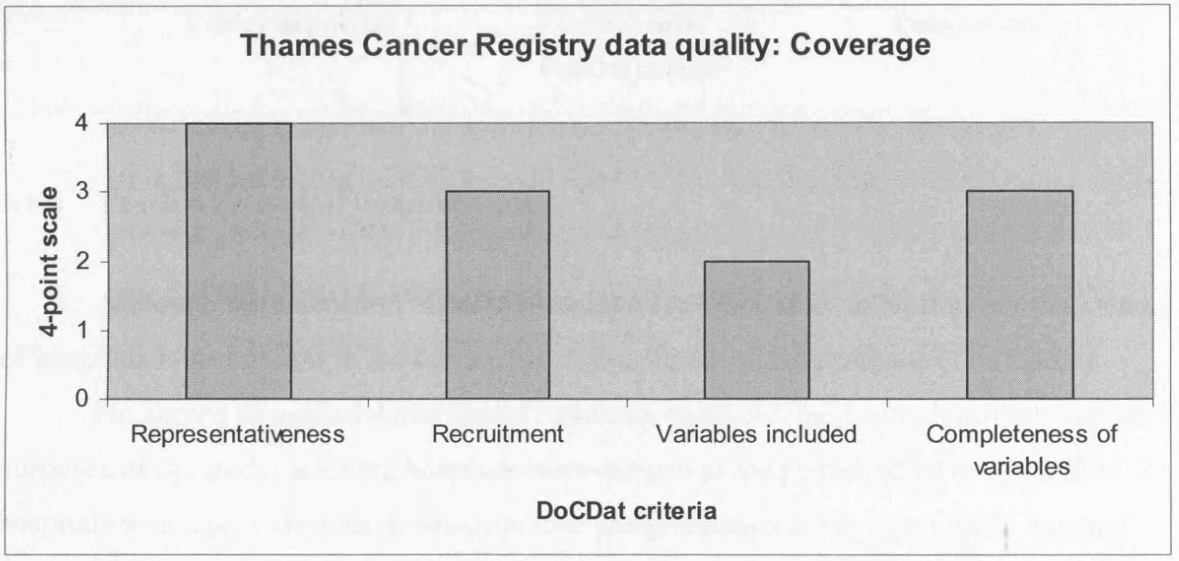
Indicator	% of missing values
Type of surgery	11.6
Adjuvant therapy	
Radiotherapy	87.3
Chemotherapy	73.6

Coverage: Ad hoc studies by the Thames Cancer Registry have shown that the database includes 90-97% of the eligible population. Systematic levels of case ascertainment in the Registry are impossible to obtain as there is no independent source with which to compare. The level of ascertainment can be judged indirectly by the proportion of cases which are registered through death certificates only (DCO).

The colorectal cancer patients in this study had a relatively low percentage of DCO cases (548 patients - 3%). Even though these cases have been excluded from analysis (see *Materials and Methods* chapter, 3.3.2.3), they have been assessed in terms of distributions per hospital trust and correlation with survival.

Within the cancer registry dataset, most of DCO cases had been assigned to the hospital trust of patient's referral area (498 assigned DCO cases in total) assuming that these patients were most probably managed by these hospitals. The information on hospital was missing in 50 cases. The percentage of DCO cases per assigned hospital trust varied from 0.8% to 10.2% (mean 3.3%; median 2.6%). No significant correlation was found between the proportion of DCO cases and 5-year relative or crude survival estimates per hospital trust (Spearman coefficient was -0.3279 (p=0.0885) and -0.2803 (p=0.1485), respectively). Appendix 1 shows distribution of DCO cases by hospital trust, along with 5-year survival estimates.

Figure 4.9 Thames Cancer Registry data quality: Coverage[xxii]



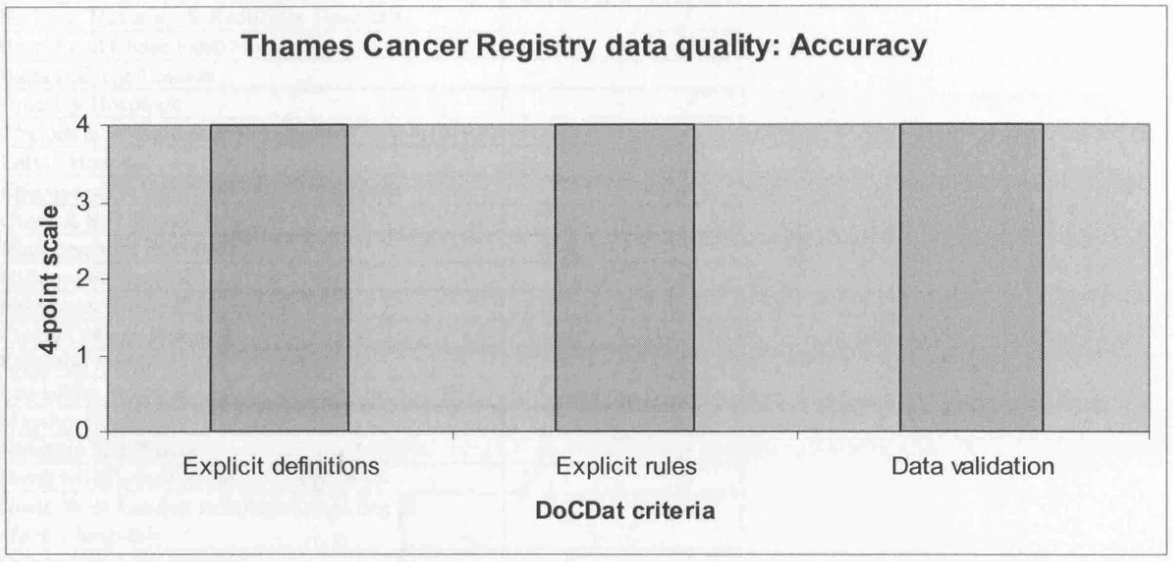
Accuracy: All or almost all cancer registry variables (>97%) have clear definitions, either within the WHO's International Classification of Diseases for Oncology or within other source documents agreed between the Department of Health and the UK Association of Cancer Registries. Likewise, most variables (>97%) have clear rules on how to code them in the database.

The Thames Cancer Registry validates its datasets by range and consistency checks, plus external validation using an alternative source. Regional registries are required to audit a sample of their cases, although this is done infrequently and differently between registers.

[xxii] assessed using DoCDat 4-point scale (http://www.docdat.org)

Proposals for a standard audit programme are currently being developed.

Figure 4.10 Thames Cancer Registry data quality: Accuracy[xxiii]



4.1.6 Teaching status of hospital trusts

Although not a separate 'dataset', teaching (or 'academic' in North America) status of hospitals is recognised in the literature as a hospital level determinant of outcomes.

No agreed or unified definition of 'teaching hospitals' has been identified. For the purposes of the study, teaching hospitals were defined as long established or specialist hospitals which provide undergraduate and/or postgraduate teaching. Out of 28 hospital trusts included in this study, 11 have been classified as 'teaching' hospital trusts and 17 – as 'non-teaching' hospital trusts (see Table 4.5). This division was based on the categorisation of hospital trusts employed by the Healthcare Commission[xxiv].

[xxiii] assessed using DoCDat 4-point scale (http://www.docdat.org)

[xxiv] http://ratings2004.healthcarecommission.org.uk/Downloads/acute_clusters.xls

Table 4.5 Assigned teaching status of hospital trusts

Hospital Trust	Teaching status	
	Yes	No
Barking, Havering & Redbridge Hospitals		√
Barnet and Chase Farm Hospitals		√
Barts and The London	√	
Bromley Hospitals		√
Chelsea & Westminster Healthcare	√	
Ealing Hospital		√
Epsom and St Helier University Hospitals		√
Guy's & St Thomas' Hospital	√	
Hammersmith Hospitals	√	
Hillingdon Hospital		√
Homerton University Hospital		√
King's College Hospital	√	
Kingston Hospital		√
Lewisham Hospital		√
Mayday Healthcare		√
Newham Healthcare		√
North Middlesex University Hospital		√
North West London Hospitals *(including St Mark's hospital)*	√	
Queen Elizabeth Hospital		√
Queen Mary's Sidcup		√
Royal Free Hampstead	√	
Royal Marsden	√	
St George's Healthcare	√	
St Mary's	√	
University College London Hospitals	√	
West Middlesex University Hospital		√
Whipps Cross University Hospital		√
Whittington Hospital		√

4.1.7 Summary points

The information for this study came from administrative sources, from cancer registry and from special surveys and initiatives. For use in the analytic model (see *Materials and Methods* chapter), the sources of data were divided into those reflecting structure, process and outcome of care:

Model	Dataset	Source	Variables
Structure	Cancer Services Peer Review (2001)	NHS Cancer Action Team	* *35 colorectal cancer multi-disciplinary team (MDT) standards*
	Acute Hospital Portfolio (2000 - 2002),	Audit Commission (currently Healthcare Commission)	* *staffing level indicators (medical; consultant; medicine consultant; anaesthetist consultant; pathology consultant; radiology consultant; radiographers; clinical nurse specialists)*
	Assigned[xxv]	Healthcare Commission	*'teaching status'*
Process	Cancer Waiting Times Statistics (2001 - 2002)	NHS Cancer Action Team;	* *two week wait target from urgent GP referral to first outpatient appointment for all patients with suspected lower gastrointestinal cancer*
	Hospital Episode Statistics (1997 - 2001)	NHS Health and Social Care Information Service	* *average annual hospital volume of patients*
	Cancer registration data	Thames Cancer Registry (1996 – 2001)	* *individual level indicators of patients' case-mix* * *type of treatment (surgery)*
Outcome	Cancer registration data	Thames Cancer Registry (1996 – 2001)	*5-year survival*

This division is partly arbitrary, since datasets listed, for instance, under 'structure' category may well contain data on process indicators and so on. For example, some of the colorectal cancer MDT standards reflect the aspects of process of care. Likewise, hospital volume of patients may be indicative not only of processes of care, but also structural aspects of hospitals. However, this division helps to illustrate the main focus of the datasets and their potential place within the framework of proposed model.

Indicators for the analysis were selected from the datasets, based on relevance to literature findings on organisational determinants of survival, study objectives, completeness of data and following discussions with a number of healthcare professionals and researchers.

Table 4.6 below specifies the number of hospital trusts for which data were available per each dataset; and Table 4.7 indicates completeness of data, expressed as percentage of

[xxv] http://ratings2004.healthcarecommission.org.uk/Downloads/acute_clusters.xls

variables at least 95% complete within each dataset.

Table 4.6 Number of hospital trusts for which data were available within each dataset

Dataset	No. of hospital trusts
Acute Hospital Portfolio	23 to 27 *(depending on topic)**
Hospital Episode Statistics	27
Cancer Waiting Times	28
Cancer Standards Peer Review	25
Thames Cancer Registry	28

*detailed Table on number of hospital trusts available per each staffing level indicator considered is presented in Table 4.2

Table 4.7 Completeness of data (% variables at least 95% complete)*

Datasets	Few (<50%) or unknown	Some (50-79%)	Most (80-97%)	All or almost all (>97%)
Acute Hospital Portfolio			x	
Hospital Episode Statistics			x	
Cancer Waiting Times				x
Cancer Services Peer Review			x	
Thames Cancer Registry			x**	

*assessment of variables employed in analysis
**tumour stage was missing in 20.9% of cases

As indicated previously, further discussions on feasibility of using available datasets to investigate hospital-level determinants of colorectal cancer survival in London, are provided in *Discussion* chapter.

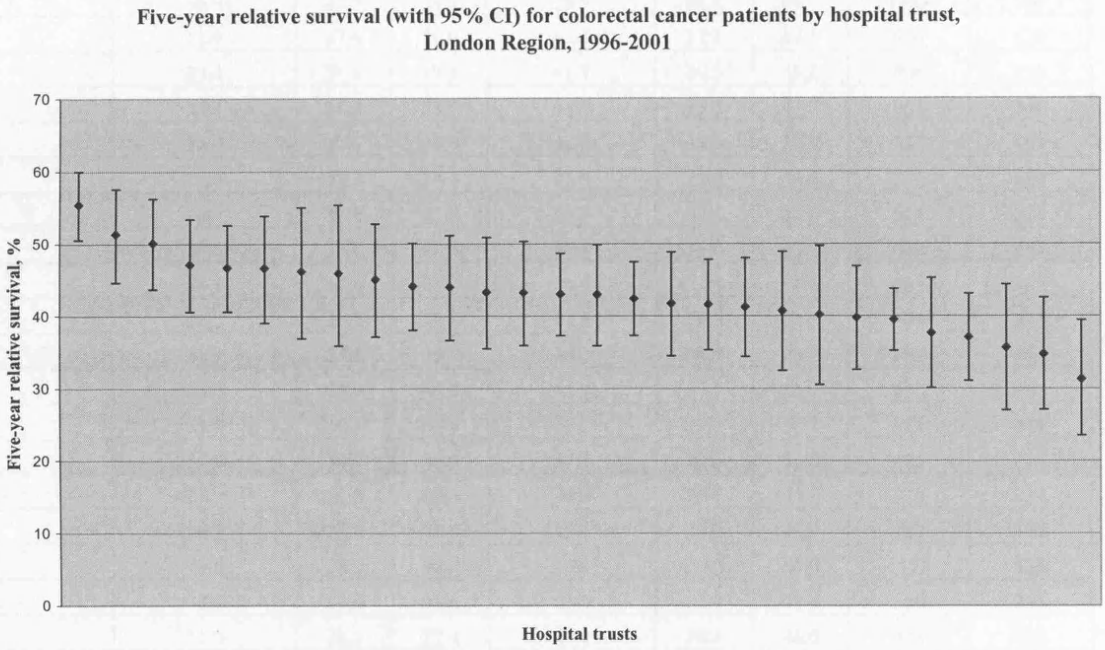
4.2 Descriptive statistics. Hospital level analysis

4.2.1 Five-year colorectal cancer survival estimates for hospital trusts in London

Both relative and crude five-year survival of colorectal cancer patients by hospital trust of treatment were calculated. Crude survival was considered for comparative, illustrative purposes only, since it is still widely used in the literature. However, relative survival estimates are preferred, as they take into account population background mortality.

As indicated in the *Materials and Methods* chapter, the study used colorectal cancers incident in London residents during 1996-2001 and followed up until December 31, 2001, drawn from the Thames Cancer Registry (TCR). *Figure 4.11* below shows that, after taking account of differential background mortality by age, sex and social deprivation (IMD 2000, income quintile), variability in five-year relative survival between hospital trusts remains significant, ranging from 31.3% (95% CI 23.4% – 39.4%) to 55.4% (95% CI 50.6% - 60.0%) (see also Table 4.8).

Figure 4.11*



*dots represent cumulative relative survival rate, and the lines are 95% confidence intervals

[Ranking of hospital trusts based on relative or crude survival rates brings about similar results. These two estimates were highly correlated: Spearman rank correlation coefficient between crude and relative survival measures was 0.94 ($p<0.001$).]

Table 4.8 Five-year crude and relative survival estimates for colorectal cancer patients in London, by hospital trust, 1996-2001 years

Hospital trust	Crude Survival (%)	95% Confidence Interval		Relative Survival (%)	95% Confidence Interval		No. of patients	No. of deaths
A	30.9	27.5	34.3	39.5	35.2	43.7	1443	760
B	31.9	27.8	36.0	42.4	37.3	47.5	856	470
C	33.4	27.6	39.3	41.7	34.5	48.8	506	255
D	33.4	28.3	38.6	41.6	35.3	47.8	664	346
E	34.7	27.6	41.9	46.2	36.9	55.0	337	169
F	27.0	20.3	34.1	35.6	27.0	44.4	308	180
G	36.7	31.8	41.7	46.7	40.6	52.6	614	315
H	27.6	23.0	32.3	37.1	31.0	43.1	638	367
I	24.8	18.6	31.5	31.3	23.4	39.4	505	271
J	32.7	26.7	38.8	43.3	35.5	50.8	420	233
K	31.5	23.9	39.3	40.2	30.5	49.7	298	154
L	35.2	28.9	41.7	45.1	37.1	52.7	403	206
M	31.4	26.1	36.9	43.2	35.9	50.3	657	339
N	35.8	30.7	40.9	47.1	40.6	53.4	605	316
O	27.9	21.8	34.4	34.7	27.0	42.5	378	211
P	29.9	23.7	36.4	37.6	30.0	45.2	287	172
Q	42.9	38.9	46.7	55.4	50.6	60.0	1173	525
R	33.0	27.6	38.6	43.0	35.9	49.8	559	295
S	31.9	26.5	37.4	41.2	34.4	48.0	538	287
T	39.7	34.4	44.9	51.3	44.6	57.6	561	272
U	34.6	29.8	39.5	44.1	38.1	50.0	632	335
V	34.7	27.2	42.4	45.9	35.9	55.4	364	171
W	31.9	26.1	37.8	39.8	32.6	46.9	443	245
X	42.3	36.9	47.7	50.1	43.7	56.2	596	256
Y	34.7	28.9	40.6	44.0	36.6	51.1	423	221
Z	37.9	31.7	44.0	46.6	39.1	53.8	397	194
AA	32.2	25.6	39.1	40.7	32.4	48.9	291	165
BB	33.0	28.5	37.7	43.0	37.3	48.7	569	329

4.2.2 Distribution of selected individual level indicators by hospital trust in London

Table 4.9 shows the distribution of individual patient characteristics by hospital trust which are then adjusted for in the model. For the purposes of visualisation, only one item from each 'concept' (indicator) within the model is presented below (see Table 4.9). Full distributions of each individual-level indicators are available in Appendices 2-5.

Table 4.9 Distribution (%) of selected individual level indicators by hospital trust in London

Hospital trust	Age group, years		Sex		Social deprivation (income quintile)		Tumour stage	
	15-39	80-99	Male	Female	1	5	I	IV
A	1.9	22.6	50.9	49.1	9.0	35.3	22.0	21.6
B	2.0	30.6	51.3	48.7	8.1	10.9	16.4	22.0
C	2.4	17.0	58.7	41.3	1.0	83.8	11.1	28.5
D	1.0	25.4	49.5	50.4	51.7	5.3	8.9	21.4
E	3.0	25.5	51.3	48.7	19.9	7.7	11.3	24.0
F	3.6	29.5	54.2	45.8	4.9	20.8	13.6	27.9
G	1.6	29.5	45.4	54.6	32.7	12.2	21.3	22.3
H	2.5	20.4	54.2	45.8	4.7	68.0	13.5	21.2
I	2.6	20.2	54.6	45.3	8.5	26.7	14.1	22.6
J	1.2	26.7	54.5	45.5	14.5	2.6	30.5	23.6
K	2.7	24.5	54.7	45.3	0.0	98.3	15.8	29.5
L	2.7	21.3	52.6	47.4	1.2	67.0	13.1	22.6
M	0.8	33.5	47.5	52.5	43.4	2.9	19.6	21.3
N	1.5	25.8	48.4	51.6	10.4	14.2	24.0	21.5
O	2.6	20.4	48.9	51.1	0.3	97.6	13.8	33.3
P	2.8	19.9	49.1	50.9	0.7	72.1	12.9	21.9
Q	2.8	24.7	51.9	48.1	6.3	14.1	25.9	22.0
R	1.2	24.0	52.6	47.4	3.0	58.1	28.4	20.2
S	0.6	25.8	51.3	48.7	22.3	11.3	8.4	26.9
T	2.7	22.1	49.0	51.0	5.5	20.9	18.4	20.7
U	2.1	25.6	53.6	46.4	10.1	11.2	19.8	21.8
V	2.7	21.7	56.6	43.4	2.7	44.8	22.8	21.4
W	2.7	22.1	53.9	46.0	0.4	55.8	24.8	21.4
X	6.5	11.6	55.2	44.8	27.7	13.4	2.7	5.5
Y	2.6	21.7	50.8	49.2	0.7	70.4	37.6	20.8
Z	2.5	21.9	51.1	48.9	3.8	60.7	32.5	18.4
AA	1.7	29.2	48.8	51.2	33.3	8.2	14.8	22.3
BB	1.9	30.8	52.7	47.3	2.5	30.9	45.2	23.4

There were relatively balanced distributions of age and sex by hospital trust. On the other hand, distribution of the deprivation indicator varied considerably, particularly if we compare 1st (least deprived) and 5th (most deprived) income quintiles. Likewise, there were considerable variations for tumour stage. However, in case of stage variable, the presence of missing values should be taken into account (for full distribution of tumour stage by hospital trust, including 'Not Known' values, see Appendix 5).

Table 4.10 below presents a summary of frequencies and relative frequencies for individual level variables obtained from the TCR. Except 'tumour stage' (with 20.9% of missing values), all other variables were complete.

Table 4.10 Frequencies and relative frequencies of individual level variables from the Thames Cancer Registry (TCR)

Variable	Frequency	Relative frequency (%)
Age group:		
15-39	349	2.3
40-49	665	4.3
50-59	1812	11.7
60-69	3722	24.1
70-79	5169	33.4
80-99	3748	24.2
Sex:		
Male	8002	51.7
Female	7463	48.3
Tumour stage:		
I	3065	19.8
II	2964	19.2
III	2795	18.1
IV	3411	22.1
Not known	3230	20.9
Social deprivation (income quintile):		
1 *(least deprived)*	1932	12.5
2	2221	14.4
3	2784	18.0
4	3508	22.7
5 *(most deprived)*	5020	32.5

4.2.3 Distribution of selected hospital level indicators by hospital trust in London

Table 4.11 illustrates the variations in distribution of hospital-level indicators: one variable has been taken from each data set as used within the model.

Table 4.11 Distribution of selected hospital level indicators by hospital trust in London

Hospital trust	Volume: average annual number of patients	Waiting time: percentage of meeting two week wait target	Staffing level: consultant WTE per 1000 admissions	Compliance with standards: "Operational policy – MDT review of cancer patients" standard (Yes – 1; No – 0)	Teaching status of hospitals (Yes – 1; No-0)
A	1491	92.6	1.7	n/a	0
B	602	87.9	2.1	n/a	0
C	1090	92.9	2.5	1	1
D	N/A	98.3	n/a	1	0
E	245	95.8	2.5	1	1
F	254	95.4	1.8	0	0
G	627	94.7	2.5	0	0
H	1205	78.4	3.2	0	1
I	1511	96.1	2.6	1	1
J	286	85.4	1.9	0	0
K	150	90.8	2.1	1	0
L	362	96.9	3.6	1	1
M	339	96.8	2.9	0	0
N	404	98.7	2.2	1	0
O	313	97.0	1.7	1	0
P	792	96.9	2.0	1	0
Q	563	80.7	2.4	n/a	0
R	430	94.6	1.9	1	1
S	325	95.7	1.6	0	0
T	484	94.2	n/a	0	0
U	892	95.9	3.2	1	1
V	776	98.1	3.2	1	1
W	285	100.0	2.4	0	1
X	2525	100.0	2.3	1	1
Y	374	75.4	2.3	1	0
Z	837	93.6	n/a	1	1
AA	284	91.1	2.6	1	0
BB	593	94.1	2.1	0	0

The average annual number of colorectal cancer patients per hospital trust in London varied from 150 to 2525 (mean 754; median 593 patients). A percentage of meeting two week wait standard varied from 75.4% to 100% per hospital trust (mean 92.4%; median 94.6%). There was a range of 1.6 to 3.9 consultants per hospital trust as measured by Whole Time Equivalent (WTE) per 1000 admissions (mean 2.4; median 2.3).

(For full distribution of all staffing level indicators per hospital trust, see Appendix 7). As indicated previously (see Table 4.5), 11 hospital trusts were assigned teaching status, while 17 hospital trusts were considered non-teaching.

Sixteen hospital trusts were compliant with "Operational policy – MDT review of cancer patients" standard, and six hospital trusts were not compliant with that standard (for full distribution of compliance with all cancer standards, see Table 4.27). As shown in Table 4.12, depending on standard, the number of compliant hospital trusts ranged from 4 to 25 (the maximum number of hospital trusts available to the study in relation to compliance with cancer standards). All hospital trusts were in compliance with the 'standard 1' (*"Named Lead clinician for the colorectal specialist MDT"*). Also, only one hospital trust was non-compliant with the standards 7 and 29 (*"Lead imaging consultant for the MDT"* and *"Treatment planning decisions recorded"*, respectively). These three standards were therefore not considered in subsequent multivariate relative survival modelling, because of their statistical distributions.

Table 4.12 Number of hospital trusts compliant with each colorectal cancer specific standard

Cancer standards	No. of compliant hospital trusts
1. Named Lead clinician for the colorectal specialist MDT	25
2. Lead clinician written responsibilities	23
3. Names of core members of MDT	23
4. Lead Histopathologist for the MDT	23
5. Histopathologist attendance at MDT	17
6. Consistency between histopathologist audit	7
7. Lead imaging consultant for the MDT	24
8. Lead imaging consultant attendance at MDT	7
9. Pre-operative core MDT members	14
10. MDT meetings – frequency and attendance records	17
11. Core members attendance at MDT	17
12. Cover arrangements for core members	16
13. Operational policy meetings	15
14. Operational policy – MDT review of new cancer patients	16
15. Written operational policy – communication of a patient's diagnosis to their general practitioner	18
16. Implementation of the policy – timeliness of communication of a patient diagnosis to their general practitioner following diagnosis	4
17. Written operational policy – provision of information on the appropriateness and timeliness of urgent referrals	13
18. Colorectal nurse specialist qualifications – registered ENB 237 course	5
19. Colorectal nurse specialist qualifications – obtained ENB 237 course	6
20. Colorectal nurse specialist qualifications – obtained the ENB 216 and/or cancer related nursing degree	12
21. Written agreement describing referrals guidelines – core team and clinical oncologist	6
22. Written operational policy for stabilising and treating emergency admissions	11
23. Names of extended team members	18
24. Arrangements for access to MDT	22
25. Survey of patients experience undertaken/being undertaken	14
26. Survey results presented and discussed at MDT	5
27. Actions taken as a result of the survey	4
28. Written information material *(for patients)* available	22
29. Treatment planning decisions recorded	24
30. Network wide clinical guidelines for the cancer site	9
31. Referral guidelines for the cancer site	14
32. Network wide dataset for the cancer site	19
33. Recording of dataset for individual patients	19
34. Network wide audits	6
35. List of agreed clinical trials	13

4.2.4 Distribution of clinical treatment indicators by hospital trust in London

As indicated previously, information on adjuvant therapy (chemotherapy, radiotherapy or other) was mainly missing in the Thames Cancer Registry dataset (see Table 4.4). Therefore, only data on type of surgical treatment have been considered in this study. Table 4.13 shows apparent variations in distribution of type of treatment by hospital trust in London. For example, the proportion of radical surgery ('partial removal of organ') by hospital trust varied from 16.3% to 59.8%; while the proportion of patients who underwent investigative procedure only ranged from 4.2% to 13.2% by hospital trust. This division into five treatment categories was defined by the Thames Cancer Registry (TCR).

Table 4.13 Distribution (%) of type of treatment by hospital trust in London

Hospital trust	Type of treatment				
	Total removal of organ	Partial removal of organ	Tumour/lymph node removal or exclusion	Non-tumour removing surgery	Investigative procedure only
A	21.2	51.9	8.1	4.2	7.0
B	16.7	58.2	6.3	2.6	6.0
C	24.5	39.9	12.1	1.2	11.5
D	19.0	43.4	8.1	2.6	10.1
E	20.8	47.2	10.7	5.0	9.2
F	20.4	45.8	5.5	3.6	8.8
G	17.1	57.2	4.9	4.4	10.1
H	15.7	48.3	8.9	3.1	9.9
I	15.6	45.9	11.5	1.8	9.7
J	20.7	49.0	5.5	5.0	12.6
K	28.2	38.9	10.4	2.0	10.4
L	12.2	55.3	7.2	3.0	9.7
M	19.0	57.4	5.6	4.0	6.7
N	13.5	59.8	5.0	7.1	6.6
O	32.8	36.0	10.0	1.6	13.2
P	21.2	47.4	3.8	5.2	4.2
Q	17.7	54.0	7.1	3.5	10.2
R	19.3	50.6	9.8	1.4	8.0
S	17.1	51.1	9.7	1.3	8.4
T	22.3	50.1	8.0	0.7	10.2
U	15.5	50.9	13.3	2.1	9.8
V	12.6	56.6	12.6	2.2	11.3
W	17.6	45.4	13.1	1.8	9.3
X	4.7	16.1	1.8	21.0	1.3
Y	16.5	57.4	11.8	3.1	5.0
Z	13.1	51.6	15.9	0.8	11.6
AA	14.8	49.5	9.3	1.4	8.2
BB	18.8	52.5	8.4	6.5	6.0

Table 4.14 below presents a summary of frequencies and relative frequencies for 'type of treatment' variable obtained from the TCR. As indicated previously (see Table 4.4), 'type of treatment' variable had 11.6% of missing values.

Table 4.14 Frequencies and relative frequencies for 'type of treatment' variable from the Thames Cancer Registry dataset

Variable	Frequency	Relative frequency (%)
Type of treatment (surgery):		
Total removal of organ	2783	18.0
Partial removal of organ	7673	49.6
Tumour/lymph node removal or excision	1305	8.4
Non-tumour removing surgery	589	3.8
Investigative procedures only	1322	8.5
Not known	1793	11.6

4.3 Individual variables – univariate relative survival model

Initially, a relative survival model was used to assess the impact of four individual level variables - age, sex, deprivation category and tumour stage. These four variables reflect patient case-mix and are widely considered to be among the main factors influencing survival of cancer patients. As shown in Table 4.15, all these variables were significantly associated with five-year relative survival.

Table 4.15 Relationship between age, sex, social deprivation and tumour stage and relative excess risk of death[xxvi] within five years of diagnosis, for colorectal cancer (univariate model)

Variable	Relative excess risk of death (RER)	95% confidence interval (CI)	p-value
Age group: 15-39	1.00		
40-49	1.09	0.89 – 1.33	0.406
50-59	1.20	1.001 – 1.43	0.048
60-69	1.29	1.09 – 1.53	0.003
70-79	1.83	1.56 – 2.17	< 0.001
80-99	2.95	2.42 – 3.60	< 0.001
Sex: Male	1.00		
Female	1.06	1.005 – 1.12	0.031
Deprivation category: 1 (least deprived)	1.00		
2	1.05	0.90 – 1.21	0.540
3	1.02	0.93 – 1.13	0.665
4	1.05	0.96 – 1.14	0.269
5 (most deprived)	1.17	1.06 – 1.28	0.001
Tumour stage: I	1.00		
II	0.83	0.73 – 0.94	0.003
III	1.33	1.20 – 1.49	< 0.001
IV	5.55	5.06 – 6.08	< 0.001

[xxvi] The *excess* risk of death in a given group of patients within, say, five years of diagnosis is the risk of death *over and above* what would have been expected if they had experienced only the death rates seen in the general population for the same age, sex and deprivation. The *relative excess risk of death* reflects the extent to which the excess risk of death differs from the excess risk in a baseline group, after adjustment for other covariates.

There was an expected gradient effect of age on survival, with patients in age-group 80-89 having almost 3 times higher relative excess risk of death (RER) as compared with patients younger than 40 years old (RER 2.9; 95% CI 2.4 – 3.6).

Likewise, patients in stage IV had more than five times higher RER than patients in stage I (RER 5.5; 95% CI 5.1 – 6.1). There was a higher proportion of older (age group 80-89) and more deprived patients among those with missing tumour stage. Also, a higher proportion of patients with known tumour stage received more radical surgery (total or partial removal of organ) as compared with patients whose stage information was missing (79.6% vs. 60.8%), while more patients in the latter group underwent an investigative procedure only (15.7% vs. 8.45%). These patients had slightly lower five-year relative survival than patients whose tumour stage was recorded in the TCR (41.0% vs. 44.2%) (see Table 4.16).

Table 4.16 Five-year relative survival and patient distribution by tumour stage

Tumour stage	No. & % of patients	No. of deaths	Relative survival, %	95% CI
I	3065 (19.82%)	1196	64.52	61.25 - 67.59
II	2964 (19.17%)	1041	66.34	63.14 - 69.34
III	2795 (18.07%)	1249	45.64	42.41 - 48.80
IV	3411 (22.06%)	2784	9.94	8.48 - 11.54
All patients with known stage	12235 (79.11%)	6270	44.17	42.72 - 45.60
Stage 'Not Known'	3230 (20.89%)	1789	41.03	38.34 - 43.71
All patients	15465 (100%)	8059	43.54	42.27 - 44.80

The gradient effect was not so clear for deprivation; however the most deprived patients had a significant 17% rise in RER as compared with the least deprived patients (RER 1.17; 95% CI 1.1 – 1.3). Also, women seemed to have relatively smaller survival disadvantage compared with men (RER 1.06; 95% CI ≈1.0 – 1.1), although analysis indicated that the sex effect changes with age. Male patients tended to have higher relative

survival as compared with females, in younger age groups (from 15 to 49), while female patients experienced higher relative survival, in older age groups (from 50 onwards) (see Table 4.17).

Table 4.17 Five-year relative survival by sex and age group

Sex	Age groups, years						Total
	15-39	40-49	50-59	60-69	70-79	80-99	
	Rel**	Rel**	Rel**	Rel**	Rel**	Rel**	Rel**
Male	**61.42** (51.31-70.04)	**58.03** (51.15-64.29)	**49.21** (44.73-53.53)	**47.66** (44.38-50.85)	**37.45** (34.08-40.82)	**28.47** (23.49-33.64)	**43.11** (41.28-44.93)
Female	**56.91** (46.79-65.81)	**52.88** (44.62-60.47)	**51.79** (46.81-56.53)	**51.65** (47.96-55.21)	**42.63** (39.49-45.73)	**32.93** (29.12-36.78)	**43.85** (42.08-45.59)
All patients	**59.22** (52.07-65.67)	**55.74** (50.50-60.65)	**50.37** (47.05-53.59)	**49.38** (46.93-51.78)	**40.30** (37.98-42.60)	**31.46** (28.40-34.56)	**43.54** (42.27-44.80)

*5-year crude survival (%) with 95% Confidence Interval (in brackets)
** 5-year relative survival (%) with 95% Confidence Interval (in brackets)

4.4 Adjusted relative survival model. Assessing hospital predictors of survival

The relationship between hospital predictors and relative survival has been analysed within an adjusted relative survival model. As was indicated in the *Materials and Methods* chapter, the estimates of RER were calculated after adjustment for differences in years of follow-up, age, sex, deprivation category and tumour stage. Standard errors were adjusted for clustering effect on NHS hospital trust. The relationship was considered as statistically significant when p value was less than 0.05 or 95% confidence interval (CI) did not contain "1".

Time dependent covariates (interaction with follow-up time) were statistically significant for age ($p<0.001$), sex ($p<0.001$) and tumour stage ($p<0.001$). For this reason, interaction terms with these three variables were included into the model in all subsequent analysis.

The relationship between potential predictors and relative survival was also assessed separately by year of follow-up (1-year; 2-5 years) because short term associations may differ from long term associations. However, in general, there was no statistically significant interaction effect between year of follow-up and potential predictors.

For missing data, particularly the tumour stage variable, a 'complete case analysis'

was conducted. Thus, 'not known' stage values were considered missing in the analysis and patients with 'not known' stage were excluded from the analysis. However, analyses of potential predictors were repeated *a)* including 'not known' values as an additional separate category and *b)* after multiple imputation of missing values (see *Materials and Methods* chapter). Neither of these methods had substantial impact on statistical significance or direction of associations found (see Table 4.28).

Overall, similar results to those estimated using multivariable relative survival model were obtained when hazard ratios were calculated using the Cox proportional hazard model. For illustrative purposes only, hazards ratios from Cox model are indicated in a few examples with cancer standards (see 4.4.7).

4.4.1 Hospital trust and cancer survival

To examine whether observed variability in five-year relative survival between hospital trusts remained statistically significant, after adjusting for patient case-mix, 'hospital trust of treatment' was assessed within the multivariate relative survival model as an independent variable. The results of this analysis are presented in Table 4.18.

Overall significance of the effect of being treated at a particular hospital trust was assessed based on the likelihood-ratio test comparing models with and without hospitals. Hospital trust with the highest estimate of five-year relative survival (55.4% - hospital 'Q') was considered as a 'baseline variable' with relative excess risk of death (RER) equal to '1'.

After adjustment for case-mix, there remained a statistically significant association between being treated at particular hospital trust and five-year relative survival for colorectal cancer patients in London (overall p-value<0.001).

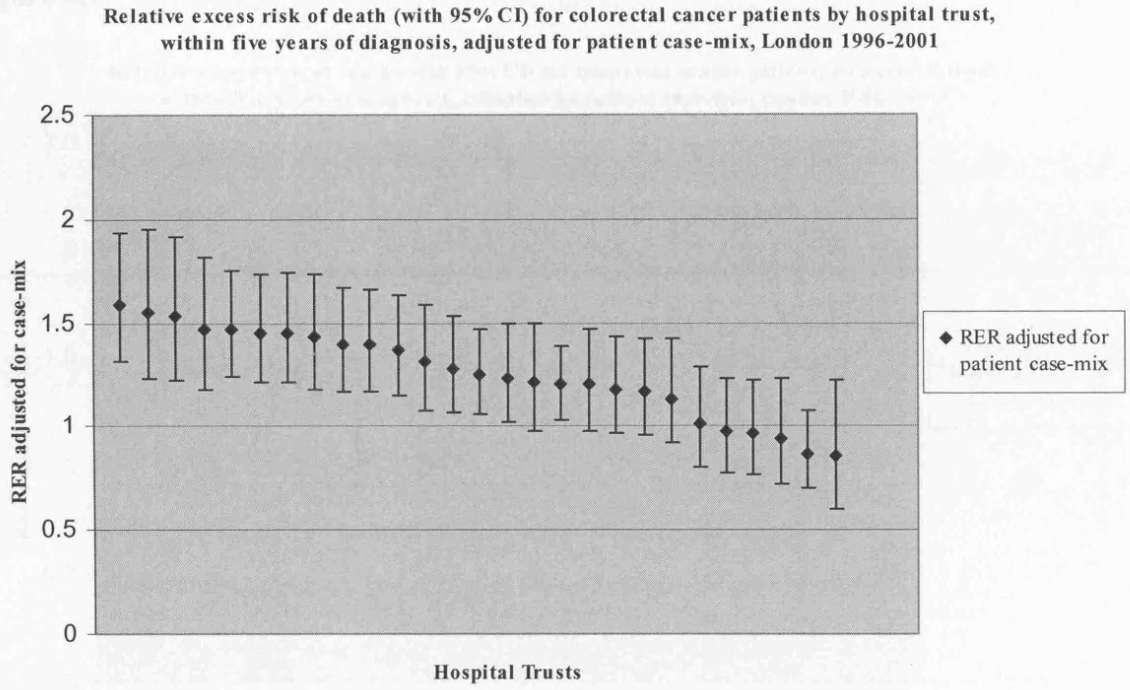
Table 4.18 Relative excess risk of death for colorectal cancer patients by hospital trust of treatment, within five years of diagnosis, unadjusted and adjusted for patient case-mix (age, sex, social deprivation (income quintiles) and stage)

Hospital trust	RER			95% CI		
	unadjusted for patient case-mix*	adjusted for patient case-mix**	Adjusted for case-mix; after multiple imputation of missing tumour stage values**	unadjusted for patient case-mix*	adjusted for patient case-mix**	Adjusted for case-mix; after multiple imputation of missing tumour stage values**
Q	1					
A	1.36	1.20	1.28	1.19-1.56	1.03-1.39	1.23-1.33
B	1.44	1.25	1.35	1.23-1.67	1.06-1.47	1.30-1.40
C	1.29	0.87	0.91	1.07-1.54	0.70-1.08	0.85-0.97
D	1.33	1.17	1.26	1.13-1.57	0.96-1.42	1.19-1.35
E	1.28	1.01	1.06	1.04-1.58	0.80-1.29	0.97-1.17
F	1.75	1.47	1.52	1.44-2.14	1.18-1.82	1.43-1.61
G	1.30	1.37	1.31	1.10-1.54	1.15-1.63	1.26-1.37
H	1.52	1.45	1.43	1.29-1.78	1.21-1.73	1.35-1.52
I	1.41	1.31	1.31	1.18-1.68	1.08-1.59	1.26-1.36
J	1.59	1.59	1.55	1.33-1.91	1.31-1.93	1.48-1.62
K	1.53	0.94	0.94	1.24-1.90	0.72-1.23	0.87-1.02
L	1.35	1.21	1.28	1.11-1.63	0.98-1.50	1.22-1.34
M	1.38	1.40	1.30	1.17-1.63	1.17-1.67	1.23-1.37
N	1.27	1.28	1.19	1.07-1.50	1.07-1.53	1.17-1.22
O	1.61	0.98	1.00	1.33-1.95	0.78-1.23	0.94-1.08
P	1.61	1.55	1.58	1.31-1.97	1.23-1.95	1.52-1.65
R	1.36	1.45	1.44	1.14-1.62	1.21-1.74	1.38-1.50
S	1.39	1.23	1.21	1.17-1.66	1.02-1.50	1.15-1.28
T	1.27	1.18	1.19	1.07-1.52	0.97-1.43	1.12-1.26
U	1.41	1.40	1.44	1.19-1.66	1.17-1.66	1.40-1.48
V	1.09	0.97	0.99	0.87-1.35	0.77-1.22	0.95-1.04
W	1.44	1.43	1.46	1.20-1.73	1.18-1.73	1.41-1.52
X	0.98	0.86	1.05	0.82-1.17	0.60-1.22	0.98-1.13
Y	1.25	1.20	1.17	1.03-1.52	0.98-1.47	1.11-1.22
Z	1.27	1.13	1.14	1.04-1.55	0.92-1.42	1.09-1.20
AA	1.50	1.53	1.39	1.22-1.85	1.22-1.92	1.33-1.45
BB	1.46	1.47	1.39	1.24-1.73	1.24-1.75	1.35-1.44

*adjusted for follow-up time
**including interaction terms with follow-up time for age, sex and tumour stage

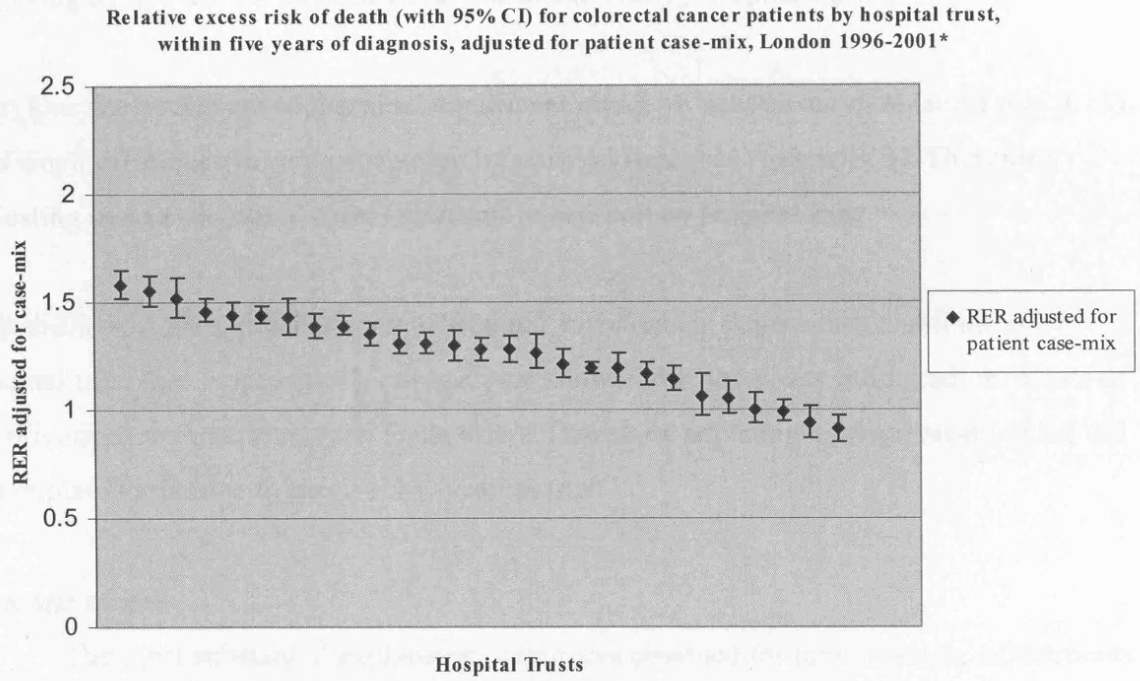
Figure 4.12 below shows that after taking into account differences in years of follow-up, age, sex, social deprivation and tumour stage, variability in RER remains significant, ranging from 0.86 (95% CI 0.60-1.22) to 1.59 (95% CI 1.31- 1.93). Note, in comparing this with unadjusted data (Figure 4.11), Figure xx shows Relative Excess Risk of death estimates adjusted for patient case-mix and years of follow-up, while Figure 4.11 shows five-year unadjusted relative survival estimates only, unadjusted for years of follow-up.

Figure 4.12



After multiple imputation of missing tumour stage, confidence intervals of RER became noticeably narrower and thus variation in Trust-specific RER turned to be more significant (see Table 4.18 and Figure 4.13), ranging from 0.91 (95% CI 0.85 – 0.97) to 1.58 (95% CI 1.52 – 1.65).

Figure 4.13



*after multiple imputation of missing tumour stage values

To illustrate the relative 'importance' of case-mix indicators in explaining survival differences between hospital trusts, the subsequent results in this section are presented for two hospital trusts with the highest ('hospital Q') and the lowest ('hospital I') five-year relative survival estimates (see Table 4.8), with the highest survival trust as a 'baseline variable'. Case-mix indicators were considered separately and as a group.

As shown in Tables 4.18 and 4.19, in a model without case-mix indicators, patients treated in 'hospital I' had 41% increase in excess mortality as compared with patients at 'hospital Q' (RER 1.41, 95% CI 1.18 – 1.68; $p<0.001$). Even after adjustment for all available case-mix indicators (age, sex, social deprivation and tumour stage), patients treated at hospital 'I' still had 31% higher relative excess risk of death within five year of diagnosis, than patients treated at hospital 'Q' (RER 1.31, 95% CI 1.08 – 1.59; $p=0.006$).

Separate adjustments for age, sex and, to some extent, social deprivation did not explain observed differences in survival. This may be due to the following reasons.

Age: Although there was clear gradient effect of 'age' on survival (see Table 4.15), there was small difference in age distribution by hospital trusts (see Appendix 2). Therefore, adjusting by age did not explain variations in survival by hospital trust.

Sex: Our analyses showed marginal significant effect of 'sex' on survival (see Table 4.15) and small difference in sex distribution by hospital trust (see Appendix 3). Therefore, adjusting by sex did not explain variations in survival by hospital trust.

Deprivation: Although there were substantial variations in deprivation distribution by hospital trust (see Appendix 4), our analyses showed that there was little gradient effect of 'deprivation' with survival (see Table 4.15). Therefore, adjusting by deprivation index did not explain variations in survival by hospital trust.

Tumour stage:

The most substantial explanatory value was obtained for tumour stage, adjustments for which decreased the difference in excess mortality between hospital trusts by 37% (RER 1.41 for the model without adjustment decreases to 1.26 after adjustment for stage – the highest level decrease, as compared with other indicators). However, the remaining variance of more than 60% between hospital trusts remained unexplained. After multiple imputation of missing values for stage, this result did not change substantially, with RER decreasing from 1.41 to 1.29, leaving even more proportion of unexplained variations. Our analyses showed that increasing stage significantly decreases survival (see Table 4.15), and as shown in Appendix 5, there was considerable difference in relative frequencies distribution of tumour stage (including 'Not Known' values) between hospital trusts.

Table 4.19 Relative 'importance' of case-mix indicators in explaining survival differences between hospital trusts with the highest and the lowest five-year relative survival for colorectal cancer in London

Model*	RER	95% CI		p-value
Trust only	1.41	1.18	1.68	< 0.001
Trust + age group	1.42	1.20	1.69	< 0.001
Trust + sex	1.41	1.18	1.68	< 0.001
Trust + social deprivation	1.39	1.16	1.66	< 0.001
Trust + tumour stage	1.26	1.03	1.53	0.023
Trust + case-mix**	1.33	1.10	1.61	0.003
Trust + case-mix** + interaction***	1.31	1.08	1.59	0.006

*the highest survival trust was considered as a 'baseline variable'
**age, sex, social deprivation and tumour stage
*** including interaction terms with follow-up time for age, sex and tumour stage

***Type of treatment*:**

In addition, the effect of type of treatment (surgery) as a possible explanatory factor in observed survival differences between hospital trusts was assessed (see Table 4.20). Type of surgery may be considered as a 'proxy' for patient severity and, thus, case-mix. However, adjustment for type of surgery did not result in a substantial difference from that of case-mix indicators *per se* (RER 1.36 for the model with adjustment for type of treatment and RER 1.31 after case-mix adjustment), and particularly tumour stage (RER 1.26 after adjustment).

There was a clear gradient effect of 'type of treatment' on survival: more radical surgery was associated with improved survival (see Table 4.22). In fact, as shown in Appendix 6, there was a difference in relative frequencies distribution of type of treatment by hospital trust, though to a lesser extent compared with stage distribution (see Appendix 5).

Table 4.20 Relative 'importance' of type of treatment and case-mix indicators in explaining survival differences between hospital trusts with the highest and the lowest five-year relative survival for colorectal cancer in London

Model*	RER	95% CI		p-value
Trust only	1.41	1.18	1.68	< 0.001
Trust + type of surgery****	1.36	1.12	1.66	0.002
Trust + type of surgery**** + case-mix**	1.34	1.09	1.65	0.005
Trust + type of surgery**** + case-mix** + interaction***	1.33	1.09	1.64	0.006
Trust + type of treatment*****	1.38	1.13	1.68	0.001
Trust + type of treatment***** + case-mix**	1.34	1.09	1.64	0.006
Trust + type of treatment***** + case-mix** + interaction***	1.32	1.07	1.62	0.008

*the highest survival trust was considered as a 'baseline variable'
**age, sex, social deprivation and tumour stage
*** including interaction terms with follow-up time for age, sex and tumour stage
****divided into five categories (see *Methods*, page 76)
*****divided into two categories (see *Methods*, page 76)

To conclude, even after considering the effects of case-mix variables or tumour stage, there still remained unexplained variation between hospital trusts suggesting that other factors related to hospital may be important. The potential impact of unknown confounders is discussed in *Discussion* chapter.

At the next stage of the analysis, along with the type of treatment (surgery), the impact of each available hospital level independent variables of structure and process of care was assessed within the multivariate relative survival model to ascertain their effect on survival.

As mentioned in *Materials and Methods* chapter, bivariate correlations among all covariates were examined to avoid potential problems due to collinearity. Consequently, all hospital predictors were tested in the model separately, since they were significantly correlated with each other ($p<0.01$).

4.4.2 Type of treatment (surgery) and cancer survival

Patients who underwent investigative procedures only had a more than two-fold increase in excess mortality as compared with patients who underwent surgical intervention (RER 2.52, 95% CI 2.22 – 2.86) (see Table 4.21).

Table 4.21 Relationship between type of treatment and relative excess risk of death within five years of diagnosis, for colorectal cancer, after adjustment for age, sex, social deprivation (income quintiles) and stage*

Type of treatment	RER	95% CI	p-value
Any surgical operation	1		
Investigative procedures only	2.52	2.22 – 2.86	< 0.001

*including interaction terms with follow-up time for age, sex and tumour stage

Survival improved along with the increasing extent of surgery: patients who underwent radical surgery (total or partial removal of an organ) had a better prognosis than patients who had only a non-radical intervention (tumour/lymph node removal or non-tumour removing surgery) (see Table 4.22).

Table 4.22 Relationship between type of surgery and relative excess risk of death within five years of diagnosis, for colorectal cancer, after adjustment for age, sex, social deprivation (income quintiles) and stage*

Type of treatment	RER	95% CI	p-value
Total removal of organ	1		
Partial removal of organ	1.08	0.97 – 1.20	0.141
Tumour/lymph node removal or excision	2.01	1.71 – 2.36	< 0.001
Non-tumour removing surgery	3.58	2.87 – 4.46	< 0.001
Investigative procedures only	3.20	2.79 – 3.67	< 0.001

*including interaction terms with follow-up time for age, sex and tumour stage

4.4.3 Average annual hospital volume of patients and cancer survival

No relationship was found between the average annual number of patients treated at hospital trust and 5-year relative survival (see Table 4.23).

Table 4.23 Relationship between average annual number of patients per hospital trust and relative excess risk of death within five years of diagnosis, for colorectal cancer, after adjustment for age, sex, social deprivation (income quintiles) and stage*

Variable	No. of hospital trusts	No. of patients	RER	95% CI	p-value
Volume (in quartiles):**					
1st (lowest)	9	3670	1		
2nd	6	3724	0.91	0.77 – 1.08	0.27
3rd	6	3087	1.00	0.86 – 1.15	0.95
4th (highest)	6	4320	0.95	0.81 – 1.10	0.48

*including interaction terms with follow-up time for age, sex and tumour stage
** number of patients is divided into equal quartiles based on predictor values of pooled data for all trusts; because Trusts are of different sizes, the total of Trusts per quartile differ, see also Materials and Methods, 3.6.1.2

4.4.4 Meeting two week wait target and cancer survival

Meeting two week wait target was assessed separately for urgent referrals received within the 24 hours and urgent referrals not received within the 24 hours, as was presented in original dataset. However, neither of these 'waiting time' indicators was found to be associated with 5-year relative survival (see Table 4.24).

Table 4.24 Relationship between meeting 2-week wait standard and relative excess risk of death within five years of diagnosis, for colorectal cancer, after adjustment for age, sex, social deprivation (income quintiles) and stage*

Variable	No. of hospital trusts	No. of patients	RER	95% CI	p-value
Waiting time (achievement quartiles):**					
1st (lowest)	6	3808	1		
2nd	6	3767	1.01	0.84 – 1.21	0.942
3rd	7	3493	1.10	0.93 – 1.30	0.250
4th (highest)	9	4397	1.02	0.85 – 1.22	0.818
Waiting time - referrals received within 24 hours (achievement quartiles):**					
1st (lowest)	4	3674	1		
2nd	8	3833	1.05	0.88 – 1.25	0.619
3rd	7	3956	1.05	0.89 – 1.24	0.558
4th (highest)	9	4002	1.00	0.82 – 1.22	0.996

*including interaction terms with follow-up time for age, sex and tumour stage
** number of patients is divided into equal quartiles based on predictor values of pooled data for all trusts; because Trusts are of different sizes, the total of Trusts per quartile differ, see also Materials and Methods, 3.6.1.2

4.4.5 Teaching status and cancer survival

Colorectal cancer patients who were treated at teaching hospitals had a statistically significant 13% reduction of excess mortality compared with patients who were treated at non-teaching hospitals (RER 0.87, 95% CI 0.77 – 0.99; p=0.032) (see Table 4.25).

Table 4.25 Relationship between teaching status of hospitals and relative excess risk of death within five years of diagnosis, for colorectal cancer, after adjustment for age, sex, social deprivation (income quintiles) and stage*

Teaching status	RER	95% CI	p-value
No	1		
Yes	0.87	0.77 – 0.99	0.032

*including interaction terms with follow-up time for age, sex and tumour stage

4.4.6 Staffing level and cancer survival

No relationship was found between indicators of staffing level at hospital trusts and 5-year relative survival for colorectal cancer patients (see Table 4.26).

Table 4.26 Relationship between medical, ward and radiology staffing level indicators and relative excess risk of death within five years of diagnosis, for colorectal cancer, after adjustment for age, sex, social deprivation (income quintiles) and stage*

Staffing level indicator	No. of hospital trusts	No. of patients	RER	95% CI	P value
Medical WTE per 1000 admissions (in quartiles):** 1st (lowest)	4	2928	1		
2nd	6	2919	1.11	0.98 – 1.26	0.101
3rd	6	3093	1.01	0.90 – 1.14	0.815
4th (highest)	7	3171	0.98	0.82 – 1.18	0.866
Consultant WTE per 1000 admissions (in quartiles):** 1st (lowest)	5	3087	1		
2nd	7	3597	1.05	0.92 – 1.19	0.453
3rd	6	3669	0.87	0.73 – 1.04	0.140
4th (highest)	7	3490	1.06	0.94 – 1.20	0.336
Medicine consultant WTE per 1000 admissions (in quartiles):** 1st (lowest)	5	3176	1		
2nd	7	3380	1.05	0.90 – 1.23	0.532
3rd	6	3375	1.06	0.94 – 1.20	0.315
4th (highest)	7	3912	0.91	0.79 – 1.06	0.238
Anaesthetist consultant WTE per 1000 admissions (in quartiles):** 1st (lowest)	4	3185	1		
2nd	5	3362	0.91	0.75 – 1.09	0.296
3rd	9	3718	0.94	0.82 – 1.08	0.419
4th (highest)	7	3578	0.92	0.77 – 1.09	0.333
Pathology consultant WTE per 1000 admissions (in quartiles):** 1st (lowest)	6	3184	1		
2nd	5	3559	0.98	0.82 – 1.17	0.827
3rd	7	3500	1.10	0.94 – 1.29	0.214
4th (highest)	7	3600	1.06	0.92 – 1.22	0.406
Radiology consultant WTE per 1000 admissions (in quartiles):** 1st (lowest)	6	2534	1		
2nd	6	4220	0.99	0.86 – 1.14	0.890
3rd	6	3483	0.85	0.72 – 1.01	0.062
4th (highest)	7	3606	1.08	0.95 – 1.23	0.225
Radiographers per 1000 FCEs (in quartiles):** 1st (lowest)	6	3246	1		
2nd	5	3263	0.95	0.78 – 1.15	0.574
3rd	7	4298	1.03	0.90 – 1.17	0.697
4th (highest)	9	4235	0.99	0.86 – 1.15	0.940
Clinical nurse specialists WTE per 1000 FCEs (in quartiles):** 1st (lowest)	5	2807	1		
2nd	5	2500	1.00	0.87 – 1.16	0.947
3rd	7	3008	0.96	0.83 – 1.10	0.549
4th (highest)	7	3109	0.92	0.77 – 1.10	0.377

*including interaction terms with follow-up time for age, sex and tumour stage

** number of patients is divided into equal quartiles based on predictor values of pooled data for all trusts; because Trusts are of different sizes, the total of Trusts per quartile differ, see also Materials and Methods, 3.6.1.2

4.4.7 Compliance with colorectal cancer MDT standards and cancer survival

The effect of compliance of hospital trusts with cancer standards on cancer survival have been assessed in more detail because of their potential practical impact and the fact that they have never been explored in this way before.

Firstly, the impact of the composite score for all 35 standards was considered, and found to be positively associated with five-year relative survival, although the effect seemed to be marginal (RER 0.98, 95% CI 0.97-0.997; p=0.012). Subsequently, each standard was examined separately within the model, as it had been by peer review.

In examining compliance with individual colorectal MDT standards, no relationship was found between the majority of published standards and cancer survival. However, positive independent relationships were found for four aspects of the cancer standards peer review: compliance with standards defining the structure of MDT (standard 3); operational policies (standard 14); availability of patient information (standard 28); and clinical guidelines (standard 30). The results are presented in Table 4.27.

All 35 colorectal cancer MDT standards were grouped under 11 sub-headings (topics) within the Manual of Cancer Services Standards to describe various aspect of management of colorectal cancer patients by multi-disciplinary teams (see Table 4.27). Number of standards grouped under each topic varied from one to ten. However, some of the groupings seem arbitrary. For example, a standard 'Names of extended team members ' under the 'Extended team' sub-heading reflects the same theme as standards gathered under the 'MDT structure'. On the other hand, 'Consistency between histopathologist audit' included under 'MDT structure' reflects rather a process of care than a structure of MDT.

Only one standard out of eight under the 'MDT structure' (standard 3) showed significant association with survival. Particularly, compliance with that standard was associated with statistically significant 17% reduction of excess mortality compared with non-compliant trusts (RER 0.83, 95% CI 0.78-0.88; p<0.001). Similar results were obtained when the association was tested using Cox proportional hazard model (HR 0.84; 95% CI 0.81 – 0.88; p<0.001).This may be due to the fact, that essentially this standard defines the structure of MDT as a whole, and thus may partly reflect other standards under the 'MDT structure'. However, only 2 NHS hospital trusts were not in compliance with this standard.

None of the four standards grouped under the topic 'MDT meetings' showed

association with survival, although one of those standards – 'Pre-operative core MDT members', reflects rather a structure of MDT than 'MDT meetings' per se.

Only one out of ten standards under the 'Organisational policies' (standard 14) showed significant association with survival. Particularly, compliance with that standard was associated with statistically significant 14% reduction of excess mortality compared with non-compliant trusts (RER 0.86, 95% CI 0.78-0.95; p=0.002). Similar results were obtained when the association was tested using Cox proportional hazard model (HR 0.88; 95% CI 0.82 – 0.96; p=0.002). This is one of the important standards within the topic which defines the availability of operational policies on MDT review of new cancer patients, and therefore, may partly reflect other standards included in that topic.

The availability of patient information (standard 28) also showed positive association with survival. Particularly, compliance with the standard was associated with statistically significant 16% reduction of excess mortality compared with non-compliant trusts (RER 0.84, 95% CI 0.79-0.90; p<0.001). Similar results were obtained when the association was tested using Cox proportional hazard model (HR 0.87; 95% CI 0.82 – 0.93; p<0.001). Other four standards within the 'Functions of the team providing patient centred care' were not significantly associated with survival.

Compliance with the 'clinical guidelines' standard (standard 30) was associated with statistically significant 19% reduction of excess mortality compared with non-compliant trusts (RER 0.81, 95% CI 0.72-0.92; p=0.001). Similar results were obtained when the association was tested using Cox proportional hazard model (HR 0.84; 95% CI 0.77 – 0.91; p<0.001).

However, compliance with standards on referral guidelines or treatment planning decisions was not associated with survival. Likewise, compliance with standards on network-wide datasets and audits, as well as clinical trials, did not show significant association with survival.

It should be noted that out of 35 colorectal cancer MDT standards analysed in this study, three standards were excluded from the model since either all hospital trusts were compliant with the standard (standard 1) or only one hospital trust was not compliant with the standard (standards 7 and 29).

Table 4.27 Relationship between compliance with selected colorectal cancer MDT standards (Cancer Services Peer Review 2001) and relative excess risk of death (RER) within five years of diagnosis for colorectal cancer, after adjustment for age, sex, social deprivation (income quintiles) and stage*

Cancer standards	Compliant		RER	95% CI	p-value
	No. of hospital trusts	No. of patients			
MDT structure					
1. Named Lead clinician for the colorectal specialist MDT	*All hospital trusts were compliant with this standard*				
2. Lead clinician written responsibilities	23	10765	1.01	0.82 – 1.24	0.934
3. Names of core members of MDT	23	11265	0.83	0.78 – 0.88	< 0.001
4. Lead Histopathologist for the MDT	23	11307	1.06	0.81 – 1.38	0.668
5. Histopathologist attendance at MDT	17	8081	0.98	0.87 – 1.11	0.771
6. Consistency between histopathologist audit	7	3024	0.86	0.72 – 1.02	0.076
7. Lead imaging consultant attendance at MDT	*Only one hospital trust was not compliant with this standard*				
8. Lead imaging consultant attendance at MDT	7	3544	1.03	0.91 – 1.17	0.610
MDT meetings					
9. Pre-operative core MDT members	14	6461	1.06	0.94 – 1.18	0.344
10. MDT meetings – frequency and attendance records	17	7801	1.03	0.92 – 1.15	0.640
11. Core members attendance at MDT	17	8324	1.02	0.90 – 1.14	0.776
12. Cover arrangements for core members	16	7689	0.91	0.81-1.01	0.082
Operational policies					
13. Operational policy meetings	15	6983	0.95	0.85 – 1.06	0.383
14. Operational policy – MDT review of new cancer patients	16	7245	0.86	0.78 – 0.95	0.002
15. Written operational policy – communication of a patient's diagnosis to their general practitioner	18	8554	0.98	0.87 – 1.10	0.688
16. Implementation of the policy – timeliness of communication of a patient diagnosis to their general practitioner following diagnosis	4	2096	1.04	0.90 – 1.19	0.605
17. Written operational policy – provision of information on the appropriateness and timeliness of urgent referrals	13	6305	0.92	0.82 – 1.04	0.176
18. Colorectal nurse specialist qualifications – registered ENB 237 course	5	2292	0.93	0.77 – 1.12	0.427
19. Colorectal nurse specialist qualifications – obtained ENB 237 course	6	2998	0.96	0.83 – 1.11	0.569
20. Colorectal nurse specialist qualifications – obtained the ENB 216 and/or cancer related nursing degree	12	5481	0.98	0.87 – 1.10	0.721
21. Written agreement describing referrals guidelines – core team and clinical oncologist	6	2897	0.95	0.83 – 1.09	0.455
22. Written operational policy for stabilising and treating emergency admissions	11	4703	0.99	0.87 – 1.13	0.872
Extended team					
23. Names of extended team members	18	8869	0.99	0.88 – 1.12	0.903
Functions of the team providing patient centred care					
24. Arrangements for access to MDT	22	10398	0.94	0.82 – 1.07	0.338
25. Survey of patients experience undertaken/being undertaken	14	6393	0.99	0.88 – 1.11	0.845
26. Survey results presented and discussed at MDT	5	2451	1.10	0.98 – 1.24	0.119
27. Actions taken as a result of the survey	4	1882	1.06	0.91 – 1.23	0.469
28. Written information material *(for patients)* available	22	10756	0.84	0.79 – 0.90	< 0.001
Treatment planning decision					
29. Treatment planning decisions recorded	*Only one hospital trust was not compliant with this standard*				
Clinical guidelines					
30. Network wide clinical guidelines for the cancer site	9	3853	0.81	0.72 – 0.92	0.001
Referral guidelines					
31. Referral guidelines for the cancer site	14	6861	0.92	0.82 – 1.03	0.148
Data collection					
32. Network wide dataset for the cancer site	19	9152	0.90	0.80 – 1.01	0.081
33. Recording of dataset for individual patients	19	8982	0.94	0.84 – 1.05	0.248
Network audit					
34. Network wide audits	6	2962	0.93	0.84 – 1.01	0.101
Participation in approved clinical trials					
35. List of agreed clinical trials	13	5709	0.90	0.81 – 1.01	0.080

*including interaction terms with follow-up time for age, sex and tumour stage

Full definitions of those standards which seem to significantly predict survival for colorectal cancer are specified below. The definitions of cancer standards provided are taken from the Manual of Cancer Services Standards (December 2000) [14].

Standard 3. Names of core members of MDT
The MDT should provide the names of core team members for named roles in the team. The core team specific to the colorectal MDT should include: designated colorectal surgeon(s); oncologist(s); physician gastroenterologist; radiologist; histopathologist; skilled colonoscopist of any discipline; nurse specialist(s).
Notes: The MDT may choose to name additional core members, for instance stoma nurse. This may or may not be one of the skills of the nurse specialist. These are not subject to assessment. Where a medical specialty is referred to, the core team member should be a consultant. The cover for this member need not be a consultant.
Demonstration of compliance: Name of each core team member with their role, agreed by the Lead Clinician of the MDT.

Standard 14. Operational policy – MDT review of new cancer patients
There should be an operational policy for the team whereby it is intended that all new cancer patients will be reviewed by a multidisciplinary team.
Notes: As stated in the NHS Cancer Plan, the care of all patients should be formally reviewed by a specialist team. This will be done either through direct assessment or through formal discussion with the team by the responsible clinician. This will help ensure that all patients have the benefit of the range of expert advice needed for high quality care.
Demonstration of compliance: Operational policy.

Standard 28. Written information material [for patients] available
The MDT should provide written material for patients which includes: information specific for that MDT about local provision of the services offering the treatment for tat cancer site; information about patients self-help groups if available; information about the services offering psychological, social and spiritual/cultural support if available; information specific to the MDTs cancer site or group of cancers about the disease and its treatment options
Demonstration of compliance: The written (visual an audio is used – see note below) material.
Notes: Its content and format are not subject to assessment save as per the standard. It is recommended however that it is available in languages and formats understandable by patients including local ethnic minorities. This may necessitate the provision of visual and audio material.

Standard 30. Network wide clinical guidelines for cancer site
The MDT should agree specified network-wide clinical guidelines[xxvii] with the Network Site Specific Group (NSSG) for that cancer site. Where there are agreed national clinical guidelines, the network and the MDT should accept these.Notes: Regionally agreed clinical guidelines are not precluded but are not part of the standard since networks may operate in parts of more than one region. For compliance the NSSG should produce an agreed guideline and the individual MDT, for their compliance, should agree to abide by it.
Demonstration of compliance: The clinical guidelines agreed by the Lead Clinician of the MDT and the Chair of the NSSG
Note: The contents, completeness or judgements on the appropriateness of the guidelines are not subject to assessment save as per the standard.

[xxvii] i.e. how a given patient should be clinically managed (usually at the level of which modality of treatment is indicated for a given set of clinical circumstances, rather than detailed regimens or details of surgical techniques etc). Source: *Manual of Cancer Services Standards (December 2000).*

4.4.8 Comparison of results obtained using alternative approaches to handle missing stage data

As mentioned earlier in this chapter, a 'complete case analysis' was conducted in relation to tumour stage variable, which contained 20.9% of missing values. This implies that 'not known' values were considered missing in the analysis and patients with 'not known' stage were excluded from the analysis. However, for comparative purposes, analyses were repeated including 'not known' values as an additional separate category. Analyses were also repeated after multiple imputation of missing values. (see Table 4.28)

As indicated in *Materials and Methods* chapter, the main disadvantage of using 'complete case analysis' is in its inefficiency as cases with missing data are excluded from the analysis. On the other hand, although creating an additional 'Not Known' category is widely used by epidemiologists for handling missing data because of its simplicity, it was found to produce biased estimates under most conditions[289;303]. The impact of this method depends on how the missing values are divided among the real categories, and how the probability of a value being missing depends on other variables. This method can lead to misleading results as very dissimilar classes may be lumped into one category.

Multiple imputation technique, although still under development, is currently considered as a method of choice for handling missing data as it allows imputation of missing values based on all available variables.

However, using either of those methods brought about similar results. The Table 4.28 below specifies and compares the results obtained using three alternative approaches in an example of significant predictors of survival, described in this chapter.

This comparison shows no difference between estimates of RER under any of employed approach of handling missing data. For example, RER for 'clinical guidelines' standard under 'complete case analysis' was equal to 0.81 (95% CI 0.72-0.92), under 'additional Not Known category' – 0.80 (0.71-0.90), and using multiple imputation of missing values – 0.82 (0.74-0.91). These last two methods did not change significance or direction of associations found. The comparison suggests that the mechanism of missing data was 'missing completely at random'.

Data is said to be missing completely at random (MCAR) when there are no systematic differences between complete and incomplete records[285;286]. Missing values are

not related to any observed or unobserved values, and that the missing cases are a random sample of the complete cases.

Table 4.28 Comparison of results obtained using alternative approaches to handle missing stage data

Indicator	'Not known' values considered 'missing'			'Not known' values included as additional separate category			Multiple imputation of missing values		
	RER	95% CI	p value	RER	95% CI	p value	RER	95% CI	p value
Type of treatment: Total removal of organ	1								
Partial removal of organ	1.08	0.97 – 1.20	0.141	1.09	0.99 – 1.20	0.064	1.09	1.00 - 1.20	0.06
Tumour/lymph node removal or excision	2.01	1.71 – 2.36	< 0.001	1.93	1.64 – 2.28	< 0.001	1.87	1.58 - 2.20	<0.001
Non-tumour removing surgery	3.58	2.87 – 4.46	< 0.001	3.36	2.63 – 4.29	< 0.001	3.18	2.39 - 4.23	<0.001
Investigative procedures only	3.2	2.79 – 3.67	< 0.001	3.07	2.68 – 3.52	< 0.001	2.95	2.57 - 3.38	<0.001
Teaching status: No	1								
Yes	0.87	0.77 – 0.99	0.032	0.88	0.77 – 0.99	0.037	0.89	0.79 - 0.99	0.038
Cancer standards: Standard 3. Names of core members of MDT	0.83	0.78 – 0.88	< 0.001	0.81	0.76 – 0.85	< 0.001	0.81	0.77 - 0.86	<0.001
Standard 14. Operational policy – MDT review of new cancer patients	0.86	0.78 – 0.95	0.002	0.85	0.77 – 0.94	0.002	0.87	0.80 - 0.96	0.005
Standard 28. Written information material *[for patients]* available	0.84	0.79 – 0.90	< 0.001	0.84	0.78 – 0.91	< 0.001	0.85	0.79 - 0.92	<0.001
Standard 30. Network wide clinical guidelines for the cancer site	0.81	0.72 – 0.92	0.001	0.8	0.71 – 0.90	< 0.001	0.82	0.74 - 0.91	<0.001

CHAPTER 5

DISCUSSION

5 DISCUSSION

5.1 Introduction

This study was undertaken during the period of implementation of the Cancer Plan for England (DH 2000), and is based on data relating to the start of the Plan. The Plan set a ten-year programme of change for NHS cancer services, through increasing resources for treatment (including staffing, equipment, pharmaceuticals) and new organisation of services (including waiting times, multi-disciplinary teams and cancer networks linking units and centres).

Cancer is unique among the main diseases in having, through cancer registration, a nation-wide system recording incidence and death. Incidence data from cancer registration have been used to investigate disease aetiology, through classic studies of time, place and person, and trends in incidence can be used to assess the impact of environmental changes and preventive interventions[304]. However, linking cancer registration to deaths, which is feasible in the UK through the NHS Central Register provides data on survival – a reflection of the ability of health services to treat cancer at population level[2].

Clinical trials can show the efficacy of a specific intervention. But the results of trials may not be translated into effectiveness, the impact on the population, for several reasons: the intervention may not be implemented everywhere; implementation may not be at the standard of the original trial; and the trial may have been selective in the population sub-groups studied. Surveillance using cancer registration allows public health assessment of the overall impact of new treatments in cancer services.

The Department of Health for England commissioned 'Improving Outcomes Guidance' reports for several tumour types[9-13;37;38], including colorectal[12;13;37;38] cancer, providing extensive reviews of determinants of cancer outcomes. The reviews suggest that there has been more intervention research on clinical practice, usually trials, than on organisational interventions. There was partial evidence on the benefits of reducing waiting times, while multi-disciplinary teams and cancer networks had not been researched.

Colorectal cancer is the second commonest cancer in England by incidence, and cause of cancer death, and has an average 5-year survival of around 40-45% - providing a statistically sufficient number of events for the statistical analysis chosen in this study.

Clinical reports indicate that the quality of surgical treatment is important in survival, especially for rectal cancer[172;174-184] and the Cancer Plan for England considers that the organisation of treatment at hospital level can also have an impact. Data on colorectal cancer survival in London were available through the Thames Cancer Registry, and formed the dependent variable for analysis in the study, while measures of hospital characteristics were drawn from several sources. The study demonstrates the feasibility of identifying and using explanatory variables from these datasets, which has not been done before. It also demonstrates limited feasibility in terms of limitations of inferences while using routine databases for explanatory purposes. Interpretation is limited due to the methodological limitations, temporal relationships, incomplete adjustments for confounding factors, lack of some disease-specific indicators (e.g. cancer-specific staffing), and concerns over data accuracy. The analysis supports some, but not all, hypotheses based on the literature.

5.2 Data sets

At the time of this study, each of the five data sets was currently used alone by the health service. Cancer survival data has been available for many years through cancer registration and death certification. Hospital Episode Statistics in England started in 1989, while the other three data sets were only available for the period of 2000 onwards. The study has made the first national use of the cancer standards, and the other data sets have not previously been used together to address cancer services. The data sets were assembled, assessed for quality, and individual items from each were drawn to use as explanatory variables within the model.

5.2.1 Quality of the data

Although major concerns have been expressed about the completeness and accuracy of diagnosis and procedures[30;69], missing data[70;71;305]; and variations in data collection [123], routine datasets have been used in performance evaluation and outcome research. Availability, relative inexpensiveness and coverage of defined or regional populations are among the main reasons [30;119]. Hence, initial steps in this study were to assess the quality of the data, 'clean' them if possible, and to consider potential limitations during statistical analysis and subsequent inferences.

- **Properties**

DoCDat assessment tool was used to review the properties of the datasets[277]. This structured questionnaire has proved useful for structured appraisal of national datasets (see *Results* chapter and Appendices 11–15), although it was originally developed for datasets, which contain individual level data[114;277] and, thus, has limitations in describing properties of hospital level data. Nevertheless, the present study suggests that the criteria developed by DoCDat can be applied broadly to assess quality for research use, taking into account specific circumstances in each case.

Data quality (coverage and accuracy) was assessed using a 4-point scale, where "4" indicates the highest level of quality, and "1" - the lowest level of quality, in accordance to DoCDat assessment tool.

- **Coverage**

Cancer Services Peer Review

All cancer unites and centres in England are covered by the dataset. (level 4 for 'representativeness'). However, out of 28 hospital trusts included in the study, data for 3 hospital trusts could not be included in the analysis because of differences in structure of hospitals between the Thames Cancer Registry and the Cancer Services Peer Review datasets. Therefore, only data on 25 hospital trusts in London were considered in the model (level 2 for 'recruitment'). No data on major confounders are available in the dataset; therefore, level 2 was assigned for the 'variables included' in the dataset criterion.
Data were mostly complete (level 3 for 'completeness of variables'). For more details, see 4.1.1 and Appendix 14.

Acute Hospital Portfolio (AHP)

All NHS acute hospital Trusts are covered by the dataset (level 4 for 'representativeness'). However, as per Table 4.2, not all indicators within the AHP were available for all 28 NHS Trusts considered in this study. This availability ('recruitment') varied from 23 to 27 hospital trusts (level 2). Dataset does not include information on major known confounders (level 2 for 'variable included'). Data were mostly complete (level 3 for 'completeness of variables'). For more details, see 4.1.2 and Appendix 11.

Cancer Waiting Times

All urgent referrals of patients with suspected cancer are included in the dataset. However, it does not include non-urgent referrals and those admitted to the hospital without GP referral. Therefore, there is only "some evidence" that the eligible population is representative (level 2 for 'representativeness'). On the other hand, all 28 hospital trusts included in the study were covered by the dataset (level 4 for 'recruitment'). Dataset does not include information on major known confounders (level 2 for 'variables included'). Data were mostly complete (level 4 'completeness of variables'). For more details, see 4.1.3 and Appendix 13.

Hospital Episode Statistics (HES)

All NHS patients treated in NHS Trusts are covered by the dataset (level 4 for 'representativeness'). Out of 28 hospital trusts included in the study, only data on one hospital trust were not available in the dataset (level 3 for 'recruitment'). Various administrative and clinical data, along with some of the known confounders and outcome data are recorded in the HES (level 3 for 'variables included'). On a national level, most variables are at least 95% complete (level 3 for 'completeness of variables'). For more details, see 4.1.4 and Appendix 12.

Cancer Registry

Total population of the covered region included (level 4 for 'representativeness'). Dataset includes 90-97% of the eligible population (level 3 for 'recruitment'). Various administrative and clinical variable are included in the dataset. However, not all confounding factors are available there (level 2 for 'variables included'). All variables necessary for survival analyses were complete except for tumour stage and type of treatment received (level 3 for 'completeness of variables'). For more details, see 4.1.5 and Appendix 15.

- **Accuracy**

Cancer Peer Review

Explicit definitions and rules for coding were set out in the Manual of Cancer Services

Standards (Department of Health, 2001). (level 4 for 'explicit definitions' and 'explicit rules') However, no information on data validation has been identified (level 1 for 'data validation') . For more details, see 4.1.1 and Appendix 14.

Acute Hospital Portfolio (AHP)

The definitions of most variables are provided in accompanied reports or guides to indicators (level 4 for 'explicit definitions'). However, coding rules were available for indicators of medical staffing and radiology, but not for ward staffing (level 3 for 'explicit rules'). No information on data validation has been identified (level 1 for 'data validation'). For more details, see 4.1.2 and Appendix 11.

Cancer Waiting Times

All variables have clear definitions and coding rules (level 4 for 'explicit definitions' and 'explicit rules'). No published information has been identified as to whether data have been validated (level 1 for 'data validation'). For more details, see 4.1.3 and Appendix 13.

Hospital Episode Statistics (HES)

All or almost all variables have clear definitions and coding rules (level 4 for 'explicit definitions' and 'explicit rules'). Data are validated by range and consistency checks (level 3 for 'data validation'). There are also reports on regular external audits, although no vigorous validation at source is conducted. For more details, see 4.1.4 and Appendix 12.

Cancer registry

All or almost all variable have clear definitions and rules of coding (level 4 for 'explicit definitions' and 'explicit rules'). Data are being validated by range and consistency checks, supplemented by external validation using an alternative source (level 4 for 'data validation'). For more details, see 4.1.5 and Appendix 15.

Coverage of datasets vary depending on criteria, and, in general, allowed for feasibility of getting and analysing data. Nevertheless, lack of information on some major known confounders, as well as noticeable proportion of missing tumour stage data in cancer registry were the main limitations in terms of data coverage. In relation to data accuracy, datasets normally provided with the clear definitions and rules of coding for variables

included in the study. However, lack of data validation for most of the datasets may hinder feasibility in terms of limitations of inferences due to concerns over data accuracy.

- **DCO registrations**

One indicator of the quality of the cancer data was the proportion of death certificate only (DCO) registrations[31;73]. DCO cases are excluded from survival analysis since their date of diagnosis and subsequent follow-up information is not available. Studies by the Thames Cancer Registry have shown that DCO registrations are higher with increasing age and decreasing survival[32]. Whereas in the literature, the percentage of DCO cases varied from 1% to 25% of all registrations[59;61;73], our study had a low percentage of DCO cases (548 patients - 3%), which were excluded from the analysis.

- **Selection of variables**

Selected variables from the larger datasets were used for analysis in this study. Factor analyses can be used to reduce the number of variables and detect structure in the relationships between variables of data sets [306]. However, the method is statistical and does not value the dimensions in a qualitative way. The selection for this study was based on the completeness of the data, their relevance to study objectives, in relation to the literature findings, and the time period covered in relation to other datasets, supported with expert advice.

5.2.2 Handling missing data

One of the main concerns for data quality in the five datasets was missing data. Some variables were not recorded or available for particular hospital trusts (or sometimes the hospital trusts themselves were differently designated because they were merging or splitting). According to personal communications from representatives of the Healthcare Commission, the main reason of lack of data for some hospital trusts and variables within the Acute Hospital Portfolio was failure to provide the data. Also, data were missing for specific variables within individual datasets, in particular tumour stage or type of treatment information from TCR. For this reason, not all statistical analyses were run for all patients or all hospital trusts. In fact, as was noted in the *Results* chapter, depending on the predictor

examined, the number of Trusts included in the analysis varied from 23 (medical staffing) to all 28 (waiting times; teaching status).

Of several common approaches which researchers use to deal with missing data[282;284;307], four – least observation carried forward; creating an extra category for the missing variable; replacing missing observations by the mean of the variable; and mean imputation using regression – are not recommend, since they can give unpredictable results and are not underpinned by statistical theory[282;283]. (Although, the use of 'creating an extra category' approach is particularly widespread in the literature.) A new approach to dealing with missing data is multiple imputation[284]. However, this method was not available in Stata statistical package until 2004/5, and for categorical variables and it is still under development[290]. This study therefore employed 'complete case analysis'.

In complete case analysis, all 'not known' or not recorded values are considered as 'missing' for statistical investigations and modelling. However, this approach is 'inefficient', since it reduces the numbers of study subjects, and gives varying totals for each data item analysed. In addition, this method implies a 'missing at random' assumption which is difficult to prove. On the other hand, as was indicated in *Materials and Methods* and *Results* chapters, analyses of potential predictors were repeated including 'not known' values as an additional separate category (i.e. using 'creating an extra category' approach) and after multiple imputation of missing values. This did not have substantial impact on the statistical significance or direction of associations found.

Tumour stage was an important prognostic variable for which analysis was limited because it is not well recorded in cancer registry datasets. The overall trend of distribution by age, sex and deprivation between patients with known and missing stage information was similar, although there were more older (age 80-89) and more deprived patients among those with missing tumour stage. It is known that these two factors are associated with poor prognosis[33;35;36;73;140;141]. A more visible difference is observed when comparing relative frequencies by type of treatment received. A higher proportion of patients with known tumour stage received more radical surgery (total or partial removal of organ) as compared with patients whose stage information was missing (79.6% vs. 60.8%), while more patients in the latter group underwent an investigative procedures only (15.7% vs. 8.45%). As indicated in *Results* chapter, more radical surgery appeared to be associated with better survival. Hence, patients with missing tumour stage information were more likely to have worse prognosis than those whose tumour stage was recorded.

More older and more deprived patients had missing tumour stage (see *Results* chapter, 4.3). On the other hand, adjustments for age and deprivation index did not explain variations in survival by hospital trust. The most significant explanatory value was obtained for tumour stage (see *Results* chapter, 4.4.1). It is impossible to accurately determine whether patients with missing data had more advanced tumour stage as this very information was missing. A higher proportion of patients with known tumour stage who received more radical surgery as compared with patients whose stage information was missing may suggest such possibility, although the presence of comorbid conditions may have an impact too.

On the other hand, as mentioned above and specified in *Results* chapter (see 4.4.8), the comparison of results obtained using alternative approaches to handle missing stage data showed that regardless of the method employed (including multiple imputation of missing values), it did not have an impact on significance or direction of associations found, i.e. there were no systematic differences between complete and incomplete records. This suggests that the mechanism of missing data was 'missing completely at random'[285;286].

5.3 Statistical and methodological considerations

5.3.1 Sample size and power

Sample size estimation and power calculation for survival analysis of clustered data is not straightforward and still under development. There are no sound statistical tools and programmes available similar to those for studies with control groups[301;308-310]. According to some assessments, in order to get reliable survival and hazard function estimates with their standard errors at each time interval, the minimum recommended sample size is 30[311]. Also, the power of a survival analysis is related to the number of events (i.e. deaths) rather than the number of participants. Simulation work has suggested that at least 10 events need to be observed for each covariate studied and anything less will lead to problems, for instance the regression coefficients become biased[301].

In the current study, the total sample size was comprised of 15465 patients treated at 28 hospital trusts; there were 8059 events (deaths) observed and the maximum number of covariates in any one model was 10, depending on specific organisational determinant considered and including interaction terms where appropriate. Even though, as was noted, not all conducted analyses included all patients or hospital trusts, the numbers were still large enough to get reasonable power for statistical tests.

Although the number of cases was sufficient for estimating survival, the other limiting factor was the variability, in aggregate, of the organisational determinants, based on hospital trusts. While survival showed significant differences between the 28 hospital trusts (see Figures 4.11 – 4.13), the variance was smaller for some of the non-continuous variables. Thus, three cancer standards (see Table 4.27, standards 1; 7 and 29) were excluded from the analysis, since either all hospital trusts complied with them or only one Trust was non-compliant; and still included in the model were five standards (see Table 4.27, standards 2; 3; 4; 24; 28) where only two or three hospital trusts were non-compliant with the standards.

5.3.2 Choice of the method for cancer survival estimation

Five-year survival is routinely used as the main outcome measure for cancer care. From the patient and service perspectives, other measures of outcome may also be of great importance, such as postoperative mortality, postoperative complications (or complications after chemo- or radio-therapy), cancer recurrence rate and quality of life after discharge. In fact, quantifying such qualitative complaints or conditions as pain or discomfort, loss of mobility etc. is quite difficult and needs to be validated by rigorous research. These important issues are not addressed here because routinely collected data for these indicators are not available, but this might be of interest in future studies.

As indicated in *Materials and Methods* chapter (3.6.2), there are two main approaches to estimate survival for cancer patients in epidemiological studies: 'cohort analysis' and 'complete analysis'. Cohort method requires full period of follow-up time for all patients, thus reflecting the full five-year follow-up experience of all patients included in the study. On the other hand, for the that reason, cohort measures of cancer survival are less up-to-date, require more time to accomplish and could be more appropriate in clinical follow-up studies.

Another approach, widely used in cancer epidemiology and employed in this study is 'complete analysis', which takes into account experience of patients who have not had the opportunity to be followed-up for the full period of time. A complete analysis of five-year survival would include the probability of surviving one year estimated form the experience of patients diagnosed up to one year ago, the probability of surviving two years from patients diagnosed up to two years ago, and so forth. Therefore, complete estimates are more up-to-date than cohort estimates as the estimation of survival includes more recently diagnosed patients. However, if survival is improving over time, or new effective treatment or diagnostic methods introduced, this will affect the five-year survival estimates, making them higher than those obtained using the cohort method. While acknowledging that survival could be changing over five years, it must be noted that no substantial changes in treatment or diagnoses were introduced over the study time frame for colorectal cancer patients. Also, a sub-analysis comparing annual trends in colorectal survival (Appendix 9) shows that, while national survival for colorectal cancer was rising over the period, in London there was no significant change.

This approach has limitations in relation to temporal relationships as more patients

were in early years of the time frame of this study when no information on organisational factors was available. However, relative survival modelling employed to assess relationships between organisational determinants and survival takes into account differences in follow-up time by adjusting it within the model (see 3.6.3, *Materials and Methods* chapter).

5.3.3 Use of multiple testing

According to various simulation studies, the danger with conducting numerous comparisons is that the type I error rate (i.e. that rejecting the null hypothesis when it is true and concluding that there is an effect when in reality there is none) increase substantially[312;313]. The recommendation to avoid such 'chance alone' effect detection is to perform a small number of tests chosen to relate to the primary aims of the study. In testing compliance with the cancer standards, separate statistical tests were made with each variable. An alternative was to combine standards and create a single score based on the number of standards that had been met, the approach used by Morris[46]. However, as the cancer standards data set had not been used before in a national study, and because the 35 colorectal cancer standards had been formally chosen by a peer-review process, it was decided to examine associations with all the variables separately, along with the composite score (see also 5.5.1). For the other larger data sets (Hospital Episode Statistics, Acute Hospital Portfolio) individual variables were selected.

5.3.4 Hierarchical data

This study used data of hierarchical nature with variables reflecting two levels – patient and hospital trusts. To take into consideration the hierarchical nature of the data, a clustering effect of NHS hospital trusts has been accounted for within the model. Adjustment of standard errors for clustering effect of NHS hospital trusts allowed for the fact that patients treated within the same NHS hospital Trust may have more similar characteristics, treatment or referral patterns and experiences than those from other hospitals[299]. Studies that fail to allow for this have been shown to underestimate standard

errors and, hence, overestimate effects[300]. Therefore, the adoption of this approach increases the reliability of study results.

Another potential option to deal with the hierarchical data would be to use multilevel modelling (MLwiN softfware)[314;315]. However, the use of multilevel modelling with relative survival has yet to be developed. In fact, no study was identified to use this approach involving relative survival estimates.

5.3.5 Temporal relationships

- **Exploring new data**

The Bradford Hill criteria for inferring causality in epidemiological studies include the temporal relationship. Nevertheless, cross sectional studies are frequently used for exploratory epidemiological studies where longitudinal data do not exist. In the present study, the survey of cancer standards in 2000 was the first ever in the country (indeed, perhaps in the world) and has not previously been used for statistical analysis. Moreover, other data sets, including Waiting Times and the Acute Hospital Portfolio were also only available for the first time at 2001-2. Apart from cancer survival, only the Hospital Episode Statistics data set was collected in the 1990s. Therefore, the study made the best use of newly available data.

- **Contemporary data**

The study used data from different sources to obtain a unique set of explanatory factors for survival. Multiple datasets have been used previously to provide more comprehensive data for the research, where a single source has only limited indicators for different domains of health care [30;87;88]. Cancer registrations of adult residents in London, who were diagnosed with colorectal cancer between 1996 and 2001, and with follow-up to the end of 2001, were available for analysis. Survival data reflect back in time[83-86], and, thus, preceded organisational data in time. However, these were the most recent available data. The chosen time frame (1996-2001) allowed sufficient numbers of cases and events (deaths) for estimation of five-year relative survival on hospital level. The other data sets reflected the time period around 2000 to 2002 (see Figure 3.1), which is the period of the start of the Cancer Plan for England.

- **Changing services**

The underlying assumption of this study was that the organisational determinants estimated in 2000-2002 were of similar value over the five years for which the cancer diagnosis made and treatment given. Unknown differences during the time periods covered by various datasets is a limitation of the study. While multi-disciplinary teams were beginning to be implemented for breast cancer during the 1990s[46], and were proposed for colorectal cancer in the Improving Outcomes Guidance for colorectal cancer in 1997[13], there is no information about their use in colorectal cancer at that time. Indeed, the development of multidisciplinary teams for most cancers, and cancer networks, followed implementation of the Cancer Plan for England.

Likewise, no comparative data were available for referral waiting time and staffing level to indicate changes (if any) in indicators between 1996 and 2001. However, average annual volume of patients admitted to NHS hospital trusts did not change from 1997/98 to 2001/02: 1997/98 – 704; 1998/99 – 655; 1999/00 – 663; 2000/01 – 653; 2001/02 – 676 (Appendix 8). While it was not feasible to assess accurately the state of organisational determinants back to 1996-1999, this study suggests that the employed methodology could be feasible for future analyses when data become available.

- **Period analysis**

A potential tool for improving temporal relationships in future research is period analysis of cancer survival data. First described by Brenner and Gefeller (1997)[316], this approach includes the most recent probabilities of death, and excludes probabilities obtained from patients diagnosed in the past, to make future calculations of survival based on contemporary data. However, the calculation of period survival is analogous to the calculation of life-expectancy at birth from a period life table: while it provides estimates of future trends, it needs cautious interpretation since it does not relate to the real experience of a specific group of patients.

5.4 Individual level determinants of survival

5.4.1 Patient case-mix

Comparisons of outcomes between hospital are very dependent on the condition of the patients admitted, that is, patient case-mix[27;67]. Risk-adjusted models have been proposed to take into account differences in severity of illness and, thus, provide more reliable estimates of observed associations[25;94-99;101-103]. However, there is a problem of knowing when adjustment of severity is sufficient[67].

Although the data obtained from the Thames Cancer Registry (TCR) were quality assured and the methods of their collection were uniform across the region, they only contain limited information on the extent (stage) of disease for each patient, and none on comorbidity. The HES dataset contains patient level information on comorbidities, number and type of intervention, method of admission (elective; emergency; other) for patients and their length of stay[68]. But at the time of the study, methods to link HES and cancer registry data at individual level had not been developed. (This work is now being undertaken[xxviii;xxix;xxx]) If successful, and available for researchers, this will provide an important new approach for survival analyses, to include patient case-mix.

No personal data on socioeconomic conditions were available for the study. However, in the absence of individual data on personal conditions, the socioeconomic status of cancer patients is routinely determined using an ecological approach. A census-derived or area-based score reflects aspects of material deprivation or socioeconomic status in the geographic area in which a person resides[278].

Whilst this study has not been able to adjust comprehensively for all factors that could affect outcome, it has attempted to adjust for the most important prognostic factors suggested in the literature[33-36;129;130;140;141]: age, stage and level of social deprivation have been accounted for. All these individual level variables were significantly associated with five-year relative survival for colorectal cancer in London and the patterns of associations observed were similar to those shown in cancer literature[35;73;85;125-128;141]. Moreover, stage is of greater prognostic importance in cancer outcomes than co-morbidity[164;167;168]. In the

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[xxviii] http://www.canceruk.net/

[xxix] http://www.nycris.org.uk/

[xxx] http://www.lshtm.ac.uk/ncdeu/cancersurvival/research/index.htm

present study, even after adjusting for stage, significant relationships were still found for some factors in the statistical analysis. In general, while epidemiological studies may always have the possibility of unknown confounding factors, either clinical or organisational, the hypothesis tested in the present analysis was based on expected predictive factors and a clear analytic model.

However, adjustments for tumour stage requires careful evaluation of the investigations used to determine the stage of disease[137;138]. Stage-specific comparisons may be biased by so-called "stage migration", or Will Rogers phenomenon[139]. Data suggest that a higher proportion of older and more deprived patients were among those with missing tumour stage (4.3). On the other hand, adjustments for age and deprivation index did not explain variations in survival by hospital trust, and the most significant explanatory value was obtained for tumour stage (4.4.1). Therefore, missing stage information (in 20.9% of patients) was one of the main limitations of this study. However, the comparison of study results using alternative methods of handling missing data (including multiple imputation of missing values) suggests that the mechanism of missing data was 'missing at random' (4.4.8). Further discussion on handling missing data and its impact on study results is provided in 5.2.2.

5.4.2 Type of surgery

The type of surgery received by colorectal cancer patients was an independent predictor of the outcome (five-year relative survival): the more radical the surgery, the better the survival. Equally, patients who only had investigations, without formal treatment, had a more than two-fold excess mortality. There were also statistically significant interactions between the type of surgical treatment, age and tumour stage. These results are expected, and concur with the findings nationally[128;131] Choice of type of surgery is strongly related to clinical characteristics at presentation, and is not an independent prognostic factor.

There were no data available to assess the influence of adjuvant therapy (radio-and chemo-therapy), which may modify the effect of the main surgical treatment. One of the explanatory variables of the difference found between hospitals was their compliance with 'clinical guidelines' standard, and this might have been led to differences in adjuvant

therapy. On the other hand, adjuvant radiotherapy and chemotherapy are recommended only for a relatively small proportion of colorectal cancer patients, particularly those with advanced stages and with rectal cancer (for radiotherapy)[37].

5.5 Organisational determinants of survival

Hospital Trusts are the standard level for analysis of much NHS administrative data and for performance management and comparison purposes[22;317;318]. However, changes in population boundaries (catchment areas) and structure of hospital trusts over time may influence the validity of comparisons between them. Also, while justification was provided (see *Materials and Methods* chapter) in allocating the hospital trust of first attendance as 'hospital of treatment', this issue remains an unresolved problem in cancer research and should be regarded as a limitation of the study.

The study shows that variability in five-year relative survival between hospital trusts in London was significant and wide ranging from 31.3% (95% CI 23.4%-39.4%) to 55.4% (95% CI 50.6%-60.0%). These differences were not completely accounted for by differences in patient case-mix: even after considering the effect of case-mix variables, there still remained unexplained variation, which may be accounted for by other factors related to the hospital.

5.5.1 Compliance with cancer standards

Clinical guidelines are commonly regarded as a means of assisting physicians in making therapeutic decisions, and compliance with guidelines was assessed in the literature mainly in relation to clinical interventions[40-43;257;258]. However, another purpose of guidelines implementation reflects organisational goals and aimed at managed care[44]. This aspect has been less explored in the literature.

Management of cancer patients intrinsically involves participation of specialists from various disciplines. The organisation and functioning of MDTs were set out in the Manual of Cancer Services Standards [14]. These standards were not evidence-based, but developed with expert opinion, current directions of cancer policy and general consensus among professionals. There were overall about 200 standards, divided into ten groups reflecting organisational characteristics of clinical services. Compliance with cancer

standards was determined by teams of health care professionals and managers in the course of peer review visits at each cancer unit and centre at NHS hospital trusts.

One of the ten groups of standards was for multi-disciplinary teams (MDT), for each of four cancer diagnoses – breast, lung, colorectal and gynaecological. There were 35 colorectal cancer specific MDT standards in the Manual and dataset.

To investigate the impact of MDT criteria on cancer survival, two approaches were considered: composite score (overall measurement for the compliance with all 35 cancer standards), and compliance with the 35 individual cancer standards. The composite score was marginally but significantly associated with five-year relative survival. While no relationship was found between compliance with majority of standards and five-year relative survival, positive independent associations with cancer survival were observed for standards defining

- the structure of MDT;
- operational policies;
- availability of patient information;
- and clinical guidelines.

However, the use of individual scores has disadvantages. There may be problems of collinearity. The individual standards reflect different aspects of care under MDT management of cancer patients: some of these aspects are described by one standard, and some by a group of standards. While all 35 standards carried equal weight in the analyses, adherence to some may have had more influence on clinical outcomes than others. For example, compliance with the 'clinical guidelines' standard is arguably more important than 'recorded attendance at MDT meetings'. Also, as indicated in this chapter above (see 5.3.3), while testing all 35 standards separately ("use of multiple testing"), the possibility to obtain associations by 'chance alone' increases.

Although all these findings could potentially have important policy implications, the strongest association was found in relation to compliance with 'clinical guidelines' standard. Even after adjustment for available case-mix indicators of age, sex, tumour stage and social deprivation, patients treated at hospital trusts which complied with 'Having a written agreement describing clinical guidelines' standard, had a 19% reduction of excess mortality compared with patients treated at hospital trusts 'not having such an agreement' (relative excess risk of death 0.81, 95% CI 0.72-0.92; p=0.001). This finding fits with the

concept that delivery of efficacious treatment can have clinical impact.

No study has previously explored the association between compliance with the published cancer standards, as assessed by national peer review, and cancer survival. However, Morris studied adherence to self-assessed MDT standards (total score) for colorectal cancer patients in 14 hospital teams in Yorkshire region (UK)[46]. The results of her study were similar to our findings. She concluded that 25% increase in adherence was related to around 8% reduction in the risk of death after one and two-year follow-up.

But compliance with 'clinical guidelines' standard reflects only the fact that clinical guidelines have been 'agreed' by MDT. Their actual adherence or implementation was not subject to the Cancer Services Peer Review, and, thus, was not considered in this study. This is true for all 35 standards assessed.

Taking into account the significant association of compliance with specific cancer standards (in particular, 'clinical guidelines' one) and survival, we can propose that hospital trusts which had 'agreed guidelines' were more likely to adhere to them in practice as compared to non-compliant trusts. However, it was not possible to validate this assumption. Nevertheless, the results of the study gave an initial indication that, if the assumption is true, compliance with 'clinical guidelines' could significantly improve population-level survival of colorectal cancer patients. This, in turn, could have important policy implications and practical impact in clinical settings, stressing the necessity to conform to guidelines to achieve better outcomes. However, these results need to be viewed within the context of the study as a whole, taking into account its weaknesses and limitations.

5.5.2 Teaching status of hospitals

Unlike in US[115;250] or Canada[254], no formal definition or taxonomy was identified in the UK for a 'teaching hospital'. In this study, teaching hospitals were defined as long-established or specialist hospitals which provide undergraduate and/or postgraduate teaching. Out of 28 hospital trusts in London providing colorectal cancer care, 11 have been classified as 'teaching' and 17 – as 'non-teaching' hospitals. The complete list is provided in the *Results* chapter.

In the literature, teaching hospitals were not shown to have consistently better outcomes compared with non-teaching hospitals[250:254-256] and there was insufficient and

equivocal evidence in relation to colorectal cancer survival[244;256]. These inconsistencies may partly be explained by various definitions employed and degree of adjustments for patient case-mix.

In this study, there was a 13% survival advantage for patients treated at teaching hospitals as compared with patients in non-teaching hospitals. The definition of 'teaching hospital' employed, and subsequent division of hospitals into two groups, was a practical way to examine the effect of teaching status on the outcomes of care. In fact, our grouping of teaching and non-teaching hospitals was similar to the categorisation of hospital trusts employed by the Healthcare Commission[xxxi]. It would be useful for any future studies in the UK to use a unified and agreed formal definition of 'teaching hospital', to get more repeatable results.

Behind from the identify of a 'teaching' hospital itself, there are structures and processes of care which, according to the literature and common knowledge, may be important determinants of outcomes of care. Possible explanations of the observed variations may include differences in the process of care in teaching and non-teaching hospitals involving greater use of multidisciplinary teams in teaching hospitals, and differences in resources[214;249-252]. However, incomplete adjustment for case-mix; different patterns of detection; referral or artefact of misclassification of cases by disease stage may also play role in the observed differences.

Teaching hospitals may also be more likely to adhere to clinical guidelines than non-teaching hospitals[246;261]. Our analyses showed that 50% of teaching hospitals were in compliance with the 'clinical guidelines' standard, while only 27% of non-teaching hospitals did comply with it. In addition, there was a statistically significant correlation between teaching status of hospitals and compliance with the 'clinical guidelines' standard. There was also a statistically significant correlation between teaching status and hospital volume. However, lack of significant survival impact of the volume effect may suggest that factors associated with teaching status of hospitals play a more important role. These issues need further investigation.

[xxxi] http://ratings2004.healthcarecommission.org.uk/Downloads/acute_clusters.xls

5.5.3 Staffing level

No study was identified that had examined the relationships between different levels or types of staffing and cancer survival. Evidence from other fields suggests that doctor and nurse staffing may have an impact on postoperative mortality and complications[20;212;213].

A national study in England concluded that medical staffing level was one of the main predictors of risk-adjusted mortality across 183 hospital trusts in England[22]. It was therefore included as a predictive variable in the present study. However, no relationship was found between indicators of staffing level and five-year relative survival. It is of note that the indicators were not cancer specific but rather reflected general staffing at hospital trusts.

On the other hand, colorectal cancer patients were usually managed by general, rather than colorectal cancer-specific staff. Overall, the development of cancer-specific specialisation was not in place for a time frame referred in the thesis. Also, only limited number of hospital trusts (5 to 12, depending on standard) were in compliance with three 'colorectal nurse specialist qualification' related standards in a peer review assessment in 2001 (see *Results* chapter, Table 4.27). Compliance with these standards was not shown to be associated with five-year relative survival. In addition, no dataset for cancer-specific staffing was available for the study purposes.

Therefore, staffing level data which were available for the study could only be viewed as a proxy for true staffing. Since the Cancer Plan for England proposed increases in specialist cancer staff, both medical and nursing, as a major area of clinical improvement, it would be appropriate in future research to investigate the independent effect of staffing levels on colorectal cancer survival.

5.5.4 Volume

This study found no relationship between average annual volume of patients treated at NHS hospital trust and five-year relative survival. There is conflicting research evidence about the potential benefits of care provided by high-volume providers, specialists or in specialists units, compared with that provided by low-volume providers and non-specialists. A systematic review of 'improving outcome' for colorectal cancer

commissioned by the National Institute for Health and Clinical Excellence (NICE) showed a strong association of higher volume with better outcomes for rectal cancer, but little or no effect for colon cancer[37].

Generally, several studies in the literature emphasise that volume can be covariate for other factors more critical to patient care, including high volume hospitals may have more surgeons who specialise in specific procedures, more consistent processes for postoperative care[224]; better staffed intensive care units, and greater resources, in general, for dealing with postoperative complications[228]; physicians who use effective treatments, eg adjuvant chemotherapy, more often than their low-volume counterparts[226;227]. However, many volume-outcome studies, including a study by Ko et al[229], indicated the issue of 'reverse causality': one cannot be sure that hospitals get good results because they are high-volume, or whether hospitals with good results consequently become high-volume.

The current study used HES data to identify the average annual number of patients treated at the hospital trusts for1997-2001. (It was not until 1997 that HES started assigning unique patient identifiers, which distinguish individual patients over different episodes of care or multiple admissions within a year, thus preventing their over-counting.) Moreover, in the present research, unlike many other reported studies, 'volume' refers not only to surgical patients (although they constituted majority) but to all colorectal cancer patients admitted to the hospital. This gave compatibility with the cancer registry survival data set, which included all cancer patients regardless the type of treatment received.

Another important factor is that volume (workload) cut-off points were arbitrary, and based on statistical factors (see *Materials and Methods* chapter). However, there is no consensus or agreed definitions on appropriate volumes or caseloads (hospital- and surgeon-specific) for colorectal cancer patients[37;38]. The only figure suggested in the literature was from a study by Hermanek & Hohenberger, who proposed monthly average of between one and two radical resections for colorectal cancer as a minimum[319].

The lack of association between hospital volume of patients and survival might partly be explained because admission rates to hospital trusts in London are above some 'critical' minimum volume level, so that all of them 'complied' with a (lower) 'volume standard' (say, more than 100 patients per year). The average annual volume of patients for these trusts varied from 150 to 2525 patients a year (see Appendix 8,), while in majority of literature studies hospital volume ranged from 17 to 55 cases a year[232;320-323].

5.5.5 Specialists

The study had no specific measure of individual specialist care, but the literature, mainly supports the belief that specialist care improves patient outcomes[230;233-238;244]. Outcomes following specialist treatment appear to be independent of case-mix [227;235].

Specialisation in relation to cancer surgery has been implemented widely in the management of breast cancer patients in England. In contrast, the move towards surgical site-specialisation in colorectal cancer has been slower and many colorectal cancer patients during the period of this study would have been operated on by general surgeons.

It is not clear what constitutes 'sufficient' experience for a colorectal specialist. Comparisons will depend on the frequency of the adverse event of interest. For example, to accurately assess inter-surgeon variation in peri-operative mortality, around 150 cases for each surgeon will be required[324]. The lack of formal accreditation means that there is no way of assessing the experience of a surgeon. A colorectal surgeon is (only) 'expected' to attend the MDT meeting, to be a member of the specialist association and to contribute to local and national audit of their colorectal cancer work[172].

Although this study could not investigate specialisation, the likely benefit of patients being treated by specialists, as shown in the literature[230;235;236;244], suggests that this issue needs to be addressed in future research.

5.5.6 Waiting time

Meeting 'two week wait' target by hospital trusts in London was not found to be associated with five-year relative survival for colorectal cancer patients. There may be several reasons for this finding.

No primary study was identified to investigate the associations between waiting times and colorectal cancer survival. Analysis of this association was carried out within the framework of current study.

Various studies have described the so called 'waiting time paradox': patients with longer waiting times generally have less advanced disease and better survival[265-268]. The traditional view is that delay caused by organisational deficiencies has an adverse effect on the disease and this influences survival. As a possible explanation of these trends, it was

suggested that patients with advanced disease were 'fast-tracked' by GPs and hospitals, and had shorter delays. Also, consultants may be able to differentiate patients at greater risk and to ensure faster diagnosis and treatment. On the other hand, due to severity of condition, survival of 'fast-tracked' patients was poor, affecting overall outcome among patients received prompt treatment within the target.

In addition, the 'two week wait' target does not necessarily reflect the process of care of cancer patients alone. The review of Cancer Waiting Times Statistics[325] showed that the majority of patients urgently referred by GPs with suspected cancer do not have cancer. (See Appendix 10: for data from quarter 3 in 2005/2006, there were 141052 two-week wait referrals for all patients with suspected cancer, but in the same period only 17137 patients (12.15%) received treatment for cancer within the two month wait standard.) Moreover, a substantial proportion of all colorectal cancer patients are diagnosed by other pathways, not 'urgent' GP referral. Thus, lack of association found in this study was expected from by other studies.

The Department of Health changed its targets for NHS hospital trusts from 95% achievement of two-week wait standard to 98% from 2004, since most hospitals had complied with the standard by that time. Also, from the quarter 4, 2004/2005 they began monitoring a one-month wait target from diagnosis to treatment, and a two-month wait target from GP urgent referral to treatment for all cancers (i.e. moving from delay in GP referral to delay in diagnosis and treatment). The impacts of these new measures on survival remain to be seen and should be ascertained in future research.

CHAPTER 6

CONCLUSION

6 CONCLUSION

6.1 Overview

There is a growing interest in defining and measuring health care outcomes, both to achieve intrinsic improvements in health care and also to demonstrate cost-effectiveness. These perspectives have stimulated new approaches to using routinely collected, administrative/clinical data for outcome research[65]. Yet, even though the field of quality measurement is nearly 20 years old, experts disagree about how adequately the quality of care can be measured today[249]. Although outcome measures may be used as evidence for quality of care, outcomes do not indicate directly how care might be improved[326].

Donabedian's model remains central in thinking about quality of health care[29;50;51]. However, structure, process and outcome are not themselves attributes of quality. They are only attributes and measures from which one can infer that quality is good or not. Inferences about quality examine the relation among the three dimensions, so that structure influences process and process influences outcomes. But this is a much simplified version of a much more complex reality, and it is somewhat arbitrary to say where "structure" ends and "process" begins.

One of the main limitations of research using routine data is the lack of information about important confounding factors (with the exception of age and sex). Case-mix adjustment has been shown to be important for comparisons of hospitals and specialists. In cancer care, stage is an important attribute for prognosis, but there is doubt about the reliability of the measurement of stage. Stage level increases with the amount of investigation (eg number of lymph nodes examined pathologically, scanning of distant organs), so that hospitals with similar patients may report different stage levels. For this reason, it is not necessarily helpful for health services research (in contrast with clinical studies) to compare hospital outcomes by stage, unless there are standardised definitions. Differences in recording of additional diagnoses may equally limit the use of co-morbidity as a prognostic factor.

Administrative datasets were not designed to assess quality of care or patients outcomes.

They were developed to answer administrative questions. For this reason, they are probably most useful as screening tools that highlight areas in which quality should be investigated in greater depth[30]. However, with additional clinical data, either incorporated within the existing datasets or through the linkage to other sources of data, opportunities for asking questions about quality of care and looking at patient outcomes now exist.

- **'Ideal' dataset**

'Ideal' datasets, to quote Iezzoni[30], should contain adequate clinical information "generated not only by clinicians and electronic reporting systems (such as those in laboratories and pharmacies) but also by patients." Additional sets of data, particularly those reflecting palliative care, screening activities and health behaviour (smoking; diet; physical exercise and so on), should be incorporated too, when available and appropriate, to enhance the analytical potential of datasets. Linking primary care and hospital datasets will enhance their capabilities to capture patient pathway including prevention, diagnosis, treatment, rehabilitation and patient education. Nationally approved codes should be used across the datasets to ensure feasibility of their linkage. There should be unified definitions of similar variables contained across the national datasets with explicit coding rules stated. Clinicians should participate in these efforts and ensure that ultimate coding schemes are clinically meaningful. Also, continuous validation at source (e.g. through audit or case-note studies) and external validations with other related data sources should be conducted to ensure their accuracy.

This issue is high on the current agenda for cancer information policy in England, and present study may assist in future developments. Particularly, NHS Connecting for Health[xxxii] initiative came into operation in April 2005 as an agency of Department of Health. It aims to combine information from different sources within the NHS into a single structure. Among the main priorities of this initiative is to link GP and hospital data sets and give patients access to their personal health information.

[xxxii] http://www.connectingforhealth.nhs.uk/

- **Main findings**

This study has tested the hypothesis that hospital organisational factors contribute to survival at population level independently of individual patient factors. It also assessed the feasibility of using secondary data about the hospitals for these purposes.

Particularly, study shows that secondary data on various hospital level organisational determinants of cancer survival exist, although there is lack of some disease-specific indicators (e.g. cancer-specific staffing) which hinders more robust testing of possible explanatory associations. It was feasible to draw data together and analyse it. However, conclusion on statistical methods must include reservations due to limitations in temporal relationships, incomplete adjustments for confounding factors, and concerns over data accuracy. In general, literature shows that despite limitations, authors continue using routine data sets for explanatory purposes to draw tentative conclusions which need to be tested again in other settings, with indicated further research implications.

Several possible factors indicated in the literature have not proved to be supported by the study – including hospital volume, delay (waiting-time) and staffing levels. On the other hand, two dimensions have proved to be statistically associated: teaching hospital status and compliance with a small number of cancer service standards, especially use of guidelines.

The Cancer Plan for England was created, in part, with the knowledge from Eurocare-1 that England appeared to have poorer survival, and – along with significantly higher levels of NHS funding – set about improving organisation (eg through multi-disciplinary teams), and practice (eg through waiting time targets). The Cancer Plan for England is currently under mid-term review. The present study raises the question which organisational interventions will in fact improve survival. Staffing at a general level was not associated with survival, nor waiting times, nor hospital volume, whereas academic hospital status, and some elements of cancer standards, appeared to be related. There are of course reservations from the design of this study, both in its cross-sectional associations rather than longitudinal relationships, and in the limits of investigating co-variants. However, most importantly, the study shows that research is able to investigate dimensions of the organisation of cancer services that are part of public policy. It would therefore be appropriate for further research

to be commissioned which looks in greater detail at the issues identified by this feasibility study, and seeks to determine whether the investments and changes in cancer services over the past decade in England have been successful – and thus to provide lessons for future practice.

6.2 Implications for future research

- This study shows that it is feasible to use national data which reflect dimensions of structure and process to monitor the impact of changing service provision. However, it also demonstrates limited feasibility in terms of limitations of inferences while using routine databases for explanatory purposes. A larger number of hospitals would give greater power. New ways could also be used to adjust for case-mix, for example by linking HES data and cancer registry data at individual level.

- The present study used data in cross-sectional form at the start of implementation of the Cancer Plan for England. Further research could repeat this analysis using longitudinal data, relating changes in cancer survival at hospital level with changes in organisational characteristics. This would allow proper accounting of temporal relationships between compliance with standards and cancer survival.

- It would be useful to investigate the possibilities of using other methodological approaches designed to deal with hierarchical data (e.g. multilevel modelling) and allow calculating more current survival estimates (e.g. period analysis).

- Further investigations into variations in treatment, and implementation of MDT practice, provided in different hospitals and its effect on cancer survival would be desirable. More detailed treatment information, including adjuvant therapy, would enable outcomes to be assessed, fully accounting for treatment impact. Such data are becoming available through the national audit procedures, and would form an important opportunity for collaboration.

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APPENDICES

Appendix 1

Table A1 Distribution of DCO cases by hospital trust

Hospital trust	No. of patients	No. of deaths	Relative Survival (%)	DCO cases	
				No.	%
A	1443	760	39.49	56	3.74
B	856	470	42.41	25	2.84
C	506	255	41.75	12	2.32
D	664	346	41.61	24	3.49
E	337	169	46.23	17	4.80
F	308	180	35.63	4	1.28
G	614	315	46.72	5	0.81
H	638	367	37.06	27	4.06
I	505	271	31.27	55	9.82
J	420	233	43.29	5	1.18
K	298	154	40.19	4	1.32
L	403	206	45.11	10	2.42
M	657	339	43.24	11	1.65
N	605	316	47.13	21	3.35
O	378	211	34.74	12	3.08
P	287	172	37.65	31	9.75
Q	1173	525	55.44	24	2.00
R	559	295	42.98	7	1.24
S	538	287	41.25	11	2.00
T	561	272	51.32	16	2.77
U	632	335	44.14	17	2.62
V	364	171	45.90	18	4.71
W	443	245	39.78	12	2.64
X	596	256	50.14	5	0.83
Y	423	221	44.03	16	3.64
Z	397	194	46.64	6	1.49
AA	291	165	40.73	33	10.18
BB	569	329	43.04	14	2.40

* based on analysis of the Thames Cancer Registry data

Appendix 2

Table A2 Relative frequencies of age group distribution by hospital trust in London (1996-2001)*

Hospital trust	Five-year relative survival, %	Age groups, years					
		15-39	40-49	50-59	60-69	70-79	80-99
Q	55.44	2.81	4.60	13.30	25.49	29.07	24.72
T	51.32	2.67	3.21	14.62	22.46	34.94	22.10
X	50.14	6.54	7.89	20.47	26.17	27.35	11.58
N	47.13	1.49	4.79	8.26	26.12	33.55	25.79
G	46.72	1.63	2.44	10.10	20.20	36.16	29.48
Z	46.64	2.52	4.03	10.83	26.70	34.01	21.91
E	46.23	2.97	5.34	14.24	20.18	31.75	25.52
V	45.9	2.75	5.22	10.71	27.20	32.42	21.70
L	45.11	2.73	5.96	10.17	27.05	32.75	21.34
U	44.14	2.06	4.75	13.29	21.04	33.23	25.63
Y	44.03	2.60	4.02	12.29	25.06	34.28	21.75
J	43.29	1.19	3.33	9.76	24.76	34.29	26.67
M	43.24	0.76	3.65	9.74	20.09	32.27	33.49
BB	43.04	1.93	3.51	10.37	19.86	33.57	30.76
R	42.98	1.25	3.76	9.30	24.69	37.03	23.97
B	42.41	1.99	2.57	10.63	21.96	32.24	30.61
C	41.75	2.37	6.72	13.04	26.68	34.19	17.00
D	41.61	1.05	2.86	9.79	24.10	36.75	25.45
S	41.25	0.56	2.97	10.59	24.35	35.69	25.84
AA	40.73	1.72	2.75	8.93	24.05	33.33	29.21
K	40.19	2.68	6.38	11.41	20.47	34.56	24.50
W	39.78	2.71	4.51	12.64	25.96	32.05	22.12
A	39.49	1.94	4.23	10.53	24.81	35.90	22.59
P	37.65	2.79	5.57	14.63	24.74	32.40	19.86
H	37.06	2.51	5.02	11.44	25.24	35.42	20.38
F	35.63	3.57	3.90	13.31	20.45	29.22	29.55
O	34.74	2.65	4.76	9.52	26.46	36.24	20.37
I	31.27	2.57	4.36	15.45	27.33	30.10	20.20

* based on analysis of the Thames Cancer Registry data

Appendix 3

Table A3 Relative frequencies of sex distribution by hospital trust in London (1996-2001)*

Hospital trust	Five-year relative survival, %	Sex	
		Male	Female
Q	55.44	51.92	48.08
T	51.32	49.02	50.98
X	50.14	55.20	44.80
N	47.13	48.43	51.57
G	46.72	45.44	54.56
Z	46.64	51.13	48.87
E	46.23	51.34	48.66
V	45.9	56.59	43.41
L	45.11	52.61	47.39
U	44.14	53.64	46.36
Y	44.03	50.83	49.17
J	43.29	54.52	45.48
M	43.24	47.49	52.51
BB	43.04	52.72	47.28
R	42.98	52.59	47.41
B	42.41	51.29	48.71
C	41.75	58.70	41.30
D	41.61	49.55	50.45
S	41.25	51.30	48.70
AA	40.73	48.80	51.20
K	40.19	54.70	45.30
W	39.78	53.95	46.05
A	39.49	50.87	49.13
P	37.65	49.13	50.87
H	37.06	54.23	45.77
F	35.63	54.22	45.78
O	34.74	48.94	51.06
I	31.27	54.65	45.35

* based on analysis of the Thames Cancer Registry data

Appendix 4

Table A4 Relative frequencies of distribution by social deprivation (IMD 2000, income quintile), by hospital trust in London (1996-2001)*

Hospital trust	Five-year relative survival, %	IMD 2000, income quintile				
		1	2	3	4	5
Q	55.44	6.31	15.69	30.86	32.99	14.15
T	51.32	5.53	19.79	32.62	21.21	20.86
X	50.14	27.68	18.62	18.12	22.15	13.42
N	47.13	10.41	17.85	19.83	37.69	14.21
G	46.72	32.74	25.73	18.08	11.24	12.21
Z	46.64	3.78	13.35	7.56	14.61	60.71
E	46.23	19.88	19.88	16.62	35.91	7.72
V	45.9	2.75	16.48	17.86	18.13	44.78
L	45.11	1.24	5.71	1.49	24.57	67.00
U	44.14	10.13	17.09	28.96	32.59	11.23
Y	44.03	0.71	3.55	20.09	5.20	70.45
J	43.29	14.52	20.24	22.14	40.48	2.62
M	43.24	43.38	32.88	17.05	3.81	2.89
BB	43.04	2.46	11.60	17.22	37.79	30.93
R	42.98	3.04	7.33	16.64	14.85	58.14
B	42.41	8.06	25.70	30.72	24.65	10.86
C	41.75	0.99	3.36	4.94	6.92	83.79
D	41.61	51.66	6.78	17.47	18.83	5.27
S	41.25	22.30	32.71	17.29	16.36	11.34
AA	40.73	33.33	5.50	15.81	37.11	8.25
K	40.19	0.00	0.00	0.34	1.34	98.32
W	39.78	0.45	0.23	8.35	35.21	55.76
A	39.49	9.01	15.04	21.76	18.85	35.34
P	37.65	0.70	1.39	9.06	16.72	72.13
H	37.06	4.70	2.98	4.23	20.06	68.03
F	35.63	4.87	6.49	16.56	51.30	20.78
O	34.74	0.26	0.53	1.59	0.00	97.62
I	31.27	8.51	15.45	14.65	34.65	26.73

* based on analysis of the Thames Cancer Registry data

Appendix 5

Table A5 Relative frequencies of tumour stage distribution by hospital trust in London (1996-2001)*

Hospital trust	Five-year relative survival, %	Tumour stage				
		I	II	III	IV	Not Known
Q	55.44	25.92%	21.40%	19.27%	21.99%	11.42%
T	51.32	18.36%	20.14%	18.54%	20.68%	22.28%
X	50.14	2.68%	7.21%	6.21%	5.54%	78.36%
N	47.13	23.97%	14.55%	22.98%	21.49%	17.02%
G	46.72	21.34%	28.01%	24.27%	22.31%	4.07%
Z	46.64	32.49%	5.04%	18.64%	18.39%	25.44%
E	46.23	11.28%	16.62%	14.84%	24.04%	33.23%
V	45.9	22.80%	21.43%	23.63%	21.43%	10.71%
L	45.11	13.15%	27.79%	17.62%	22.58%	18.86%
U	44.14	19.78%	25.47%	22.15%	21.84%	10.76%
Y	44.03	37.59%	12.06%	17.49%	20.80%	12.06%
J	43.29	30.48%	14.76%	20.48%	23.57%	10.71%
M	43.24	19.63%	26.79%	23.59%	21.31%	8.68%
BB	43.04	45.17%	5.27%	22.32%	23.37%	3.87%
R	42.98	28.44%	22.72%	23.08%	20.21%	5.55%
B	42.41	16.36%	23.36%	18.22%	21.96%	20.09%
C	41.75	11.07%	15.02%	9.49%	28.46%	35.97%
D	41.61	8.89%	18.07%	10.09%	21.39%	41.57%
S	41.25	8.36%	23.23%	9.85%	26.95%	31.60%
AA	40.73	14.78%	14.43%	22.68%	22.34%	25.77%
K	40.19	15.77%	6.71%	3.36%	29.53%	44.63%
W	39.78	24.83%	26.19%	19.19%	21.44%	8.35%
A	39.49	22.04%	19.89%	19.40%	21.62%	17.05%
P	37.65	12.89%	21.60%	21.25%	21.95%	22.30%
H	37.06	13.48%	26.80%	22.10%	21.16%	16.46%
F	35.63	13.64%	25.65%	17.86%	27.92%	14.94%
O	34.74	13.76%	6.88%	2.91%	33.33%	43.12%
I	31.27	14.06%	19.80%	22.77%	22.57%	20.79%

* based on analysis of the Thames Cancer Registry data

Appendix 6

Table A6 Relative frequencies of type of treatment (surgery) distribution by hospital trust in London (1996-2001)*

Hospital trust	Five-year relative survival, %	Type of treatment					
		Total removal of organ	Partial removal of organ	Tumour/lymph node removal or exclusion	Non-tumour removing surgery	Investigative procedure only	Not Known
Q	55.44	17.73%	54.05%	7.08%	3.50%	10.23%	7.42%
T	51.32	22.28%	50.09%	8.02%	0.71%	10.16%	8.73%
X	50.14	4.70%	16.11%	1.85%	20.97%	1.34%	55.03%
N	47.13	13.55%	59.83%	4.96%	7.11%	6.61%	7.93%
G	46.72	17.10%	57.17%	4.89%	4.40%	10.10%	6.35%
Z	46.64	13.10%	51.64%	15.87%	0.76%	11.59%	7.05%
E	46.23	20.77%	47.18%	10.68%	5.04%	9.20%	7.12%
V	45.9	12.64%	56.59%	12.64%	2.20%	11.26%	4.67%
L	45.11	12.16%	55.33%	7.20%	2.98%	9.68%	12.66%
U	44.14	15.51%	50.95%	13.29%	2.06%	9.81%	8.39%
Y	44.03	16.55%	57.45%	11.82%	3.07%	4.96%	6.15%
J	43.29	20.71%	49.05%	5.48%	5.00%	12.62%	7.14%
M	43.24	19.03%	57.38%	5.63%	3.96%	6.70%	7.31%
BB	43.04	18.80%	52.55%	8.44%	6.50%	5.98%	7.73%
R	42.98	19.32%	50.63%	9.84%	1.43%	8.05%	10.73%
B	42.41	16.71%	58.18%	6.31%	2.57%	5.96%	10.28%
C	41.75	24.51%	39.92%	12.06%	1.19%	11.46%	10.87%
D	41.61	18.98%	43.37%	8.13%	2.56%	10.09%	16.87%
S	41.25	17.10%	51.12%	9.67%	1.30%	8.36%	12.45%
AA	40.73	14.78%	49.48%	9.28%	1.37%	8.25%	16.84%
K	40.19	28.19%	38.93%	10.40%	2.01%	10.40%	10.07%
W	39.78	17.61%	45.37%	13.09%	1.81%	9.26%	12.87%
A	39.49	21.21%	51.91%	8.11%	4.16%	7.00%	7.62%
P	37.65	21.25%	47.39%	3.83%	5.23%	4.18%	18.12%
H	37.06	15.67%	48.28%	8.93%	3.13%	9.87%	14.11%
F	35.63	20.45%	45.78%	5.52%	3.57%	8.77%	15.91%
O	34.74	32.80%	35.98%	10.05%	1.59%	13.23%	6.35%
I	31.27	15.64%	45.94%	11.49%	1.78%	9.70%	15.45%

* based on analysis of the Thames Cancer Rregistry data

Appendix 7

Table A7 Medical, ward and radiology staffing level for hospital trusts in London (2000/2001-2001/2002 financial years)*

Hospital trust	Medical WTE per 1000 admissions	Consultant WTE per 1000 admissions	Medicine consultant WTE per 1000 admissions	Anaesthetist consultant WTE per 1000 admissions	Pathology consultant WTE per 1000 admissions	Radiology consultant WTE per 1000 admissions	Radiographers per 1000 FCEs	Clinical nurse specialists WTE per 1000 admissions
A	5.17	1.73	1.55	0.77	1.00	1.76	0.78	0.77
B	6.01	2.12	2.11	0.85	1.88	2.04	0.71	0.39
C	8.83	2.54	1.83	1.47	3.06	2.13	1.12	N/A
D	N/A	N/A	N/A	N/A	N/A	N/A	0.69	N/A
E	7.54	2.49	1.88	1.00	0.00	1.90	0.86	0.70
F	5.58	1.79	1.42	0.94	1.53	1.46	0.99	0.93
G	7.33	2.49	1.63	0.75	3.17	2.27	1.09	0.50
H	8.41	3.18	2.17	1.65	2.08	2.83	0.89	0.57
I	7.47	2.63	2.05	1.35	3.48	2.57	0.78	0.37
J	5.97	1.92	1.68	0.89	1.47	2.06	0.78	0.06
K	7.09	2.06	2.55	1.64	1.22	1.22	0.94	0.54
L	9.22	3.58	2.92	1.94	3.37	2.42	1.00	0.73
M	7.45	2.91	1.63	1.27	3.21	3.31	0.90	0.23
N	5.95	2.16	2.33	0.95	2.36	2.05	0.69	0.77
O	5.22	1.75	2.30	1.12	1.18	0.37	0.74	0.58
P	6.40	2.04	1.60	1.01	2.92	2.46	0.71	0.87
Q	N/A	2.45	2.27	0.89	1.78	2.44	0.75	N/A
R	N/A	1.94	1.60	0.78	2.47	1.76	0.98	0.51
S	4.96	1.63	1.58	0.98	1.66	0.03	0.64	0.59
T	N/A	N/A	N/A	N/A	N/A	N/A	1.24	0.32
U	9.56	3.25	2.73	1.48	3.18	2.80	0.66	0.48
V	8.54	3.18	2.07	1.30	3.60	2.28	0.67	0.96
W	6.04	2.45	1.95	1.06	3.50	1.56	0.70	0.82
X	6.51	2.33	0.85	2.65	3.23	6.50	0.95	2.31
Y	6.52	2.26	2.34	1.31	2.00	2.17	N/A	0.65
Z	N/A	N/A	N/A	N/A	N/A	N/A	1.48	0.50
AA	8.21	2.62	1.59	1.03	3.02	2.59	0.95	0.74
BB	5.53	2.11	2.08	0.82	1.84	1.02	0.74	N/A

* based on analysis of Acute Hospital Portfolio

Appendix 8

Table A8 Average annual volume of patients per hospital trust in London (1997/1998-2001/2002 financial years)*

Hospital Trust	No. of patients per year					Average annual number of patients
	1997/98	1998/99	1999/00	2000/01	2001/02	
A	1474	1463	1498	1463	1556	1491
B	644	623	663	747	333	602
C	1159	1098	1025	1068	1098	1090
D	N/A	N/A	N/A	N/A	N/A	N/A
E	177	191	176	237	446	245
F	242	237	225	283	281	254
G	574	539	N/A	744	650	627
H	1189	1203	1215	1190	1229	1205
I	1582	1413	1458	1489	1613	1511
J	234	263	296	281	358	286
K	124	117	163	170	176	150
L	353	322	396	372	366	362
M	256	244	380	411	403	339
N	413	368	481	389	368	404
O	348	301	320	292	305	313
P	864	823	828	720	725	792
Q	770	742	606	219	478	563
R	387	441	477	415	N/A	430
S	275	297	352	351	348	325
T	425	478	518	500	500	484
U	1039	925	839	882	777	892
V	1469	737	573	590	511	776
W	273	308	333	271	239	285
X	2558	2457	2342	2502	2768	2525
Y	416	371	357	362	363	374
Z	900	814	836	834	803	837
AA	311	307	267	255	281	284
BB	549	592	620	593	613	593

* based on analysis of HES dataset

Appendix 9

Temporal trends in colorectal cancer survival in London

The recent ONS reports on trends in survival for eight common cancers in England present data on colon cancer survival rates for adult patients resident in each of the government office regions and strategic health authorities in England (including London), who were diagnosed over different time periods during 1994-1999 and followed up to the end of 2001-2004[xxxv]. Table A9.1 below indicates one- and five-year relative survival rates with 95% confidence intervals.

Table A9.1 One-year and five-year relative survival estimates (England and London) for colon cancer patients, by year of diagnosis and follow-up (based on ONS reports)[xxi]

Year of diagnosis and follow-up (fu)		Men				Women			
		One-year relative survival		Five-year relative survival		One-year relative survival		Five-year relative survival	
	Place	%	95% CI	%	95% CI	%	95% CI	%	95% CI
1994-96; fu 31/12/ 2001*	England	66.2	65.6 - 66.9	43.6	42.7 - 44.4	64.3	63.6 - 65.0	44.6	43.8 - 45.4
	London	68.9	66.8 - 71.1	43.6	40.9 - 46.3	66.0	63.9 - 68.1	45.2	42.7 - 47.8
1995-97; fu 31/12/ 2002**	England	66.2	64.8 - 67.5	43.0	41.3 - 44.7	66.2	64.9 - 67.5	44.9	43.4 - 46.5
	London	68.0	63.8 - 72.2	41.3	36.1 - 46.5	67.2	63.3 - 71.2	44.5	39.6 - 49.4
1996-98; fu 31/12/ 2003***	England	67.3	66.0 - 68.6	46.8	45.1 - 48.5	66.9	65.6 - 68.1	47.5	46.0 - 49.0
	London	68.5	64.4 - 72.6	44.9	39.6 - 50.2	68.3	64.5 - 72.0	48.1	43.4 - 52.8
1997-99; fu 31/12/2004****	England	67.8	66.5 - 69.0	48.3	46.6 - 50.0	67.3	66.0 - 68.5	48.8	47.3 - 50.4
	London	67.1	63.1 - 71.1	45.1	39.9 - 50.2	67.3	63.6 - 71.0	47.3	42.6 - 52.0

*http://www.statistics.gov.uk/downloads/theme_health/SurvivalRatesbySHA2001Data.xls
**http://www.statistics.gov.uk/downloads/theme_health/SurvivalRatesbySHA2002Data.xls
***http://www.statistics.gov.uk/downloads/theme_health/SurvivalRratesbySHA2003Data.xls
****http://www.statistics.gov.uk/downloads/theme_health/SurvivalRatesbySHA2004Data.xls

Caution is required in the interpretation of any apparent changes in the rates over consecutive time periods since they overlap for two years. For example, 1995-97 period includes two years (1996 and 1997) from the previous period 1994-96 and so on. However, if we compare survival of patients diagnosed in 1994-96 vs. 1997-99, the following trends may be noticed:

1. There appear to be significant differences in survival nationally, with both one-year

[xxxv]ONS. Cancer Survival in England by Strategic Health Authority.

Source: http://www.statistics.gov.uk/statbase/Product.asp?vlnk=11991

and five-year relative survival estimates improved for patients diagnosed in 1997-1999 as compared to patients diagnosed in 1994-1996 years.

2. In contrast to national figures, survival rates for London improved to the lesser extent and were apparent particularly for five-year survival. However, there were no significant changes in survival over time (1994-96 vs. 1997-99) for London.
3. There were no significant differences in survival rates between men and women across the time periods, for England and London.

Similar analyses, based on TCR data available for the study, did not show significant time trend in London survival over time, for example, between two-year relative survival for 1996-98 vs. 1999-2000 (see Table A9.2). There was no significant difference in survival by sex (see Table 4.15); therefore, the Table A9.2 below presents combined survival (male and female).

Table A9.2 One-year and two-year relative survival estimates for colorectal cancer patients in London, by year of diagnosis (based on TCR data available for the study)

Year of diagnosis	One-year relative survival			Two-year relative survival		
	Relative survival (%)	95% Confidence Interval		%)	95% CI	
1996	72.74	70.73	74.63	62.02	59.81	64.15
1997	69.51	67.53	71.40	58.31	56.17	60.39
1998	69.53	67.57	71.39	59.23	57.11	61.28
1999	68.53	66.54	70.43	58.33	56.2	60.40
2000	70.77	68.88	72.57	-	-	-
1996-1998	**70.53**	**69.39**	**71.63**	**59.79**	**58.56**	**61.00**
1997-1999	69.19	68.06	70.29	58.63	57.41	59.83
1998-2000	69.64	68.53	70.72	58.56	57.31	59.78
1999-2000	**69.69**	**68.33**	**71.01**	**58.11**	**56.55**	**59.63**

However, for small area cancer survival statistics (London vs. England), caution is required in the interpretation both of the survival rates themselves and particularly of any apparent changes in the rates over time. The survival rates, even when based on cases accumulated over a three or two-year period, therefore have considerable uncertainty, as indicated by relatively wide confidence intervals.

Appendix 10

Table A10. The relationship between 'two week' and 'two month' waiting time standards for all cancers*

Time period	Total number of two week referrals within the quarter	Patients who were treated for cancer within the quarter under two month standard	
		Total number	Percentage (out of two week referrals)
Quarter 4, 2005/2006	142055	18401	12.95
Quarter 3, 2005/2006	141052	17137	12.15
Quarter 2, 2005/2006	145137	16028	11.04
Quarter 1, 2005/2006	142153	14299	10.06
Quarter 4, 2004/2005	117942	12114	10.27

* based on analysis of Cancer Waiting Times Statistics
(source: http://www.performance.doh.gov.uk/cancerwaits/2006/q1/archive.html)

Appendix 11

ACUTE HOSPITAL PORTFOLIO
Data Quality Assessment[xxxvi]

GENERAL ASPECTS

Background information

The Acute Hospital Portfolio (AHP) is a collection of ongoing audit reviews (not cancer-specific) that are undertaken at acute and specialist hospital trusts by former Audit Commission (currently Healthcare Commission). They focus on key service areas or resources within the hospital trust that are of concern to trust managers and patients.

The following national reviews have been published (or being undertaken) by Audit Commission/Healthcare Commission (indicated years are 'financial' years – 1st of April to 31st of March):

1. Accident and Emergency 2000/01; 2004/05
2. Admissions Management 2005/06
3. Bed Management 2002/03
4. Catering 2000/01
5. Day Surgery 2000/01; 2004/05
6. Diagnostic Services 2005/06
7. Facilities Management 2003/04
8. Information and Records 2003/04
9. Medical Staffing 2001/02
10. Medicines Management 2001/02; 2005/06
11. Operating Theatres 2002/03
12. Outpatients 2002/03
13. Pathology 2003/04
14. Procurement and Supply 2001/02
15. Radiology 2001/02

[xxxvi] *Based on Directory of Clinical Databases (DoCDat) format (http://www.lshtm.ac.uk/docdat/page.php?t=index).*

16. Therapy and Dietetics 2003/04
17. Waiting for Elective Admission 2002/03
18. Ward Staffing 2000/01; 2004/05

Source: former Audit Commission (currently Healthcare Commission)
http://www.healthcarecommission.org.uk/InformationForServiceProviders/GuidanceForNHS/Guidance/fs/en?CONTENT_ID=4006400&chk=2NeKOQ
and
http://www.healthcarecommission.org.uk/InformationForServiceProviders/ReviewsAndInspections/AcutePortfolio/fs/en):

Reference population

Common circumstance that determines inclusion in the database:
All NHS acute hospital trusts are covered by the dataset.

Geographical area covered by the database:
England and Wales.

Time period covered by the database:
2000/2001 - ongoing, depending on topic (see **Background information**). The data of the earliest period of AHP (2000/2001-2001/2002 financial years) were used in this study, since it was the most comparable with other datasets in relation to time period covered.

Level of aggregation:
Hospital

DATA SET

Content

Number of individuals or episodes of care included in the database:
The intention of the dataset is to include data on patients, staff, resources, services and activities of all NHS acute hospital trusts in England and Wales and to reflect treatment of all patients in relevant financial years.

Data collection questionnaire:
According to the Audit Commission, wherever possible, data were taken from routine national sources and standard definitions are applied. However, many areas of the portfolio are not covered by existing data, so the Audit Commission conducted national surveys for each topic at all relevant acute hospital trusts in England and Wales by providing electronic forms for trusts to complete. In some cases specially written computer software was also provided to assist hospital trusts.

Data collection forms for selected topics (medical staffing 2001/2002; radiology 2001/2002; ward staffing 2000/2001) have not been published and not available on-line. Data collection forms/tools or questionnaires are available for more recently reviewed topics.

Data linkage

Are nationally approved codes used for identifying the subject, clinician or institution?
Nationally approved codes are used to identify each hospital.

To which other databases is linkage routinely undertaken?
None known

OUTPUTS

Analysis

Can ad hockad hoc analyses be performed for health care providers?

- Locally ("the health care provider who collects the data locally is able to analyse their data even though their data are also sent to the centralised database to be analysed with the data collected from other health care providers") – no;
- Centrally (Local health care providers can obtain ad hoc analyses of their own data from the central database custodian) – yes. Healthcare Commission provides CD version of audit review data to individual trusts. The CD uses Audit Commission's software tool "Compare". Also, on-line query form is available for all AHP queries: http://www.healthcarecommission.org.uk/InformationForServiceProviders/ReviewsAndInspections/AcutePortfolio/QueryForm/fs/en

Audit reports

How frequently are multi-centre audit reports produced?
National overview reports are available for each topic completed (http://www.healthcarecommission.org.uk/NationalFindings/NationalThemedReports/AcuteAndSpecialist/AcuteAndSpecialistReports/fs/en?CONTENT_ID=4000247&chk=aJZ6hP). The intention is to audit the same topic each four years.

How frequently are provider-specific audit reports produced?
Provider specific reports for audited topics are produced each four years, as soon as audit reviews for these topics are completed. (see previous item and **Analysis**)

Publications

Bibliography
Healthcare Commission provides no references to any studies that have used these data. However, national overview reports are available for each topic completed (http://www.healthcarecommission.org.uk/NationalFindings/NationalThemedReports/AcuteAndSpecialist/AcuteAndSpecialistReports/fs/en?CONTENT_ID=4000247&chk=aJZ6hP).

The following article which was produced using AC/HC data has been identified:

1. Fittall B. Can we measure how changes in the nursing workforce affect patient care? (2004) *Journal of Nursing Management* 12, 397-402.

MANAGEMENT

Support for database

Is the database approved by any clinical or professional associations?
No.

Who is involved in the management of the database?
Doctors; statisticians; epidemiologists; IT specialists

Source of funding:
Acute Hospital Portfolio transferred from the Audit Commission to the Healthcare Commission on 1st of April 2004 under the Health and Social Care (Community Health and Standards) Act 2003.

DATA QUALITY

Coverage

Extent to which the eligible population is representative of the country:
All NHS acute hospital trusts in England are covered by the dataset.

Completeness of recruitment of eligible population:
Not all datasets within the AHP contained data for all 28 hospital trusts included in the study. *Table A11* specifies the number of hospital trusts for which information was available for each indicator considered.

Table A11. Number of hospital trusts for which data were available for each indicator considered

Variable	No. of hospital trusts
Radiology	
Radiographers per 1000 FCEs	27
Radiology consultant WTE per 1000 admissions	25
Medical staffing	
Consultant WTE per 1000 admissions	25
Medicine consultant WTE per 1000 admissions	25
Anaesthetist consultant WTE per 1000 admissions	25
Pathology consultant WTE per 1000 admissions	25
Medical WTE per 1000 admissions	23
Ward staffing	
Clinical nurse specialist WTE per 1000 FCEs	24

Variables included in the database

There are numerous variables available in Acute Hospital Portfolio for each specific topic.

Only indicators, which reflect medical, radiology or ward staffing level, were considered during this study. Here is the list of all examined variables:

- medical WTE[xxxvii] per 1000 admissions;
- consultant WTE per 1000 admissions;
- medicine consultant WTE per 1000 admissions;
- anaesthetist consultant WTE per 1000 admissions;
- pathology consultant WTE per 1000 admissions;
- radiology consultant WTE per 1000 admissions;
- radiographers per 1000 FCE[xxxviii]s;
- clinical nurse specialists per 1000 FCEs.

This selection has been made based on relevance, completeness and following discussions with a number of healthcare professionals and researchers associated with the "Measures of Quality for the Improvements of Cancer Services" study[xxxix].

Completeness of data (% variables at least 95% complete):

1) Medical Staffing – 4 variables had 11% missing values (data on 3 hospital trusts were missing); 1 variable had 18% missing values (data on 5 hospital trusts were missing).
2) Radiology – 1 variable had 4% missing values (data on 1 hospital trust were missing); 1 variable had 11% missing values (data on 3 hospital trusts were missing).
   In this topic, 'missing' includes also hospital trusts which do not provide radiology services.
3) Ward Staffing – 1 variable had 14% missing values (data on 4 hospital trusts were missing).

(see *Table A11*)

[xxxvii] Whole time equivalent (WTE)

[xxxviii] Finished consultant episode (FCE)

[xxxix] http://www.ucl.ac.uk/public-health/measuring%20cancer%20services/cancer.htm

Accuracy

Use of explicit definitions for variables:
The definitions of most of variables are provided in national overview reports or published guides to indicators.

Use of explicit rules for deciding how variables are recorded:
Data manuals (guide to indicators) are available for the following topics:

- medical staffing (http://www.healthcarecommission.org.uk/assetRoot/04/00/25/48/04002548.pdf)

- radiology (http://www.healthcarecommission.org.uk/assetRoot/04/00/25/47/04002547.pdf)

No published data manual has been identified for ward staffing topic.

Extent to which data are validated:
No published information has been identified as to whether data have been validated. Our internal analyses show some inconsistencies between data sets within the Acute Hospital Portfolio as well as between Acute Hospital Portfolio and external sources, namely Hospital Episode Statistics and Hospital Activity Statistics.

Appendix 12

HOSPITAL EPISODE STATISTICS
Data Quality Assessment[xl]

GENERAL ASPECTS

Background information

The Hospital Episode Statistics database (HES) contains information on all admitted patients treated in NHS hospitals in England. Each record contains a variety of administrative, clinical and patient information describing the care and treatment a patient received while in hospital.

The data is captured from hospital patient administration systems, and HES now collects 12 million records per year from all hospital trusts in England.

HES publishes standard tables of analyses of NHS admitted patient care by diagnosis, operation, Healthcare Resource Group, consultant specialty, hospital trust and Health Authority on their website. Users can also request specialised analyses to be performed on their behalf by the HES team.

HES is used by the NHS, Government and many other organisations and individuals who have an interest in health and healthcare administration.

Source: NHS Health and Social Care Information Service; Department of Health
http://www.dh.gov.uk/PublicationsAndStatistics/Statistics/HospitalEpisodeStatistics/fs/en

Reference population

Common circumstance that determines inclusion in the database:
HES contain data on inpatient and day cases admitted to NHS hospitals in England. It includes private patients treated in NHS hospitals, patients who were resident outside of

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[xl] *Based on Directory of Clinical Databases (DoCDat) assessments (http://www.lshtm.ac.uk/docdat/records.php?t=records&id=HES).*

England and care delivered by treatment centres (including those in the independent sector) funded by the NHS[xli].

Geographical area covered by the database:
England.

Time period covered by the database:
April 1989 - ongoing. The data from 1997/1998 to 2001/2002 financial years were used in this study, a time period comparable with other datasets.

Level of aggregation:
Patient
DATA SET

Content

Number of individuals or episodes of care included in the database:
The intention of the dataset is to include data on all in-patients at NHS hospital trusts in England.

Data collection questionnaire:
There is no questionnaire for this database.

Data linkage

Are nationally approved codes used for identifying the subject, clinician or institution?
Nationally approved codes are used to identify each hospital. Special patient identifiers were introduced in 1997, to link different episodes of care or multiple admissions within a year, thus preventing their over-counting.

To which other databases is linkage routinely undertaken?
None known.

[xli] http://www.hesonline.nhs.uk/Ease/servlet/ContentServer?siteID=1937&categoryID=456

OUTPUTS

Analysis

Can ad hockad hoc analyses be performed for health care providers?

- Locally ("the health care provider who collects the data locally is able to analyse their data even though their data are also sent to the centralised database to be analysed with the data collected from other health care providers") – yes;
- Centrally (Local health care providers can obtain ad hoc analyses of their own data from the central database custodian) – yes.

Audit reports

How frequently are multi-centre audit reports produced?

Never.

How frequently are provider-specific audit reports produced?

Annually.

Publications

Bibliography:

There are numerous references identified to studies that have used HES data with regard to different pathologies and for different purposes.

Some of the main references are listed below:

1. Aylin P, Alves B, Cook A, Bennett J, Bottle A, Best N, Catena B, Elliott P. Analysis of Hospital Episode Statistics for the Bristol Royal Infirmary Inquiry. Division Primary Care & Population Health Sciences, Imperial College School of Medicine, St. Mary's Campus. London: Crown Copyright 1999.
2. Dixon J, Sanderson C, Elliott P, Walls P, Jones J, Petticrew M. Assessment of the reproducibility of clinical coding in routinely collected hospital activity data: a study in two hospitals. *Journal of Public Health Medicine* 1998; 20:63-69.
3. Jarman B., Gault S., Alves B, Hider A, Dolan S, Cook A, Hurwitz B, Iezzoni LI. Explaining differences in English hospital death rates using routinely collected data. BMJ 1999; 318:1515-1520.
4. Lakhani A, Coles J, Eayres D, Spence C, Rachet B. Creative use of existing clinical and health outcomes data to assess NHS performance in England: Part 1 – performance indicators closely linked to clinical care. *BMJ* 2005; 330:1426-1431.

5. Lakhani A, Coles J, Eayres D, Spence C, Sanderson C. Creative use of existing clinical and health outcomes data to assess NHS performance in England: Part 2 – more challenging aspects of monitoring. *BMJ* 2005; 330:1486-1492.
6. Pollock AM, Vickers N. Trends in colorectal cancer care in southern England, 1989-1993: using HES data to inform cancer services reviews. *Journal of Epidemiology and Community Health* 1998; 52(7):433-438.
7. Williams JB & Mann RY. Hospital Episode Statistics: time for clinicians to get involved? *Clinical Medicine* 2002; 2:34-37.

MANAGEMENT

Support for database

Is the database approved by any clinical or professional associations?
No

Who is involved in the management of the database?
Doctors; statisticians; epidemiologists; IT specialists

Source of funding:
Department of Health.

DATA QUALITY

Coverage

Extent to which the eligible population is representative of the country:
Total population of country included (patients treated in NHS hospitals).

Completeness of recruitment of eligible population:
Out of 28 hospital trusts included in the study, only data for colorectal cancer patients treated at Bromley Hospitals NHS Trust were not available in HES dataset.

Variables included in the database:
There are numerous variables in HES dataset reflecting patient and provider identifiers; administrative information; condition; intervention and outcome. Due to confidentiality and

protection of patients' privacy regulations, it was not possible to receive data with the level of identifiers to allow linkage with the Thames Cancer Registry dataset. For this reason, the data on comorbidity of patients were not accounted for in the study.

For study purposes, only average annual number of colorectal cancer patients for 27 hospital trusts during 1997-2001 were used.

Completeness of data (% variables at least 95% complete):
On national level, from 80% to 97% of variables are at least 95% complete in the HES dataset (National Data Quality Indicators, 2002).

'Average annual hospital volume of patients' had 4% missing values (data on 1 hospital trust were missing).

Accuracy

Use of explicit definitions for variables:
All or almost all variables (>97%) have clear definitions. Definitions of variables are available in HES Data Dictionary (http://www.performance.doh.gov.uk/hes/dictionary/index.html)

Use of explicit rules for deciding how variables are recorded:
All or almost all variables (>97%) have clear rules on how to code them in the database (HES Data Dictionary).

Extent to which data are validated:
Range and consistency checks (continuous auto-cleaning followed by validation). There is no rigorous validation at source; however, the NHS Information Authority conducts periodic external audits.

Appendix 13

CANCER WAITING TIMES
Data Quality Assessment[xlii]

GENERAL ASPECTS

Background information

Cancer Waiting Times contain data on the waiting time of patients with suspected cancer and those subsequently diagnosed with cancer at NHS hospital trusts in England. Data are submitted quarterly by hospital trusts.

Cancer Waiting Times Statistics monitors the following waiting time targets:

- 'Two week wait' from urgent GP referral to first outpatient appointment for all patients with suspected cancer.
- 'One month wait' from urgent GP referral to treatment for children's cancers, testicular cancers and acute leukaemia.
- 'One month wait' from diagnosis to treatment for breast cancer.
- 'Two month wait' from GP referral to treatment for breast cancer.
- 'One month wait' from diagnosis to treatment for all cancers.
- 'Two month wait' from GP referral to treatment for all cancers.

It is impossible to differentiate cancer sites under 'lower gastrointestinal cancer' though it is assumed to reasonably reflect waiting times for colorectal cancer.

Only two week cancer waits were used in this study. It was the only target monitored in relation to lower gastrointestinal cancer patients in 2001/ – 2002 financial year, a time period comparable with other datasets.

[xlii] *Based on Directory of Clinical Databases (DoCDat) format (http://www.lshtm.ac.uk/docdat/page.php?t=index).*

Source: Cancer Action Team; Department of Health.
http://www.performance.doh.gov.uk/cancerwaits/

Reference population

Common circumstance that determines inclusion in the database:
All urgent GP referrals of patients with suspected cancer seen by a specialist

Geographical area covered by the database:
England

Time period covered by the database:
Data submitted quarterly, from the 1st quarter of 2001/2002 financial year – ongoing. The data of the earliest period (2001/-2002 financial year) were used in this study, since it was the most comparable with other datasets in relation to time period covered.

Level of aggregation:
Patients' records are aggregated at NHS hospital trust level. Data are available also at Strategic Health Authority level.

DATA SET

Content

Number of individuals or episodes of care included in the database:
The intention of the dataset is to include all urgent GP referrals of suspected cancer patients.

Data collection questionnaire:
There is no questionnaire for this database.

Data linkage

Are nationally approved codes used for identifying the subject, clinician or institution?
Nationally approved codes are used to identify each NHS hospital trust.

To which other databases is linkage routinely undertaken?
None known.

OUTPUTS

Analysis

Can ad hockad hoc analyses be performed for health care providers?

- Locally ("the health care provider who collects the data locally is able to analyse their data even though their data are also sent to the centralised database to be analysed with the data collected from other health care providers") – yes;
- Centrally (Local health care providers can obtain ad hoc analyses of their own data from the central database custodian) – yes.

Audit reports

How frequently are multi-centre audit reports produced?
The Department of Health issues statistical reports each quarter.
The National Audit Office[xliii] and Audit Commission[xliv] have produced audit reports on accuracy and management of NHS waiting time statistics:

How frequently are provider-specific audit reports produced?
No published information is identified.

[xliii] National Audit Office. *Inappropriate adjustments to NHS waiting lists*. London: The Stationary Office, December 2001.

[xliv] Audit Commission. *Waiting list accuracy. Assessing the accuracy of waiting list information in NHS hospitals in England*. London: 2003.

Publications

Bibliography
No references have been identified to any studies that have used these data.

MANAGEMENT

Support for database

Is the database approved by any clinical or professional associations?
No.

Who is involved in the management of the database?
Doctors; statisticians; epidemiologists; IT specialists

Source of funding:
Department of Health.

DATA QUALITY

Coverage

Extent to which the eligible population is representative of the country:
All urgent GP referrals of patients with suspected cancer are included in the dataset. However, the dataset does not include cancer patients with non-urgent GP referrals and those who admitted to the hospital without GP referral.

Completeness of recruitment of eligible population:
All 28 hospital trusts included in this study, were covered in the dataset. It is difficult to determine to what extent the recruitment of eligible population is complete, since it depends on reporting from each NHS Trust.

Variables included in the database:
Total referrals seen during the quarter, and the number of patients whose waiting times are within specific time periods (days) of the decision to refer by their GP, are the main

variables included in the dataset. There are also variables indicating cancer type, hospital trust and Strategic Health Authority (Health Authority for 2001/2002).

For study purposes, quarterly data have been summed into annual data.

Completeness of data (% variables at least 95% complete):
Data for all 28 hospital trusts included in the study are complete.

Accuracy

Use of explicit definitions for variables:
Clear definitions of all variables are available on-line (http://www.performance.doh.gov.uk/cancerwaits/) and in published Health Service Circulars (HSC 1998/242' HSC 1999/084; HSC 1999/205; HSC 2001/012; HSC 2002/005).

Use of explicit rules for deciding how variables are recorded:
All variables have clear rules on how to code them in the dataset (http://www.dh.gov.uk/assetRoot/04/01/90/66/04019066.xls and http://www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Cancer/CancerArticle/fs/en?CONTENT_ID=4001800&chk=dpRNWQ). (see also previous item)

Extent to which data are validated:
No published information has been identified as to whether data have been validated.

Appendix 14

CANCER SERVICES PEER REVIEW
Data Quality Assessment[xlv]

GENERAL ASPECTS

Background information

The Manual of Cancer Services Standards published by Department of Health in December 2000 sets out a number of quality measures (standards) in relation to the commissioning of cancer services.

At the beginning of 2001 every cancer unit and centre was intended to assess itself against these standards to measure own performance. This was then followed up with a peer review visit. The visits were carried out by teams of health care professionals and managers, all of whom are involved in the day-to-day delivery of cancer care, together with patient representatives. The main purpose of this peer review visits was to validate the self-assessment, so identifying where standards were or were not being met.
The standards look at the infra-structure and process of care rather than clinical outcomes.

The following ten topics have been considered during peer review visits:

- Patient centred care;
- Specialist multi-disciplinary teams (MDT);
- Diagnostic services;
- Provision of non-surgical oncology to cancer units;
- Radiotherapy;
- Chemotherapy;
- Specialist palliative care services;
- Education, training and continuing professional development;
- Communication between primary, secondary and tertiary sectors;

[xlv] *Based on Directory of Clinical Databases (DoCDat) format (http://www.lshtm.ac.uk/docdat/page.php?t=index).*

- Cancer services organisation and management.

Standards for specialist MDT are specified separately for breast, colorectal, lung and gynaecological cancers. No data are available for urological cancers since urology was not included in the 2001 programme.

Second round of peer review assessments is in process now, using the revised version of the Manual of Cancer Services Standards published by Department of Health in 2004[xlvi].
Source: NHS Cancer Action Team, Department of Health.
http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4002999&chk=/BiOBs

Reference population

Common circumstance that determines inclusion in the database:
All cancer units and centres.

Geographical area covered by the database:
England

Time period covered by the database:
2001

Level of aggregation:
Cancer units and centres.

xlvi

http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4090081&chk=hq28gu

DATA SET

Content

Number of individuals or episodes of care included in the database:
The intention of the dataset is to include all cancer units and centres in England.

Data collection questionnaire:
There is no questionnaire for this database.

Data linkage

Are nationally approved codes used for identifying the subject, clinician or institution?
Cancer units and centres are identified by nationally approved organisational codes. Available look-up table was used to link organisational codes to nationally approved NHS hospital trust codes.

To which other databases is linkage routinely undertaken?
None known.

OUTPUTS

Analysis

Can ad hockad hoc analyses be performed for health care providers?

- Locally ("the health care provider who collects the data locally is able to analyse their data even though their data are also sent to the centralised database to be analysed with the data collected from other health care providers") – no;
- Centrally (Local health care providers can obtain ad hoc analyses of their own data from the central database custodian) – yes.

Audit reports

How frequently are multi-centre audit reports produced?

National overview report[xlvii] (one-off) has been produced after 2001 peer review.
Second round of peer review assessments is currently in the process.

How frequently are provider-specific audit reports produced?

It is assumed that final report (one-off) to the hospital trust, Strategic Health Authority and Cancer Network has been prepared by the peer review team chair and agreed with the hospital trust. However, no published information has been identified.

Publications

Bibliography

No references have been identified to any studies that have used these data.
Professor Scrivens and colleagues conducted the evaluation of the whole process of 2001 peer review and published report[xlviii].

MANAGEMENT

Support for database

Is the database approved by any clinical or professional associations?

No.

Who is involved in the management of the database?

Doctors; statisticians; epidemiologists; IT specialists

Source of funding:

Department of Health, Cancer Action Team.

[xlvii] Department of Health. *Peer Review of Cancer Services. A National Overview.* 2002.

[xlviii] E. Scrivens, L. Coleman, D. Levy. K. Von Degenberg, K. Wilde, H. Barlow, J. Luthert. *Evaluation of National Peer Review 2001.* CASU:2002

DATA QUALITY

Coverage

Extent to which the eligible population is representative of the country:
Total population of country included. Six regions used the final version of the cancer services standards (Manual of Cancer Services Standards, 2000). Eastern Region used the draft version and Trent used "Trent Standards". These are very similar to the final version of the standards but are not mappable one to one with the standards. Hence, the dataset includes individual standard data for each Trust in the 6 regions and summary data for Trent and Eastern regions.

Completeness of recruitment of eligible population:
All cancer unites and centres in England are covered by the dataset.
Out of 28 hospital trusts included in the study, data for 3 hospital trusts have not been considered for the analysis of associations of compliance with cancer standards and survival, due to differences in structure of hospitals between the Thames Cancer Registry and Cancer Services Peer Review datasets.

Variables included in the database:
Variables represent cancer standards for each topic specified within the "Manual of Cancer Services Standards" (Department of Health, 2001).

All 35 colorectal cancer-specific MDT standards were selected for analysis in this study. Compliance with each standard was considered present or absent.

Completeness of data (% variables at least 95% complete):
The data on compliance with standards for 25 hospital trusts (out of total 28 hospital trusts) were available for study purposed. This means that the information was missing for 11% of hospital trusts.

Accuracy

Use of explicit definitions for variables:
Clear definitions of all variable are available in the "Manual of Cancer Services Standards" (Department of Health, 2001), accessible on-line at:

http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4002999&chk=/BiOBs

Use of explicit rules for deciding how variables are recorded:
No published information (e.g. data manual) has been identified. However, the "Manual of Cancer Services Standards" (Department of Health, 2001) sets out for each standard the information that would demonstrate that the standards have been complied with.

Extent to which data are validated:
No published information has been identified as to whether data have been validated.

Appendix 15

THAMES CANCER REGISTRY
Data Quality Assessment[xlix]

GENERAL ASPECTS

Background information

Cancer registration has been conducted in parts of the UK since 1929, with national coverage since 1960-s.

The Thames Cancer Registry (TCR) is one of 12 population based cancer registries in the UK and covers the residential population of London, Surrey, Sussex and Kent. The registry collects information about new cases of cancer and uses this to produce statistics about cancer incidence, prevalence, survival and mortality.

A subset of the data collected by the regional cancer registries is collated centrally by the National Cancer Intelligence Centre at the Office for National Statistics (ONS), to provide national figures on cancer incidence and survival on a regular basis.

Source: Thames Cancer Registry (TCR). http://www.thames-cancer-reg.org.uk/

Reference population

Common circumstance that determines inclusion in the database:
Diagnosis of cancer (colorectal cancer ICD-10: C18-21[l]).

Geographical area covered by the database:

[xlix] *Based on Directory of Clinical Databases (DoCDat) format (http://www.lshtm.ac.uk/docdat/page.php?t=index).*

[l] International Classification of Diseases, Tenth Revision (http://www3.who.int/icd/currentversion/fr-icd.htm)

London, Surrey, Sussex and Kent.

Time period covered by the database:
1960 – ongoing. Patients diagnosed in 1996-2001 and followed up until the end of 2001 were considered for the study.

Level of aggregation:
Patient

DATA SET

Content

Number of individuals or episodes of care included in the database:
The intention of the dataset is to include data on all cancer patients in the region (London, Surrey, Sussex and Kent).

Data collection questionnaire:
There is no questionnaire for this database.

Data linkage

Are nationally approved codes used for identifying the subject, clinician or institution?
Individual patients are identified within the system by unique codes so that separate data elements such as diagnosis and death can be accurately linked, but data that are released for analysis do not contain personal identifiers. Nationally approved codes are used to identify hospitals. Available look-up table was used to link individual hospital codes to nationally approved NHS hospital trust codes.

To which other databases is linkage routinely undertaken?
The National Health Service Central Register

OUTPUTS

Analysis

Can ad hoc analyses be performed for health care providers?

- Locally ("the health care provider who collects the data locally is able to analyse their data even though their data are also sent to the centralised database to be analysed with the data collected from other health care providers") – yes;
- Centrally (Local health care providers can obtain ad hoc analyses of their own data from the central database custodian) – yes.

Audit reports

How frequently are multi-centre audit reports produced?

Never.

How frequently are provider-specific audit reports produced?

Never.

Publications

Bibliography:

There are numerous references identified to studies that have used TCR data with regard to different pathologies and for different purposes.

Some of the main references are listed below:

1. Bullard J, Coleman MP, Robinson D, Lutz J-M, Bell J, Peto J. Completeness of cancer registration: a new method for routine use. Br J Cancer 2000; 82(5):1111-1116.

2. Gatta G, Capocaccia R, Sant M, Bell J, Coebergh JWW, Damhuis RAM et al. Understanding variations in survival for colorectal cancer in Europe: a EUROCARE high resolution study. Gut 2000; 47:533-538.

3. Pollock AM, Vickers N. The impact on colorectal cancer survival of cases registered by 'death certificate only': implications for national survival rates. Br J Cancer 1994; 70(6):1229-1231.

4. Pollock AM, Benster R, Vickers N. Why did treatment rates for colorectal cancer in

south east England fall between 1982 and 1988? The effect of case ascertainment and registration bias. J Public Health Med 1995; 17(4):419-428.

5. Pollock AM, Vickers N. Reliability of data of the Thames cancer registry on 673 cases of colorectal cancer: effect of the registration process. Qual Health Care 1995; 4(3):184-189.

6. Pollock AM, Vickers N. Why are a quarter of all cancer deaths in south-east England registered by death certificate only? Factors related to death certificate only registrations in the Thames Cancer Registry between 1987 and 1989. Br J Cancer 1995; 71(3):637-641.

7. Pollock AM, Vickers N. Reducing DCO registrations through electronic matching of cancer registry data and routine hospital data. Br J Cancer 2000; 82(3):712-717.

8. Vickers N, Pollock AM. Incompleteness and retrieval of case notes in a case note audit of colorectal cancer. Qual Health Care 1993; 2(3):170-174.

MANAGEMENT

Support for database

Is the database approved by any clinical or professional associations?
Yes – the UK Association of Cancer Registries

Who is involved in the management of the database?
Doctors; statisticians; epidemiologists; IT specialists

Source of funding:
The NHS funds the regional cancer registries and the Department of Health pays the ONS to process the data and to operate the National Cancer Registry.

DATA QUALITY

Coverage

Extent to which the eligible population is representative of the country:
Total population of the covered region included.
Completeness of recruitment of eligible population:

The database includes 90-97% of the eligible population.

Absolute levels of case ascertainment are very difficult to obtain as there is no independent source with which to compare. The level of ascertainment can be judged by the proportion of cases which are registered through death certificates only (DCO).

The study had a relatively low percentage of DCO cases (548 patients - 3%), which were excluded from the analysis.

Variables included in the database:
The following main variables from the TCR dataset have been considered for survival analysis in this study: age; sex; Index of Multiple Deprivation 2000 (income domain) quintile; tumour stage; hospital of first attendance/treatment; type of treatment/surgery; date of diagnosis; days to end of follow-up; vital status at the end of follow-up.

Completeness of data (% variables at least 95% complete):
All variables considered for survival analysis were complete, except for the tumour stage (20.9% missing values) and the type of treatment/surgery (11.6% missing values).

Accuracy

Use of explicit definitions for variables:
All or almost all variables (>97%) have clear definitions, either within the WHO's International Classification of Diseases for Oncology or within other source documents agreed between the Department of Health and the UK Association of Cancer Registries.

Use of explicit rules for deciding how variables are recorded:
All or almost all variables (>97%) have clear rules on how to code them in the database. (see previous item)

Extent to which data are validated:
Range and consistency checks plus external validation using an alternative source.

Regional registries are required to audit a sample of their cases, however in reality this is done sporadically and differently between registers. Proposals for a standard audit programme are currently being developed.